

SOLIDAGO CANADENSIS POLLEN- goldenrod injection, solution
JUNIPERUS CALIFORNICA POLLEN- juniper western injection, solution
CHENOPODIUM ALBUM POLLEN- lambs quarters injection, solution
CHENOPODIUM AMBROSIOIDES POLLEN- mexican tea injection, solution
QUERCUS AGRIFOLIA POLLEN- oak california live coast injection, solution
QUERCUS ALBA POLLEN- oak white injection, solution
CARYA ILLINOINENSIS POLLEN- pecan pollen injection, solution
PLANTAGO LANCEOLATA POLLEN- plantain english injection, solution
PYRETHRUM CINERARIIFOLIUM- pyrethrum cinerariifolium injection, solution
AMARANTHUS RETROFLEXUS POLLEN- pigweed rough redroot injection, solution
IVA ANNUA VAR ANNUA POLLEN- marshelder rough injection, solution
MELALEUCA QUINQUENERVIA POLLEN- melaleuca pollen injection, solution
PROSOPIS JULIFLORA POLLEN- mesquite injection, solution
ZEA MAYS POLLEN- corn pollen injection, solution
CANIS LUPUS FAMILIARIS SKIN- dog epithelia injection, solution
CAVIA PORCELLUS SKIN- guinea pig epithelia injection, solution
EQUUS CABALLUS SKIN- horse epithelia injection, solution
CLADOSPORIUM SPHAEROSPERMUM- cladosporium sphaerospermum injection, solution
COCHLIOBOLUS SATIVUS- helminthosporium sorokinianum injection, solution
EPICOCUM NIGRUM- epicoccum nigrum injection, solution
FUSARIUM OXYSPORUM VASINFECTUM- fusarium vasinfectum injection, solution
HELMINTHOSPORIUM SOLANI- helminthosporium solani injection, solution
MUCOR PLUMBEUS- mucor plumbeus injection, solution
NEUROSPORA INTERMEDIA- neurospora intermedia injection, solution
PENICILLIUM CHRYSOGENUM VAR CHRYSOGENUM- penicillium chrysogenum injection, solution
PHOMA EXIGUA VAR EXIGUA- phoma herbarum injection, solution
RHIZOPUS ARRHIZUS VAR ARRHIZUS- rhizopus batatas injection, solution
RHODOTORULA RUBRA- rhodotorula rubra injection, solution
STEMPHYLIUM SOLANI- stemphylium solani injection, solution
TRICHOPHYTON MENTAGROPHYTES- trichophyton mentagrophytes injection, solution
SACCHAROMYCES CEREVISIAE- saccharomyces cerevisiae injection, solution
ACACIA- acacia injection, solution
AILANTHUS ALTISSIMA POLLEN- ailanthus tree of heaven injection, solution
ALNUS INCANA SSP RUGOSA POLLEN- alder white injection, solution
MEDICAGO SATIVA POLLEN- alfalfa injection, solution
FRAXINUS VELUTINA POLLEN- ash arizona injection, solution
FRAXINUS AMERICANA POLLEN- ash white injection, solution
POPULUS TREMULOIDES POLLEN- aspen injection, solution
PASPALUM NOTATUM POLLEN- bahia grass injection, solution
MORELLA CERIFERA POLLEN- bayberry wax myrtle injection, solution
FAGUS GRANDIFOLIA POLLEN- beech injection, solution
BETULA LENTA POLLEN- birch black injection, solution
BETULA NIGRA POLLEN- birch river red injection, solution
USTILAGO MAYDIS- corn smut injection, solution
USTILAGO TRITICI- loose wheat smut injection, solution

HOUSE DUST- house dust injection, solution
BOS TAURUS SKIN- cattle epithelia injection, solution
COTTON FIBER- cotton linters injection, solution
COTTON SEED- cottonseed injection, solution
CEIBA PENTANDRA FIBER- kapok injection, solution
MUS MUSCULUS SKIN- mouse epithelia injection, solution
ORRIS- iris x germanica root injection, solution
RABBIT- rabbit injection, solution
PERIPLANETA AMERICANA- american cockroach injection, solution
BLATELLA GERMANICA- german cockroach injection, solution
ACREMONIUM STRICTUM- sarocladium strictum injection, solution
ALTERNARIA TENUIS- alternaria tenuis injection, solution
ASPERGILLUS FUMIGATUS- aspergillus fumigatus injection, solution
ASPERGILLUS NIGER VAR NIGER- aspergillus niger injection, solution
AUREOBASIDIUM PULLULANS VAR PULLULANS- pullularia pullulans injection, solution
BOTRYTIS CINEREA- botrytis cinerea injection, solution
CANDIDA ALBICANS- candida albicans injection, solution
CHAETOMIUM GLOBOSUM- chaetomium globosum injection, solution
CLADOSPORIUM CLADOSPORIOIDES- cladosporium cladosporioides injection, solution
POA ANNUA POLLEN- bluegrass annual injection, solution
ACER NEGUNDO POLLEN- box elder ash leaf maple injection, solution
BROMUS INERMIS POLLEN- brome grass injection, solution
AMARANTHUS PALMERI POLLEN- carelessweed injection, solution
JUNIPERUS ASHEI POLLEN- cedar mountain injection, solution
JUNIPERUS VIRGINIANA POLLEN- cedar red injection, solution
XANTHIUM STRUMARIUM VAR CANADENSE POLLEN- cocklebur injection, solution
TAXODIUM DISTICHUM POLLEN- cypress bald injection, solution
RUMEX ACETOSELLA POLLEN- dock sour sheep sorrel injection, solution
RUMEX CRISPUS POLLEN- dock yellow injection, solution
EUPATORIUM CAPILLIFOLIUM POLLEN- dog fennel injection, solution
ULMUS AMERICANA POLLEN- elm american injection, solution
ULMUS CRASSIFOLIA POLLEN- elm cedar injection, solution
ULMUS PUMILA POLLEN- elm chinese injection, solution
EUCALYPTUS GLOBULUS POLLEN- eucalyptus injection, solution
POPULUS DELTOIDES POLLEN- cottonwood eastern common injection, solution
POPULUS FREMONTII POLLEN- cottonwood fremont injection, solution
POPULUS DELTOIDES SSP MONILIFERA POLLEN- cottonwood western injection, solution
CUPRESSUS ARIZONICA POLLEN- cypress arizona injection, solution
CELTIS OCCIDENTALIS POLLEN- hackberry injection, solution
CORYLUS AMERICANA POLLEN- hazelnut pollen injection, solution
SORGHUM HALEPENSE POLLEN- johnson grass injection, solution
KOCHIA SCOPARIA POLLEN- kochia firebush injection, solution
ROBINIA PSEUDOACACIA POLLEN- locust black non stock injection, solution
ACER RUBRUM POLLEN- maple red injection, solution
ACER SACCHARUM POLLEN- maple sugar injection, solution

IVA XANTHIFOLIA POLLEN- marshelder burweed injection, solution
ARTEMISIA VULGARIS POLLEN- mugwort common injection, solution
MORUS RUBRA POLLEN- mulberry red injection, solution
MORUS ALBA POLLEN- mulberry white injection, solution
QUERCUS RUBRA POLLEN- oak red injection, solution
QUERCUS VIRGINIANA POLLEN- oak virginia live injection, solution
OLEA EUROPAEA POLLEN- olive pollen injection, solution
SYAGRUS ROMANZOFFIANA POLLEN- palm queen coco palm injection, solution
SCHINUS MOLLE POLLEN- pepper tree california injection, solution
AMARANTHUS SPINOSUS POLLEN- pigweed spiny injection, solution
CASUARINA EQUISETIFOLIA POLLEN- pine australian beefwood injection, solution
PINUS STROBUS POLLEN- pine white injection, solution
PINUS ECHINATA POLLEN- pine yellow injection, solution
POPULUS ALBA POLLEN- poplar white injection, solution
LIGUSTRUM VULGARE POLLEN- privet injection, solution
ELYMUS REPENS POLLEN- quack grass injection, solution
AMBROSIA ACANTHICARPA POLLEN- ragweed false bur injection, solution
AMBROSIA TENUIFOLIA POLLEN- ragweed slender injection, solution
AMBROSIA BIDENTATA POLLEN- ragweed southern injection, solution
AMBROSIA ARTEMISIIFOLIA POLLEN- ragweed short injection, solution
AMBROSIA TRIFIDA POLLEN- ragweed tall giant injection, solution
AMBROSIA PSEUDOSTACHYA POLLEN- ragweed western injection, solution
SALSOLA KALI POLLEN- russian thistle injection, solution
LOLIUM PERENNE SSP MULTIFLORUM POLLEN- rye grass italian injection, solution
ARTEMISIA FRIGIDA POLLEN- sage prairie injection, solution
ARTEMISIA TRIDENTATA POLLEN- sagebrush common injection, solution
DISTICHLIS SPICATA POLLEN- salt grass injection, solution
ATRIPLEX WRIGHTII POLLEN- saltbush annual atriplex injection, solution
LIQUIDAMBAR STYRACIFLUA POLLEN- sweetgum injection, solution
PLATANUS OCCIDENTALIS POLLEN- sycamore american injection, solution
HOLCUS LANATUS POLLEN- velvet grass injection, solution
JUGLANS NIGRA POLLEN- walnut black pollen injection, solution
JUGLANS REGIA POLLEN- walnut english pollen injection, solution
AMARANTHUS TUBERCULATUS POLLEN- water hemp injection, solution
TRITICUM AESTIVUM POLLEN- wheat pollen injection, solution
SALIX NIGRA POLLEN- willow black injection, solution
ARTEMISIA ANNUA POLLEN- wormwood common annual injection, solution
ALK-Abello, Inc.

Nonstandardized Allergenic Products

**DIRECTIONS FOR USE OF
THERAPEUTIC ALLERGENIC EXTRACTS**

WARNING

This product is intended for use by physicians who are experienced in the administration of allergenic extracts and the emergency care of anaphylaxis or for use under the guidance of an allergy specialist.

Patients should be instructed to recognize adverse reaction symptoms and cautioned to contact the physician's office if reaction symptoms occur. As with all allergenic extracts, severe systemic reactions may occur. In certain individuals, these reactions may rarely result in death. Patients should be observed for 20 to 30 minutes following treatment, and emergency measures, as well as personnel trained in their use, should be immediately available in the event of a life-threatening reaction. Patients with unstable asthma or steroid dependent asthmatics and patients with underlying cardiovascular disease are at greater risk. Adverse events are to be reported to Med Watch (1-800-FDA-1088), Adverse Event Reporting , Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852-9787.

This product should not be injected intravenously. Deep subcutaneous routes have proven to be safe. Patients receiving beta-blockers may not be responsive to epinephrine or inhaled bronchodilators. Respiratory obstruction not responding to parenteral or inhaled bronchodilators may require theophylline, oxygen, intubation and the use of life support systems. Parenteral fluid and/or plasma expanders may be utilized for the treatment of shock. Adrenocorticosteroids may be administered parenterally or intravenously.

Refer to WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS sections below.

Port Washington, NY 11050

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DESCRIPTION

Sterile therapeutic extracts are supplied in either Phenol Saline Diluent or in Diluent containing Glycerin 50% (v/v) for subcutaneous injection. Inactive ingredients may include: Sodium Chloride for isotonicity, Glycerin, and Sodium Bicarbonate as buffering agents. These products are compounded and diluted on a w/v or PNU basis. Pollens are individually extracted from pure pollen extracted in a phenol-preserved sodium bicarbonate solution. Short Ragweed and Mixed (Tall and Short) Ragweed extracts are standardized by Antigen E content and so labeled. The Antigen E content of extracts containing Short Ragweed at a concentration more dilute than a weight/volume ratio of 1:10 are obtained by calculating the Antigen E content based on the assay value of more concentrated extract. Pollen extracts are filtered aseptically and, after final packaging, they are tested for sterility and safety. Molds are individually extracted from pure powdered inactivated mold source material extracted in phenol preserved saline. Mold extracts are filtered aseptically and after final packaging are tested for sterility and safety. Molds are present in all inhabited places at all seasons of the year; they are so ubiquitous that they are prevalent at times when common allergic pollens and other inhalants are not. In the home and surroundings, molds are found in upholstered furniture, mattresses, drapes, cellar and storage room dust, woolens, leather goods,

fruits, meats, cheeses, garden soil and on plants. Spores, mycelial fragments and mold residues are thus inhaled, contacted and ingested continuously.

Miscellaneous inhalants and epidermals are individually extracted in phenol preserved saline, filtered aseptically and after final packaging are tested for sterility and safety.

CLINICAL PHARMACOLOGY

The treatment consists of the subcutaneous injection of gradually increasing doses of the allergens to which the patient is allergic. It has been demonstrated that this method of treatment induces an increased tolerance to the allergens responsible for the symptoms on subsequent exposure. The exact relationships between allergen, skin-sensitizing antibody (IgE) and the blocking antibody (IgG) have not been precisely established. Clinically confirmed immunological studies have adduced evidence of the efficacy of hyposensitization therapy.

Numerous controlled studies have demonstrated the clinical efficacy of immunotherapy with cat, dust mites and some pollen extracts. Nevertheless, responses are variable, and in a few studies patients reported no appreciable benefit.

Extracts containing Short Ragweed pollen bear a labeled potency declaration in terms of Antigen E content. Numerous studies have confirmed Antigen E (AgE) as the major antigen associated with Short Ragweed pollinosis.¹ Therefore, it is essential that the physician be aware of AgE content of allergenic extract administered for hyposensitization therapy.

Some studies have indicated that for most patients a cumulative Antigen E dosage of less than 0.1 unit is not immunizing (sufficient to stimulate specific IgG antibodies).² This, however, does not suggest that 0.1 unit is a maximum tolerated dose. Most moderately sensitive patients may tolerate a dosage of ten to fifty times greater. If results with this product are unsatisfactory with exquisitely sensitive patients who cannot tolerate an immunizing dose, the physician should consider alternative therapy.

One well-controlled study demonstrated that standard immunotherapy (gradually increasing doses of antigen given subcutaneously to a maximum tolerated peak dose) using crude ragweed extract of known Antigen E potency, was significantly superior to placebo and low dose immunotherapy (0.1 units AgE cumulative dose) in amelioration of symptoms associated with ragweed hay fever. These patients received a cumulative dose of 18-350 units Antigen E (median = 84.9 units). The maximum single dose ranged from 3.7 to 46.8 units (median = 11.1 units) prior to the ragweed hay fever season.¹⁰

Patients for this study were sensitive to Ragweed Antigen E, as determined by intradermal skin testing at a dose of 0.01 units AgE/mL. A series of 24 weekly injections were administered. Forty-seven percent of the patients experienced at least one systemic reaction with an average of 1.2 systemic reactions per patient. None of the patients were able to achieve the expected maximum dose (90 units of Antigen E) in the 24 weekly injection dosage schedule.

INDICATIONS AND USAGE

Hyposensitization (injection) therapy is a treatment for patients exhibiting allergic

reactions to seasonal pollens, dust, molds, animal danders, various other inhalants, and in situations where the offending allergen cannot be avoided.

Prior to initiation of therapy, the clinical sensitivity should be established by careful evaluation of the patient's history confirmed by diagnostic skin testing.

Hyposensitization should not be prescribed for sensitivities to allergens which can easily be avoided.

CONTRAINDICATIONS

A patient should not be immunized with preparations of allergens to which the patient has not demonstrated symptoms, IgE antibodies, positive skin tests, or properly controlled challenge testing. In most cases, immunotherapy is not indicated for those allergens that can be eliminated or minimized by environmental control.

Patients on beta-blockers are not candidates for immunotherapy, as they can be non-responsive to beta-agonists that may be required to reverse a systemic reaction (also see **WARNINGS AND ADVERSE REACTIONS**).

In the presence of active symptoms such as rhinitis, wheezing, dyspnea, etc., the indication of immunotherapy must be weighed carefully against the risk of temporarily aggravating the symptoms by the injection itself.

Also, there is some evidence, although inconclusive, that routine immunizations may exacerbate autoimmune diseases.^{3,4,5} Hyposensitization should be given cautiously to patients with this predisposition. Patients with severe cardiorespiratory symptoms are at an additional risk during a systemic reaction. The physician must weigh risk to benefit in these cases.

WARNINGS

Patients should always be observed for at least 20-30 minutes after any injection. In the event of a marked systemic reaction, application of a tourniquet above the injection site and administration of 0.2 mL to 1 mL (0.01 mg/kg) of Epinephrine Injection (1:1,000) is recommended. Maximal recommended dose for children between 2 and 12 years is 0.5 mL. The tourniquet is then gradually released at 15 minute intervals. Patients under treatment with beta-blockers may be refractory to the usual dose of epinephrine.

Volume expanders and vasopressor agents may be required to reverse hypotension. Inhalation bronchodilators and parenteral aminophylline may be required to reverse bronchospasm. In cases of respiratory obstruction, oxygen and intubation may be necessary. Life-threatening reaction unresponsive to the above may require cardiopulmonary resuscitation.

DO NOT GIVE INTRAVENOUSLY

After inserting the needle, but before injecting the dose, pull plunger of the syringe slightly. If blood returns in the syringe, discard the syringe and contents and repeat injection at another site.

Bulk concentrated extracts must be diluted for initial therapy.

Withhold allergenic extracts temporarily or reduce the dose in patients with any one of

the following conditions:

- Severe rhinitis or asthma symptoms;
- Infection or flu accompanied by fever;
- Exposure to excessive amounts of clinically relevant allergen prior to therapy.

Patients with unstable asthma or steroid dependent asthmatics and patients with underlying cardiovascular disease are at greater risk. See **PRECAUTIONS AND ADVERSE REACTIONS**.

TRANSFER OF PATIENTS

From pyridine extracted alum complexed allergenic extracts to aqueous extracts and glycerinated: In order to avoid untoward reaction, it is recommended that therapy be initiated as though patients were previously untreated. The first dose should be related to the patient's sensitivity, determined by history and confirmed by skin testing.

From unstandardized aqueous extracts to standardized aqueous extracts and glycerinated: The physician should establish the potency relationship, perhaps by comparative skin testing at equal concentration, prior to injecting the first standardized dose.

From aqueous alum precipitated or modified extracts to aqueous extracts and glycerinated: Since this subject has not been studied, it is recommended that therapy be initiated as if the patient were not previously treated.

PRECAUTIONS

INFORMATION TO PATIENTS:

Patients should be instructed to describe any active allergic symptoms such as rhinitis, wheezing, dyspnea, etc. prior to injection including any late reactions from previous administration. Patients should be instructed to remain in the office for 20 to 30 minutes after injection to monitor for adverse reactions. Also, see **ADVERSE REACTIONS** and **WARNINGS** Sections.

If the protective action of allergenic extract injections is considered essential for the patient's welfare, appropriate symptomatic therapy with antihistaminic, adrenergic or other drugs might be needed either prior to or in conjunction with the allergenic extract injections.

GENERAL:

1. Objective assessment of pulmonary function such as Peak Expiratory Flow Rate (PEFR) before allergen administration may be useful in unstable asthmatic to reduce the chances of exacerbation of the patient's asthma.
2. Store allergenic extracts between 2° and 8°C at all times, even during use.
3. Injections are to be given subcutaneously with the usual sterile precautions using a tuberculin syringe.
4. Care must be taken to avoid injecting into a blood vessel. Pull gently on syringe plunger to determine if a blood vessel has been entered (See **WARNINGS**).
5. Allergenic extracts slowly become less potent with age. During the course of treatment, it may be necessary to continue therapy with a vial of extract bearing a

later expiration date. The initial dose of the extract bearing the later expiration date should be lowered to a safe, non-reaction eliciting level which can be confirmed by comparative skin testing using end-point titration.

6. Use standard aseptic precautions when making dilutions. The first dose of the new extract should be reduced to at least 25% of the amount of the dosage from the previous extract.
7. Extracts in 50% glycerin can cause discomfort at the site of the injection.

PREGNANCY - CATEGORY C:

Animal reproduction studies have not been conducted with allergenic extracts. It is also not known whether allergenic extracts can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity.

Controlled studies of hyposensitization with moderate to high doses of allergenic extracts during conception and all trimesters of pregnancy have failed to demonstrate any risk to the fetus or to the mother. However, on the basis of histamine's known ability to contract uterine muscle, the release of significant amounts of histamine from allergen exposure or hyposensitization overdose should be avoided on theoretical grounds. Therefore, allergenic extracts should be used cautiously in a pregnant woman and only if clearly needed.

PEDIATRIC USE:

Children can receive the same dose as adults, however, to minimize the discomfort associated with dose volume it may be advisable to reduce the volume of the dose by one-half and administer the injection at two different sites.

NURSING MOTHERS:

It is not known if allergens administered subcutaneously appear in human milk. Because many drugs are excreted in human milk, caution should be exercised when allergenic extracts are administered to a nursing woman.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY:

Studies in animals have not been performed.

DRUG INTERACTIONS:

Drugs can interfere with the performance of skin tests.⁶

Antihistamines: Response to mediator (histamine) released by allergens is suppressed by antihistamines. The length of suppression varies and is dependent on individual patient, type of antihistamine and length of time the patient has been on antihistamines. The duration of this suppression may be as little as 24 hours (chlorpheniramine), and can be as long as 40 days (astemizole).

Tricyclic Antidepressants: These exert a potent and sustained decrease of skin reactivity to histamine which may last for a few weeks.

Beta₂ Agonists: Oral terbutaline and parenteral ephedrine, in general, have been shown to decrease allergen induced wheal.

Dopamine: Intravenous infusion of dopamine may inhibit skin test responses.

Beta Blocking Agents: Propranolol can significantly increase skin test reactivity (See WARNINGS).

Other Drugs: Short acting steroids, inhaled beta₂ agonists, theophylline and cromolyn do not seem to affect skin test response.

ADVERSE REACTIONS

Anaphylaxis and deaths following the injection of mite and other extracts have been reported by The British Committee on Safety in Medicine.⁷ Fatalities from immunotherapy in the United States since 1945 have been extensively reviewed by Lockey, R. F., et al⁸ and more recently by Reid, M. J. et al.⁹

With careful attention to dosage and administration, such reactions occur infrequently, but it must be remembered that allergenic extracts are highly potent to sensitive individuals and OVERDOSE could result in anaphylactic symptoms. Therefore, it is imperative that physicians administering allergenic extracts understand and be prepared for the treatment of severe reactions.

Local: Reactions at the site of injection may be immediate or delayed. Immediate wheal and erythema reactions are ordinarily of little consequence; but if very large, may be the first manifestation of a systemic reaction. If large local reactions occur, the patient should be observed for systemic symptoms for which treatment is outlined below.

Delayed reactions start several hours after injection with local edema, erythema, itching or pain. They are usually at their peak at 24 hours and usually require no treatment. Antihistamine drugs may be administered orally.

The next therapeutic dose should be reduced to the dose which did not elicit a reaction, and subsequent doses increased more slowly; i.e., use of intermediate dilutions.

Systemic: Systemic reactions are characterized by one or more of the following symptoms: Sneezing, mild to severe generalized urticaria, itching other than at the injection site, extensive or generalized edema, wheezing, asthma, dyspnea, cyanosis, tachycardia, lacrimation, marked perspiration, cough, hypotension, syncope and upper airway obstruction. Symptoms may progress to shock and death. Patients should always be observed for at least 20 to 30 minutes after any injection. Volume expanders and vasopressor agents may be required to reverse hypotension. Inhalational bronchodilators and parenteral aminophylline may be required to reverse bronchospasm. Severe airway obstruction, unresponsive to bronchodilator, may require tracheal intubation and use of oxygen. In the event of a marked systemic reaction, application of a tourniquet above the injection site and the administration of 0.2 mL to 1 mL of Epinephrine Injection (1:1,000) are recommended. Maximal recommended dose for children under 2 years of age is 0.3 mL. Maximal recommended dose for children between 2 and 12 years of age is 0.5 mL. The tourniquet should not be left in place without loosening for 90 seconds every 15 minutes.

The next therapeutic injection of extract should be reduced to the dose which did not elicit a reaction, and subsequent doses increased more slowly; i.e., use of intermediate dilutions.

OVERDOSAGE

Signs and symptoms of overdose are typically local and systemic reactions. For a description and management of overdose reactions, refer to “Adverse Reaction” section above.

DOSAGE AND ADMINISTRATION

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

When diluting bulk extracts, use of Sterile Diluent for Allergenic Extracts or Sterile Diluent for Allergenic Extracts Normal Saline with HSA (albumin saline) is recommended. Dilutions should be made with sterile disposable syringes using aseptic technique. Commonly, 10 fold dilutions are used to achieve a desired concentration for initiation and continuation of immunotherapy. For example, transferring 0.5 mL of a 10,000 PNU/mL extract into 4.5 mL of diluent will yield 5 mL of extract at 1,000 PNU/mL. For weight volume products, a 1:100 w/v dilution may be prepared from a 1:10 w/v by transferring 0.5 mL of the 1:10 w/v to 4.5 mL of diluent. Prepare as many additional serial dilutions as necessary to reach the appropriate concentration.

Starting dose for immunotherapy is related directly to a patient’s sensitivity as determined by carefully executed skin testing. Degree of sensitivity can be established by determination of D_{50} .¹¹ A general rule is to begin at 1/10 of the dose that produces sum of erythema of 50 mm (approximately a 2+ positive skin test reaction).

For example, if a patient exhibits a 2+ intradermal reaction to 1 AU/mL, the first dose should be no higher than 0.05 mL of 0.1 AU/mL. Dosage may be increased by 0.05 mL each time until 0.5 mL is reached, at which time the next 10-fold more concentrated dilution can be used, beginning with 0.05 mL, if no untoward reaction is observed.

Interval between doses in the early stages of immunotherapy is no more than once to twice a week, and may gradually be increased to once every two weeks. Generally, maintenance injections may be given as infrequently as once every two weeks to once a month.

Injections are given subcutaneously, preferably in the arm. It is advantageous to give injections in alternate arms and routinely in the same area. In some patients, a local tolerance to the allergen may develop thus preventing a possible severe local reaction.

Formal stability studies for diluted and undiluted forms of unstandardized extracts have not been performed; therefore, it is recommended that minimal amounts of the concentrate be diluted so that the diluted product is used up within a relatively short period of time; i.e., preferably not more than four weeks.

PRE-SEASONAL METHOD OF TREATMENT

Treatment of hay fever by the pre-seasonal method should be started 6-10 weeks prior to the usual onset of symptoms. Therapy should be started early enough to permit a graduated series of doses at 2-7 day intervals. It is recommended that the larger doses be spaced 5-7 days apart.

Some physicians continue therapy into or through the season by repeating a reduced or MAINTENANCE dose at weekly or biweekly intervals. If during the season, hay fever symptoms develop, relief may be provided by giving supplemental treatment. If the last

dose was well-tolerated and not more than 2 weeks has elapsed since it was given, this dose may be given again and repeated every 4 to 7 days.

PERENNIAL TREATMENT

The patient's tolerance to the offending pollen or pollens is first established by the injection of a series of graduated doses as outlined in the PRE-SEASONAL METHOD, not necessarily given pre-seasonally, since perennial therapy may be begun at any time. After completion of the ascending series of injections, from 1/4 to 1/2 of the highest well-tolerated dose is continued at 2 to 3 week intervals throughout the year. Shortly before the usual onset of symptoms (4 to 5 weeks prior to the season) the interval between injections is shortened and the dosage is gradually increased, according to the Pre-Seasonal schedule, until maximum well-tolerated dose is again attained. This top dose should be reached just before the usual onset of symptoms at which time the treatment is discontinued. If patient's symptoms persist, therapy may be continued at a reduced dosage level, usually 1/4 to 1/2 of the top dose.

DOSAGE ADJUSTMENTS

For Products Containing Short Ragweed.

In transferring patients from unstandardized to standardized product, the physician should establish the potency relationships, perhaps by comparative skin testing, prior to injecting the first standardized dose.

AgE is important in adjusting dosage of Short Ragweed extracts to accurately transfer a patient from older extracts to fresher material. In such cases, the dosage of AgE should be considered in addition to the W/V dilution or protein nitrogen units. Antigen E concentration continuously declines in Short Ragweed Pollen extracts at a rate that varies with the formulation of the product. Aqueous extracts retain Antigen E potency less effectively than glycerin 50% (v/v) extracts. These differences are reflected in the expiration date declared on the vial. The continuous decline should be considered. Also, where ragweed is a component of an allergen mixture, clinical response to the other components must be considered in adjustment of dosage based on AgE content alone. The usual course of immunotherapy is three to five years.

Caution: A small percent of individuals allergic to Short Ragweed are more sensitive to minor antigens such as Ra3 Ra5 than AgE. There is no correlation between the amount of these antigens and either AgE or PNU content.

NOTE: *For extracts of Short Ragweed or equal part mixture of Short and Tall Ragweed refer to AgE dosage schedule. The AgE content for those products is indicated on the vial label. The physician may use the formula below to determine the AgE dosage for each injection.*

AgE dosage can be monitored by using the following formula:

W/V compounded products:

Labeled AgE X Dose (mL) = dose in AgE

PNU compounded products:

Labeled AgE/mL X dose in PNU = dose in AgE

Labeled PNU/mL

HOW SUPPLIED

1. Concentrate in multiple dose vials:
2. Sterile Diluent for Allergenic Extracts (Phenol Saline) is supplied in vials of 4.5 mL, 9.0 mL, 30 mL and 100 mL.

10 mL and 50 mL, single antigens or specified mixtures, potency expressed in PNU/mL (up to and including 100,000 PNU/mL) or W/V (up to and including 1:10 W/V), aqueous or in 50% glycerin, to be diluted prior to use. 1:10 w/v short ragweed extracts contain \geq 300 units/mL of AgE.

STORAGE: To maintain stability of allergenic extracts, proper storage conditions are essential. Bulk concentrates and diluted extracts are to be stored at 2° to 8° C even during use. Bulk or diluted extracts are not to be frozen. Do not use after the expiration date shown on the vial label.

REFERENCES

1. Norman, P.S. *et al*: Immunotherapy of hayfever with ragweed antigen E. Comparisons with whole pollen extract and placebo. *J. Allergy* 42:93, 1968.
2. Van Metre, T.E. *et al*: A controlled study of the effectiveness of the Rinkel method of immunotherapy for ragweed pollen hayfever. *J. Allergy Clin. Immunol.* 65:288, 1980.
3. Umetsu, D.T. *et al*: Serum sickness triggered by anaphylaxis: a complication of immunotherapy. *J. Allergy Clin. Immunol.* 76:713, 1985.
4. Phannphak, P. and Kohler, P.F.: Onset of polyarteritis nodosa during allergic hyposensitization treatment. *Am. J. Med.* 68:479, 1980.
5. Kohler, P.F.: Immune complexes and allergic disease. In: Middleton *et al*: Allergy Principles and Practice 3rd Ed. St. Louis: CV Mosby, 1988:167.
6. Bousquet, J.: In vivo methods for the study of allergy: skin test, techniques, and interpretation. In: Middleton *et al*: Allergy Principles and Practice 3rd Ed. St. Louis: CV Mosby, 1988:167.
7. Committee on the Safety of Medicines. CSM update: desensitising vaccines. *Brit Med. J.* 293:948,1986.
8. Lockey, R.F. *et al*: Fatalities from immunotherapy (IT) and skin testing (ST). *J. Allergy Clin. Immunol.* 79:660, 1987.
9. Reid, M.J. *et al*: Survey of fatalities from skin testing and immunotherapy. 1985-1989. *J. Allergy Clin. Immunol.*; 92:6, 1993.
10. Van Metre, T.E. *et al*: A controlled study of the effectiveness of the Rinkel method and the current standard method of immunotherapy for ragweed pollen hayfever. *J. Allergy Clin. Immunol.* 66:500, 1980.
11. Turkeltaub, P.C., Rastogi, S.C., Baer, H., *et al*: A standardized quantitative skin-test assay of allergen potency and stability: studies on the allergen dose-response curve and effect of wheal, erythema, and patient selection on assay results, *J. Allergy Clin. Immunol.* 70:343, 1982.

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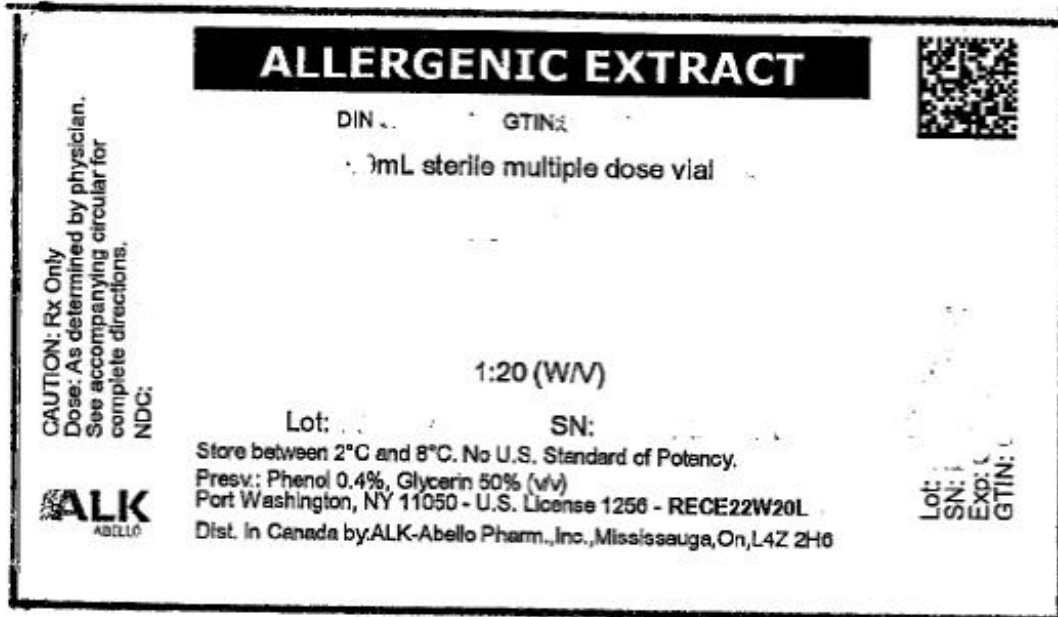
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PRINCIPAL DISPLAY PANEL

ALLERGENIC EXTRACT
 mL sterile multiple dose vial



SOLIDAGO CANADENSIS POLLEN

goldenrod injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1194 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------------|---------------------|
| SOLIDAGO CANADENSIS POLLEN (UNII: 644CZ16IR5) (SOLIDAGO CANADENSIS POLLEN - UNII:644CZ16IR5) | SOLIDAGO CANADENSIS POLLEN | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|------------------------------------|------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |

| | |
|--|-------------------|
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1194-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

JUNIPERUS CALIFORNICA POLLEN

juniper western injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1609 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|------------------------------|----------------|
| JUNIPERUS CALIFORNICA POLLEN (UNII: 0H1V4V5V9L) (JUNIPERUS CALIFORNICA POLLEN - UNII:0H1V4V5V9L) | JUNIPERUS CALIFORNICA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1609-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

CHENOPODIUM ALBUM POLLEN

lamb's quarters injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1610 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|----------------|
| CHENOPODIUM ALBUM POLLEN (UNII: 098LKX5NCN) (CHENOPODIUM ALBUM POLLEN - UNII:098LKX5NCN) | CHENOPODIUM ALBUM POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1610-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

CHENOPODIUM AMBROSIoidES POLLEN

mexican tea injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1611 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-----------------------------------|-------------------|
| CHENOPODIUM AMBROSIODES POLLEN (UNII: WB701MW2H) (CHENOPODIUM AMBROSIODES POLLEN - UNII:WB701MW2H) | CHENOPODIUM AMBROSIODES POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|--|-----------------------------|---------------------------|
| 1 | NDC:0268-1611-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1611-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| BLA | BLA103753 | 01/01/1965 | 06/30/2013 |

QUERCUS AGRIFOLIA POLLEN

oak california live coast injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1612 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------------|
| QUERCUS AGRIFOLIA POLLEN (UNII: VOT5MA71M7) (QUERCUS AGRIFOLIA | QUERCUS AGRIFOLIA | 0.05 g |

| | | | | |
|---------------------------------------|---|--|-----------------------------|---------------------------|
| POLLEN - UNII:VOT5MA71M7) | | POLLEN | in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| PHENOL (UNII: 339NCG44TV) | | | 0.004 mL in 1 mL | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | 0.009 g in 1 mL | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | 0.00275 g in 1 mL | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1612-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | | 01/01/1965 | 05/18/2023 |

| | | | | |
|--|-----------------------------|--|---------------------------|---------------------|
| QUERCUS ALBA POLLEN | | | | |
| oak white injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | | Item Code (Source) | NDC:0268-1331 |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | | Basis of Strength | Strength |
| QUERCUS ALBA POLLEN (UNII: Z4Y9ZSV4KK) (QUERCUS ALBA POLLEN - UNII:Z4Y9ZSV4KK) | | | QUERCUS ALBA POLLEN | 20000 [PNU] in 1 mL |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | 0.5 mL in 1 mL | |
| PHENOL (UNII: 339NCG44TV) | | | 0.004 mL in 1 mL | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | 0.009 g in 1 mL | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | 0.00275 g in 1 mL | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1331-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

CARYA ILLINOINENSIS POLLEN

pecan pollen injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1356 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|----------------------------|---------------------|
| CARYA ILLINOINENSIS POLLEN (UNII: PYO4JR720Y) (CARYA ILLINOINENSIS POLLEN - UNII:PYO4JR720Y) | CARYA ILLINOINENSIS POLLEN | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1356-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

CARYA ILLINOINENSIS POLLEN

pecan pollen injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1357 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------------|---------------------|
| CARYA ILLINOINENSIS POLLEN (UNII: PYO4JR720Y) (CARYA ILLINOINENSIS POLLEN - UNII:PYO4JR720Y) | CARYA ILLINOINENSIS POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1357-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

PLANTAGO LANCEOLATA POLLEN

plantain english injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1398 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------------|---------------------|
| PLANTAGO LANCEOLATA POLLEN (UNII: DO87T1U2CI) (PLANTAGO LANCEOLATA POLLEN - UNII:DO87T1U2CI) | PLANTAGO LANCEOLATA POLLEN | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1398-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

PYRETHRUM CINERARIIFOLIUM

pyrethrum cinerariifolium injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0645 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------------------|----------------|
| TANACETUM CINERARIIFOLIUM FLOWER (UNII: CGF76TP7X6) (TANACETUM CINERARIIFOLIUM FLOWER - UNII:CGF76TP7X6) | TANACETUM CINERARIIFOLIUM FLOWER | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0645-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

PYRETHRUM CINERARIIFOLIUM

pyrethrum cinerariifolium injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0646 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|----------------------------------|----------------|
| TANACETUM CINERARIIFOLIUM FLOWER (UNII: CGF76TP7X6) (TANACETUM CINERARIIFOLIUM FLOWER - UNII:CGF76TP7X6) | TANACETUM CINERARIIFOLIUM FLOWER | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0646-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 02/23/1998 | 05/18/2023 |

AMARANTHUS RETROFLEXUS POLLEN

pigweed rough redroot injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1615 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------------------|----------------|
| AMARANTHUS RETROFLEXUS POLLEN (UNII: 73B14PX5FW) (AMARANTHUS RETROFLEXUS POLLEN - UNII:73B14PX5FW) | AMARANTHUS RETROFLEXUS POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C00X) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1615-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
|-----------|---------------------------------|-----------------|---------------|
|-----------|---------------------------------|-----------------|---------------|

| Category | Citation | Date | Date |
|----------|-----------|------------|------------|
| BLA | BLA103753 | 02/23/1998 | 05/18/2023 |

IVA ANNUA VAR ANNUA POLLEN

marshelder rough injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1266 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------------|
| IVA ANNUA POLLEN (UNII: Y2U5S5PF22) (IVA ANNUA POLLEN - UNII:Y2U5S5PF22) | IVA ANNUA POLLEN | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1266-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

MELALEUCA QUINQUENERVIA POLLEN

melaleuca pollen injection, solution

Product Information

| | | | |
|--------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1273 |
|--------------|-----------------------------|--------------------|---------------|

Route of Administration SUBCUTANEOUS

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------------|----------------|
| MELALEUCA QUINQUENERVIA POLLEN (UNII: NX974IRT8E) (MELALEUCA QUINQUENERVIA POLLEN - UNII:NX974IRT8E) | MELALEUCA QUINQUENERVIA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1273-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1273-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

MELALEUCA QUINQUENERVIA POLLEN

melaleuca pollen injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1274 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------------|----------------|
| MELALEUCA QUINQUENERVIA POLLEN (UNII: NX974IRT8E) (MELALEUCA QUINQUENERVIA POLLEN - UNII:NX974IRT8E) | MELALEUCA QUINQUENERVIA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C00X) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1274-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1274-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

MELALEUCA QUINQUENERVIA POLLEN

melaleuca pollen injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1275 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------------|---------------------|
| MELALEUCA QUINQUENERVIA POLLEN (UNII: NX974IRT8E) (MELALEUCA QUINQUENERVIA POLLEN - UNII:NX974IRT8E) | MELALEUCA QUINQUENERVIA POLLEN | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1275-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

MELALEUCA QUINQUENERVIA POLLEN

melaleuca pollen injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1276 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------------|---------------------|
| MELALEUCA QUINQUENERVIA POLLEN (UNII: NX974IRT8E) (MELALEUCA QUINQUENERVIA POLLEN - UNII:NX974IRT8E) | MELALEUCA QUINQUENERVIA POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1276-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
|--------------------|--|----------------------|--------------------|

| | | | |
|-----|-----------|------------|------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |
|-----|-----------|------------|------------|

PROSOPIS JULIFLORA POLLEN

mesquite injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1279 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------------|----------------|
| PROSOPIS JULIFLORA POLLEN (UNII: 6EIJ3D04MR) (PROSOPIS JULIFLORA POLLEN - UNII:6EIJ3D04MR) | PROSOPIS JULIFLORA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1279-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

PROSOPIS JULIFLORA POLLEN

mesquite injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1280 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------------|----------------|
| PROSOPIS JULIFLORA POLLEN (UNII: 6EIJ3D04MR) (PROSOPIS JULIFLORA POLLEN - UNII:6EIJ3D04MR) | PROSOPIS JULIFLORA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C00X) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1280-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1280-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

PROSOPIS JULIFLORA POLLEN

mesquite injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1281 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------------|---------------------|
| PROSOPIS JULIFLORA POLLEN (UNII: 6EIJ3D04MR) (PROSOPIS JULIFLORA POLLEN - UNII:6EIJ3D04MR) | PROSOPIS JULIFLORA POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1281-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

CHENOPODIUM AMBROSIOIDES POLLEN

mexican tea injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1284 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|------------------------------------|-------------------|
| CHENOPODIUM AMBROSIOIDES POLLEN (UNII: WB701MW2H) (CHENOPODIUM AMBROSIOIDES POLLEN - UNII:WB701MW2H) | CHENOPODIUM AMBROSIOIDES POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

| | | | | |
|---|------------------|--|--|--|
| 1 | NDC:0268-1284-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1284-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 06/30/2013 |

CHENOPODIUM AMBROSIOIDES POLLEN

mexican tea injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1285 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|------------------------------------|-------------------|
| CHENOPODIUM AMBROSIOIDES POLLEN (UNII: WB701MW2H) (CHENOPODIUM AMBROSIOIDES POLLEN - UNII:WB701MW2H) | CHENOPODIUM AMBROSIOIDES POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1285-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1285-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| | | | |

| | | | |
|-----|-----------|------------|------------|
| BLA | BLA103753 | 01/01/1965 | 06/30/2013 |
|-----|-----------|------------|------------|

CHENOPODIUM AMBROSIOIDES POLLEN

mexican tea injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1286 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|------------------------------------|--------------------|
| CHENOPODIUM AMBROSIOIDES POLLEN (UNII: WB701MW2H) (CHENOPODIUM AMBROSIOIDES POLLEN - UNII:WB701MW2H) | CHENOPODIUM AMBROSIOIDES POLLEN | 0.025 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1286-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1286-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 06/30/2013 |

ZEA MAYS POLLEN

corn pollen injection, solution

Product Information

| | | | |
|---------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1121 |
|---------------------|-----------------------------|---------------------------|---------------|

| | | | | |
|--|--|--|-----------------------------|---------------------------|
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| | Ingredient Name | Basis of Strength | Strength | |
| | ZEA MAYS POLLEN (UNII: 74PD8J616H) (ZEA MAYS POLLEN - UNII:74PD8J616H) | ZEA MAYS POLLEN | 0.05 g in 1 mL | |
| Inactive Ingredients | | | | |
| | Ingredient Name | Strength | | |
| | GLYCERIN (UNII: PDC6A3C00X) | 0.5 mL in 1 mL | | |
| | PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL | | |
| | SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL | | |
| | SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL | | |
| | HYDROCHLORIC ACID (UNII: QTT17582CB) | | | |
| | SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1121-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1121-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | | |

| | | | |
|--|--|-----------------------------|-----------------|
| CANIS LUPUS FAMILIARIS SKIN | | | |
| dog epithelia injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0626 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| | Ingredient Name | Basis of Strength | Strength |
| | CANIS LUPUS FAMILIARIS SKIN (UNII: X2W7CLE97T) (CANIS LUPUS FAMILIARIS SKIN - UNII:X2W7CLE97T) | CANIS LUPUS FAMILIARIS SKIN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0626-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0626-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

CANIS LUPUS FAMILIARIS SKIN

dog epithelia injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0627 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------------|----------------|
| CANIS LUPUS FAMILIARIS SKIN (UNII: X2W7CLE97T) (CANIS LUPUS FAMILIARIS SKIN - UNII:X2W7CLE97T) | CANIS LUPUS FAMILIARIS SKIN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

| Packaging | | | | |
|-----------|------------------|--|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-0627-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

| CANIS LUPUS FAMILIARIS SKIN | | | |
|--|-----------------------------|---------------------|---------------|
| dog epithelia injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1600 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | Basis of Strength | Strength | |
| CANIS LUPUS FAMILIARIS SKIN (UNII: X2W7CLE97T) (CANIS LUPUS FAMILIARIS SKIN - UNII:X2W7CLE97T) | CANIS LUPUS FAMILIARIS SKIN | 10000 [PNU] in 1 mL | |
| Inactive Ingredients | | | |
| Ingredient Name | Strength | | |
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL | | |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | |

| Packaging | | | | |
|-----------|------------------|--|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1600-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|---------------------------------|-----------------|---------------|
| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
| | | | |

| Category | Citation | Date | Date |
|----------|-----------|------------|------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

CAVIA PORCELLUS SKIN

guinea pig epithelia injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0653 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------|----------------|
| CAVIA PORCELLUS SKIN (UNII: GM3H4U6QS8) (CAVIA PORCELLUS SKIN - UNII:GM3H4U6QS8) | CAVIA PORCELLUS SKIN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0653-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

CAVIA PORCELLUS SKIN

guinea pig epithelia injection, solution

Product Information

| | | | |
|---------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0654 |
|---------------------|-----------------------------|---------------------------|---------------|

| | | | | |
|--|--|--|-----------------------------|---------------------------|
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| | Ingredient Name | Basis of Strength | Strength | |
| | CAVIA PORCELLUS SKIN (UNII: GM3H4U6QS8) (CAVIA PORCELLUS SKIN - UNII:GM3H4U6QS8) | CAVIA PORCELLUS SKIN | 10000 [PNU] in 1 mL | |
| Inactive Ingredients | | | | |
| | Ingredient Name | Strength | | |
| | PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL | | |
| | SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL | | |
| | SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL | | |
| | HYDROCHLORIC ACID (UNII: QTT17582CB) | | | |
| | SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-0654-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 | |

| | | | |
|--|--|---------------------------|-----------------|
| CAVIA PORCELLUS SKIN | | | |
| guinea pig epithelia injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0655 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| | Ingredient Name | Basis of Strength | Strength |
| | CAVIA PORCELLUS SKIN (UNII: GM3H4U6QS8) (CAVIA PORCELLUS SKIN - UNII:GM3H4U6QS8) | CAVIA PORCELLUS SKIN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0655-30 | 30 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0655-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

EQUUS CABALLUS SKIN

horse epithelia injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0628 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|---------------------|----------------|
| EQUUS CABALLUS SKIN (UNII: 88VZV9HGT4) (EQUUS CABALLUS SKIN - UNII:88VZV9HGT4) | EQUUS CABALLUS SKIN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0628-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0628-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

EQUUS CABALLUS SKIN

horse epithelia injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0629 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------|---------------------|
| EQUUS CABALLUS SKIN (UNII: 88VZV9HGT4) (EQUUS CABALLUS SKIN - UNII:88VZV9HGT4) | EQUUS CABALLUS SKIN | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0629-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0629-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

CLADOSPORIUM SPHAEROSPERMUM

cladosporium sphaerospermum injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0865 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-----------------------------|---------------------|
| CLADOSPORIUM SPHAEROSPERMUM (UNII: P87YCA1U8R) (CLADOSPORIUM SPHAEROSPERMUM - UNII:P87YCA1U8R) | CLADOSPORIUM SPHAEROSPERMUM | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0865-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0865-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

CLADOSPORIUM SPHAEROSPERMUM

cladosporium sphaerospermum injection, solution

| Product Information | | | | |
|--|---|--|-----------------------------|---------------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0866 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| CLADOSPORIUM SPHAEROSPERMUM (UNII: P87YCA1U8R) (CLADOSPORIUM SPHAEROSPERMUM - UNII:P87YCA1U8R) | | CLADOSPORIUM SPHAEROSPERMUM | 1000 [PNU] in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-0866-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 | |

| CLADOSPORIUM SPHAEROSPERMUM | | | | |
|--|-----------------------------|-----------------------------|------------------|--|
| cladosporium sphaerospermum injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0867 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| CLADOSPORIUM SPHAEROSPERMUM (UNII: P87YCA1U8R) (CLADOSPORIUM SPHAEROSPERMUM - UNII:P87YCA1U8R) | | CLADOSPORIUM SPHAEROSPERMUM | 10 [PNU] in 1 mL | |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0867-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

CLADOSPORIUM SPHAEROSPERMUM

cladosporium sphaerospermum injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0868 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-----------------------------|-------------------|
| CLADOSPORIUM SPHAEROSPERMUM (UNII: P87YCA1U8R) (CLADOSPORIUM SPHAEROSPERMUM - UNII:P87YCA1U8R) | CLADOSPORIUM SPHAEROSPERMUM | 100 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0868-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0868-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

CLADOSPORIUM SPHAEROSPERMUM

cladosporium sphaerospermum injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0869 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-----------------------------|-----------------|
| CLADOSPORIUM SPHAEROSPERMUM (UNII: P87YCA1U8R) (CLADOSPORIUM SPHAEROSPERMUM - UNII:P87YCA1U8R) | CLADOSPORIUM SPHAEROSPERMUM | 0.001 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0268-0869-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

CLADOSPORIUM SPHAEROSPERMUM

cladosporium sphaerospermum injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0870 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------------|---------------------|
| CLADOSPORIUM SPHAEROSPERMUM (UNII: P87YCA1U8R) (CLADOSPORIUM SPHAEROSPERMUM - UNII:P87YCA1U8R) | CLADOSPORIUM SPHAEROSPERMUM | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0870-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0870-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

CLADOSPORIUM SPHAEROSPERMUM

cladosporium sphaerospermum injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0871 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------------|---------------------|
| CLADOSPORIUM SPHAEROSPERMUM (UNII: P87YCA1U8R) (CLADOSPORIUM SPHAEROSPERMUM - UNII:P87YCA1U8R) | CLADOSPORIUM SPHAEROSPERMUM | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0871-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0871-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

COCHLIOBOLUS SATIVUS

helminthosporium sorokinianum injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0878 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------|---------------------|
| COCHLIOBOLUS SATIVUS (UNII: 3LN5B70U4W) (COCHLIOBOLUS SATIVUS - UNII:3LN5B70U4W) | COCHLIOBOLUS SATIVUS | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0878-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0878-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

COCHLIOBOLUS SATIVUS

helminthosporium sorokinianum injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0879 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|----------------------|---------------------|
| COCHLIOBOLUS SATIVUS (UNII: 3LN5B70U4W) (COCHLIOBOLUS SATIVUS - UNII:3LN5B70U4W) | COCHLIOBOLUS SATIVUS | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0879-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0879-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

COCHLIOBOLUS SATIVUS

helminthosporium sorokinianum injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0880 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------|---------------------|
| COCHLIOBOLUS SATIVUS (UNII: 3LN5B70U4W) (COCHLIOBOLUS SATIVUS - UNII:3LN5B70U4W) | COCHLIOBOLUS SATIVUS | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0880-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0880-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

COCHLIOBOLUS SATIVUS

helminthosporium sorokinianum injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0881 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|----------------------|-----------------|
| COCHLIOBOLUS SATIVUS (UNII: 3LN5B70U4W) (COCHLIOBOLUS SATIVUS - UNII:3LN5B70U4W) | COCHLIOBOLUS SATIVUS | 0.001 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0268-0881-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

COCHLIOBOLUS SATIVUS

helminthosporium sorokinianum injection, solution

| Product Information | | | | | |
|--|------------------|--|----------------------|---------------------|---------------|
| Product Type | | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | | NDC:0268-0882 |
| Route of Administration | | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | | |
| Ingredient Name | | | Basis of Strength | Strength | |
| COCHLIOBOLUS SATIVUS (UNII: 3LN5B70U4W) (COCHLIOBOLUS SATIVUS - UNII:3LN5B70U4W) | | | COCHLIOBOLUS SATIVUS | 20000 [PNU] in 1 mL | |
| Inactive Ingredients | | | | | |
| Ingredient Name | | | Strength | | |
| GLYCERIN (UNII: PDC6A3C00X) | | | 0.5 mL in 1 mL | | |
| PHENOL (UNII: 339NCG44TV) | | | 0.004 mL in 1 mL | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | 0.009 g in 1 mL | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | 0.00275 g in 1 mL | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | | |
| Packaging | | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:0268-0882-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | | |
| 2 | NDC:0268-0882-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | | |
| Marketing Information | | | | | |
| Marketing Category | | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | | BLA103753 | 01/01/1965 | 05/18/2023 | |

| EPICOCCUM NIGRUM | | | | | |
|--------------------------------------|--|-----------------------------|--------------------|----------|---------------|
| epicoccum nigrum injection, solution | | | | | |
| Product Information | | | | | |
| Product Type | | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | | NDC:0268-0886 |
| Route of Administration | | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | | |
| Ingredient Name | | | Basis of | Strength | |

| Ingredient Name | | Strength | Strength | |
|--|--|--|----------------------|--------------------|
| EPICOCCUM NIGRUM (UNII: 87U156LEN7) (EPICOCCUM NIGRUM - UNII:87U156LEN7) | | EPICOCCUM NIGRUM | 40000 [PNU] in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-0886-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0886-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 | |

| EPICOCCUM NIGRUM | | | |
|--|-----------------------------|--------------------|--------------------|
| epicoccum nigrum injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0887 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| EPICOCCUM NIGRUM (UNII: 87U156LEN7) (EPICOCCUM NIGRUM - UNII:87U156LEN7) | | EPICOCCUM NIGRUM | 1000 [PNU] in 1 mL |
| Inactive Ingredients | | | |
| Ingredient Name | | Strength | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | |

| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | | |
|--|--|--|----------------------|--------------------|
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-0887-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 | |

| EPICOCCUM NIGRUM | | | | |
|---|-----------------------------|--|----------------------|--------------------|
| epicoccum nigrum injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0888 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | Basis of Strength | Strength | | |
| EPICOCCUM NIGRUM (UNII: 87U156LEN7) (EPICOCCUM NIGRUM - UNII:87U156LEN7) | EPICOCCUM NIGRUM | 10 [PNU] in 1 mL | | |
| Inactive Ingredients | | | | |
| Ingredient Name | Strength | | | |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL | | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-0888-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

EPICOCCUM NIGRUM

epicoccum nigrum injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0889 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-------------------|
| EPICOCCUM NIGRUM (UNII: 87U156LEN7) (EPICOCCUM NIGRUM - UNII:87U156LEN7) | EPICOCCUM NIGRUM | 100 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0889-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

EPICOCCUM NIGRUM

epicoccum nigrum injection, solution

| Product Information | | | | |
|--|--|--|----------------------|--------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0890 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| EPICOCCUM NIGRUM (UNII: 87U156LEN7) (EPICOCCUM NIGRUM - UNII:87U156LEN7) | | EPICOCCUM NIGRUM | 0.025 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| GLYCERIN (UNII: PDC6A3C00X) | | 0.5 mL in 1 mL | | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-0890-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 | |

| EPICOCCUM NIGRUM | | | |
|--------------------------------------|-----------------------------|--------------------|---------------|
| epicoccum nigrum injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0891 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |

| | | |
|---|------------------|--------------------|
| EPICOCCUM NIGRUM (UNII: 87U156LEN7) (EPICOCCUM NIGRUM - UNII:87U156LEN7) | EPICOCCUM NIGRUM | 0.001 g in 1 mL |
|---|------------------|--------------------|

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0268-0891-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

EPICOCCUM NIGRUM

epicoccum nigrum injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0892 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|------------------------|
| EPICOCCUM NIGRUM (UNII: 87U156LEN7) (EPICOCCUM NIGRUM - UNII:87U156LEN7) | EPICOCCUM NIGRUM | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |

SODIUM HYDROXIDE (UNII: 55X04QC32I)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0892-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0892-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

EPICOCCUM NIGRUM

epicoccum nigrum injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0893 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------------|
| EPICOCCUM NIGRUM (UNII: 87U156LEN7) (EPICOCCUM NIGRUM - UNII:87U156LEN7) | EPICOCCUM NIGRUM | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0893-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

FUSARIUM OXYSPORUM VASINFECTUM

fusarium vasinfectum injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0894 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------------|---------------------|
| FUSARIUM OXYSPORUM VASINFECTUM (UNII: 6M98DC08TZ) (FUSARIUM OXYSPORUM VASINFECTUM - UNII:6M98DC08TZ) | FUSARIUM OXYSPORUM VASINFECTUM | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0894-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0894-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

FUSARIUM OXYSPORUM VASINFECTUM

fusarium vasinfectum injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0895 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------------------|---------------------|
| FUSARIUM OXYSPOURUM VASINFECTUM (UNII: 6M98DC08TZ) (FUSARIUM OXYSPOURUM VASINFECTUM - UNII:6M98DC08TZ) | FUSARIUM OXYSPOURUM VASINFECTUM | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|--|-----------------------------|---------------------------|
| 1 | NDC:0268-0895-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0895-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

FUSARIUM OXYSPOURUM VASINFECTUM

fusarium vasinfectum injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0896 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|------------------------|--------------------------|-----------------|
|------------------------|--------------------------|-----------------|

| | | |
|---|--------------------------------|---------------------|
| FUSARIUM OXYSPORUM VASINFECTUM (UNII: 6M98DC08TZ) (FUSARIUM OXYSPORUM VASINFECTUM - UNII:6M98DC08TZ) | FUSARIUM OXYSPORUM VASINFECTUM | 40000 [PNU] in 1 mL |
|---|--------------------------------|---------------------|

| Inactive Ingredients | |
|--|-------------------|
| Ingredient Name | Strength |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

| Packaging | | | | |
|-----------|------------------|--|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-0896-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

FUSARIUM OXYSPORUM VASINFECTUM

fusarium vasinfectum injection, solution

| Product Information | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0897 |
| Route of Administration | SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | |
|---|--------------------------------|--------------------|
| Ingredient Name | Basis of Strength | Strength |
| FUSARIUM OXYSPORUM VASINFECTUM (UNII: 6M98DC08TZ) (FUSARIUM OXYSPORUM VASINFECTUM - UNII:6M98DC08TZ) | FUSARIUM OXYSPORUM VASINFECTUM | 1000 [PNU] in 1 mL |

| Inactive Ingredients | |
|--|-------------------|
| Ingredient Name | Strength |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0897-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

FUSARIUM OXYSPORUM VASINFECTUM

fusarium vasinfectum injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0898 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------------|------------------|
| FUSARIUM OXYSPORUM VASINFECTUM (UNII: 6M98DC08TZ) (FUSARIUM OXYSPORUM VASINFECTUM - UNII:6M98DC08TZ) | FUSARIUM OXYSPORUM VASINFECTUM | 10 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0898-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
|--------------------|--|----------------------|--------------------|

| | | | |
|-----|-----------|------------|------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |
|-----|-----------|------------|------------|

FUSARIUM OXYSPORUM VASINFECTUM

fusarium vasinfectum injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0899 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------------|-------------------|
| FUSARIUM OXYSPORUM VASINFECTUM (UNII: 6M98DC08TZ) (FUSARIUM OXYSPORUM VASINFECTUM - UNII:6M98DC08TZ) | FUSARIUM OXYSPORUM VASINFECTUM | 100 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0899-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0899-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

FUSARIUM OXYSPORUM VASINFECTUM

fusarium vasinfectum injection, solution

Product Information

| | | | |
|---------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0900 |
|---------------------|-----------------------------|---------------------------|---------------|

Route of Administration SUBCUTANEOUS

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------------------|-----------------|
| FUSARIUM OXYSPOURUM VASINFECTUM (UNII: 6M98DC08TZ) (FUSARIUM OXYSPOURUM VASINFECTUM - UNII:6M98DC08TZ) | FUSARIUM OXYSPOURUM VASINFECTUM | 0.001 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0268-0900-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

FUSARIUM OXYSPOURUM VASINFECTUM

fusarium vasinfectum injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0901 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------------------|---------------------|
| FUSARIUM OXYSPOURUM VASINFECTUM (UNII: 6M98DC08TZ) (FUSARIUM OXYSPOURUM VASINFECTUM - UNII:6M98DC08TZ) | FUSARIUM OXYSPOURUM VASINFECTUM | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------|----------|
|-----------------|----------|

| | |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C00X) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0901-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0901-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

FUSARIUM OXYSPORUM VASINFECTUM

fusarium vasinfectum injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0902 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------------|---------------------|
| FUSARIUM OXYSPORUM VASINFECTUM (UNII: 6M98DC08TZ) (FUSARIUM OXYSPORUM VASINFECTUM - UNII:6M98DC08TZ) | FUSARIUM OXYSPORUM VASINFECTUM | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0902-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0902-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

HELMINTHOSPORIUM SOLANI

helminthosporium solani injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0903 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------------|---------------------|
| HELMINTHOSPORIUM SOLANI (UNII: U6Z259H815) (HELMINTHOSPORIUM SOLANI - UNII:U6Z259H815) | HELMINTHOSPORIUM SOLANI | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0903-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
|--------------------|--|----------------------|--------------------|

| | | | |
|-----|-----------|------------|------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |
|-----|-----------|------------|------------|

HELMINTHOSPORIUM SOLANI

helminthosporium solani injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0904 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------------|---------------------|
| HELMINTHOSPORIUM SOLANI (UNII: U6Z259H815) (HELMINTHOSPORIUM SOLANI - UNII:U6Z259H815) | HELMINTHOSPORIUM SOLANI | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0904-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

HELMINTHOSPORIUM SOLANI

helminthosporium solani injection, solution

Product Information

| | | | |
|---------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0905 |
|---------------------|-----------------------------|---------------------------|---------------|

Route of Administration SUBCUTANEOUS

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------------|---------------------|
| HELMINTHOSPORIUM SOLANI (UNII: U6Z259H815) (HELMINTHOSPORIUM SOLANI - UNII:U6Z259H815) | HELMINTHOSPORIUM SOLANI | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0905-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

HELMINTHOSPORIUM SOLANI

helminthosporium solani injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0906 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------------|---------------------|
| HELMINTHOSPORIUM SOLANI (UNII: U6Z259H815) (HELMINTHOSPORIUM SOLANI - UNII:U6Z259H815) | HELMINTHOSPORIUM SOLANI | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0906-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

MUCOR PLUMBEUS

mucor plumbeus injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0911 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------------|
| MUCOR PLUMBEUS (UNII: D7401PWY6E) (MUCOR PLUMBEUS - UNII:D7401PWY6E) | MUCOR PLUMBEUS | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0911-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0911-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

MUCOR PLUMBEUS

mucor plumbeus injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0912 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------------|
| MUCOR PLUMBEUS (UNII: D7401PWY6E) (MUCOR PLUMBEUS - UNII:D7401PWY6E) | MUCOR PLUMBEUS | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0912-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0912-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

MUCOR PLUMBEUS

mucor plumbeus injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0913 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------------|
| MUCOR PLUMBEUS (UNII: D7401PWY6E) (MUCOR PLUMBEUS - UNII:D7401PWY6E) | MUCOR PLUMBEUS | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0913-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0913-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

MUCOR PLUMBEUS

mucor plumbeus injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0914 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|---------------------|
| MUCOR PLUMBEUS (UNII: D7401PWY6E) (MUCOR PLUMBEUS - UNII:D7401PWY6E) | MUCOR PLUMBEUS | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|--|-----------------------------|---------------------------|
| 1 | NDC:0268-0914-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0914-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

MUCOR PLUMBEUS

mucor plumbeus injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0915 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | | Basis of Strength | Strength | |
|--|--|--|----------------------|--------------------|
| MUCOR PLUMBEUS (UNII: D7401PWY6E) (MUCOR PLUMBEUS - UNII:D7401PWY6E) | | MUCOR PLUMBEUS | 10000 [PNU] in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-0915-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 | |

| NEUROSPORA INTERMEDIA | | | |
|--|-----------------------------|-----------------------|---------------------|
| neurospora intermedia injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0916 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| NEUROSPORA INTERMEDIA (UNII: 2072U60DUI) (NEUROSPORA INTERMEDIA - UNII:2072U60DUI) | | NEUROSPORA INTERMEDIA | 40000 [PNU] in 1 mL |
| Inactive Ingredients | | | |
| Ingredient Name | | Strength | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | |

HYDROCHLORIC ACID (UNII: QTT17582CB)

SODIUM HYDROXIDE (UNII: 55X04QC32I)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0916-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0916-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

NEUROSPORA INTERMEDIA

neurospora intermedia injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0917 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------|---------------------|
| NEUROSPORA INTERMEDIA (UNII: 2072U60DUI) (NEUROSPORA INTERMEDIA - UNII:2072U60DUI) | NEUROSPORA INTERMEDIA | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0917-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| | | |
|---|------------------|--|
| 2 | NDC:0268-0917-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product |
|---|------------------|--|

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

NEUROSPORA INTERMEDIA

neurospora intermedia injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0918 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-----------------------|-----------------|
| NEUROSPORA INTERMEDIA (UNII: 2072U60DUI) (NEUROSPORA INTERMEDIA - UNII:2072U60DUI) | NEUROSPORA INTERMEDIA | 0.001 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0268-0918-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

NEUROSPORA INTERMEDIA

neurospora intermedia injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0919 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------|---------------------|
| NEUROSPORA INTERMEDIA (UNII: 2072U60DUI) (NEUROSPORA INTERMEDIA - UNII:2072U60DUI) | NEUROSPORA INTERMEDIA | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0919-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

NEUROSPORA INTERMEDIA

neurospora intermedia injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0920 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------|---------------------|
| NEUROSPORA INTERMEDIA (UNII: 2072U60DUI) (NEUROSPORA INTERMEDIA - UNII:2072U60DUI) | NEUROSPORA INTERMEDIA | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0920-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

PENICILLIUM CHRYSOGENUM VAR CHRYSOGENUM

penicillium chrysogenum injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0921 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--|---------------------|
| PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM (UNII: 3Y1PE1GCIG) (PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM - UNII:3Y1PE1GCIG) | PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------|------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |

| | |
|--|-------------------|
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0921-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0921-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

PENICILLIUM CHRYSOGENUM VAR CHRYSOGENUM

penicillium chrysogenum injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0922 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--|---------------------|
| PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM (UNII: 3Y1PE1GCIG) (PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM - UNII:3Y1PE1GCIG) | PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0922-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0922-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

PENICILLIUM CHRYSOGENUM VAR CHRYSOGENUM

penicillium chrysogenum injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0923 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--|---------------------|
| PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM (UNII: 3Y1PE1GCIG) (PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM - UNII:3Y1PE1GCIG) | PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0923-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0923-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
|-----------|---------------------------------|-----------------|---------------|
|-----------|---------------------------------|-----------------|---------------|

| Category | Citation | Date | Date |
|----------|-----------|------------|------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

PENICILLIUM CHRYSOGENUM VAR CHRYSOGENUM

penicillium chrysogenum injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0924 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--|----------------------|
| PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM (UNII: 3Y1PE1GCIG) (PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM - UNII:3Y1PE1GCIG) | PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM | 100 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0924-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

PENICILLIUM CHRYSOGENUM VAR CHRYSOGENUM

penicillium chrysogenum injection, solution

Product Information

| | | | |
|---------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0925 |
|---------------------|-----------------------------|---------------------------|---------------|

Route of Administration SUBCUTANEOUS

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--|--------------------|
| PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM (UNII: 3Y1PE1GCIG) (PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM - UNII:3Y1PE1GCIG) | PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM | 0.001 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0268-0925-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

PENICILLIUM CHRYSOGENUM VAR CHRYSOGENUM

penicillium chrysogenum injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0926 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--|------------------------|
| PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM (UNII: 3Y1PE1GCIG) (PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM - UNII:3Y1PE1GCIG) | PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0926-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0926-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

PHOMA EXIGUA VAR EXIGUA

phoma herbarum injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0928 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|---------------------|
| PHOMA EXIGUA VAR. EXIGUA (UNII: 8JAG41IE4M) (PHOMA EXIGUA VAR. EXIGUA - UNII:8JAG41IE4M) | PHOMA EXIGUA VAR. EXIGUA | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0928-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0928-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

PHOMA EXIGUA VAR EXIGUA

phoma herbarum injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0929 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|---------------------|
| PHOMA EXIGUA VAR. EXIGUA (UNII: 8JAG41IE4M) (PHOMA EXIGUA VAR. EXIGUA - UNII:8JAG41IE4M) | PHOMA EXIGUA VAR. EXIGUA | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0929-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0929-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

PHOMA EXIGUA VAR EXIGUA

phoma herbarum injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0930 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|---------------------|
| PHOMA EXIGUA VAR. EXIGUA (UNII: 8JAG41IE4M) (PHOMA EXIGUA VAR. EXIGUA - UNII:8JAG41IE4M) | PHOMA EXIGUA VAR. EXIGUA | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0930-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0930-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

PHOMA EXIGUA VAR EXIGUA

phoma herbarum injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0932 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|---------------------|
| PHOMA EXIGUA VAR. EXIGUA (UNII: 8JAG41IE4M) (PHOMA EXIGUA VAR. EXIGUA - UNII:8JAG41IE4M) | PHOMA EXIGUA VAR. EXIGUA | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|--|-----------------------------|---------------------------|
| 1 | NDC:0268-0932-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0932-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

PHOMA EXIGUA VAR EXIGUA

phoma herbarum injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0933 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | | Basis of Strength | Strength | |
|--|--|--|----------------------|--------------------|
| PHOMA EXIGUA VAR. EXIGUA (UNII: 8JAG41IE4M) (PHOMA EXIGUA VAR. EXIGUA - UNII:8JAG41IE4M) | | PHOMA EXIGUA VAR. EXIGUA | 10000 [PNU] in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| GLYCERIN (UNII: PDC6A3C00X) | | 0.5 mL in 1 mL | | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-0933-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 | |

PHOMA EXIGUA VAR EXIGUA

phoma herbarum injection, solution

| Product Information | | | |
|--|-----------------------------|--------------------------|-----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0931 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| PHOMA EXIGUA VAR. EXIGUA (UNII: 8JAG41IE4M) (PHOMA EXIGUA VAR. EXIGUA - UNII:8JAG41IE4M) | | PHOMA EXIGUA VAR. EXIGUA | 0.001 g in 1 mL |
| Inactive Ingredients | | | |
| Ingredient Name | | Strength | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | |

HYDROCHLORIC ACID (UNII: QTT17582CB)

SODIUM HYDROXIDE (UNII: 55X04QC32I)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0268-0931-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

RHIZOPUS ARRHIZUS VAR ARRHIZUS

rhizopus batatas injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0934 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------|------------------------|
| RHIZOPUS ARRHIZUS (UNII: 8476849N1Y) (RHIZOPUS ARRHIZUS - UNII:8476849N1Y) | RHIZOPUS ARRHIZUS | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0934-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0934-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

RHIZOPUS ARRHZUS VAR ARRHZUS

rhizopus batatas injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0935 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------|------------------------|
| RHIZOPUS ARRHZUS (UNII: 8476849N1Y) (RHIZOPUS ARRHZUS - UNII:8476849N1Y) | RHIZOPUS ARRHZUS | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0935-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0935-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

RHIZOPUS ARRHZUS VAR ARRHZUS

rhizopus batatas injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0936 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|------------------------|
| RHIZOPUS ARRHZUS (UNII: 8476849N1Y) (RHIZOPUS ARRHZUS - UNII:8476849N1Y) | RHIZOPUS ARRHZUS | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|--|-----------------------------|---------------------------|
| 1 | NDC:0268-0936-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0936-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

RHIZOPUS ARRHZUS VAR ARRHZUS

rhizopus batatas injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0937 |
| Route of Administration | SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | | | |
|---|--|--|----------------------|--------------------|
| Ingredient Name | Basis of Strength | Strength | | |
| RHIZOPUS ARRHZUS (UNII: 8476849N1Y) (RHIZOPUS ARRHZUS - UNII:8476849N1Y) | RHIZOPUS ARRHZUS | 20000 [PNU] in 1 mL | | |
| Inactive Ingredients | | | | |
| Ingredient Name | Strength | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL | | | |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL | | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-0937-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0937-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 | |

RHODOTORULA RUBRA

rhodotorula rubra injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0939 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------|------------------------|
| RHODOTORULA RUBRA (UNII: 15W81V867R) (RHODOTORULA RUBRA - UNII:15W81V867R) | RHODOTORULA RUBRA | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0939-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0939-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

STEMPHYLIUM SOLANI

stemphylium solani injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0957 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------|---------------------|
| STEMPHYLIUM SOLANI (UNII: 1IEK4UDP5M) (STEMPHYLIUM SOLANI - UNII:1IEK4UDP5M) | STEMPHYLIUM SOLANI | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0957-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0957-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

| STEMPHYLIUM SOLANI | | | | |
|--|--|---|----------------------|--------------------|
| stemphylium solani injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0958 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| STEMPHYLIUM SOLANI (UNII: 1IEK4UDP5M) (STEMPHYLIUM SOLANI - UNII:1IEK4UDP5M) | | STEMPHYLIUM SOLANI | 0.001 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-0958-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |

| | | | |
|-----|-----------|------------|------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |
|-----|-----------|------------|------------|

STEMPHYLIUM SOLANI

stemphylium solani injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0959 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------|---------------------|
| STEMPHYLIUM SOLANI (UNII: 1IEK4UDP5M) (STEMPHYLIUM SOLANI - UNII:1IEK4UDP5M) | STEMPHYLIUM SOLANI | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0959-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0959-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

TRICHOPHYTON MENTAGROPHYTES

trichophyton mentagrophytes injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0961 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------------|---------------------|
| TRICHOPHYTON MENTAGROPHYTES (UNII: 199I7J3JIV) (TRICHOPHYTON MENTAGROPHYTES - UNII:199I7J3JIV) | TRICHOPHYTON MENTAGROPHYTES | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0961-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0961-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

TRICHOPHYTON MENTAGROPHYTES

trichophyton mentagrophytes injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0962 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------------|---------------------|
| TRICHOPHYTON MENTAGROPHYTES (UNII: 199I7J3JIV) (TRICHOPHYTON MENTAGROPHYTES - UNII:199I7J3JIV) | TRICHOPHYTON MENTAGROPHYTES | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0962-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

TRICHOPHYTON MENTAGROPHYTES

trichophyton mentagrophytes injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0963 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-----------------------------|---------------------|
| TRICHOPHYTON MENTAGROPHYTES (UNII: 199I7J3JIV) (TRICHOPHYTON MENTAGROPHYTES - UNII:199I7J3JIV) | TRICHOPHYTON MENTAGROPHYTES | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0963-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

TRICHOPHYTON MENTAGROPHYTES

trichophyton mentagrophytes injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0965 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-----------------------------|-----------------|
| TRICHOPHYTON MENTAGROPHYTES (UNII: 199I7J3JIV) (TRICHOPHYTON MENTAGROPHYTES - UNII:199I7J3JIV) | TRICHOPHYTON MENTAGROPHYTES | 0.005 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0268-0965-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

TRICHOPHYTON MENTAGROPHYTES

trichophyton mentagrophytes injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0966 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-----------------------------|---------------------|
| TRICHOPHYTON MENTAGROPHYTES (UNII: 199I7J3JIV) (TRICHOPHYTON MENTAGROPHYTES - UNII:199I7J3JIV) | TRICHOPHYTON MENTAGROPHYTES | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0966-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

TRICHOPHYTON MENTAGROPHYTES

trichophyton mentagrophytes injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0967 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------------|---------------------|
| TRICHOPHYTON MENTAGROPHYTES (UNII: 199I7J3JIV) (TRICHOPHYTON MENTAGROPHYTES - UNII:199I7J3JIV) | TRICHOPHYTON MENTAGROPHYTES | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0967-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

SACCHAROMYCES CEREVISIAE

saccharomyces cerevisiae injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0968 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|---------------------|
| SACCHAROMYCES CEREVISIAE (UNII: 978D8U419H) (SACCHAROMYCES CEREVISIAE - UNII:978D8U419H) | SACCHAROMYCES CEREVISIAE | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|------------------------------------|------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |

| | |
|--|-------------------|
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0968-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

SACCHAROMYCES CEREVISIAE

saccharomyces cerevisiae injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0969 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|---------------------|
| SACCHAROMYCES CEREVISIAE (UNII: 978D8U419H) (SACCHAROMYCES CEREVISIAE - UNII:978D8U419H) | SACCHAROMYCES CEREVISIAE | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

| | | | | |
|----------|------------------|--|--|--|
| 1 | NDC:0268-0969-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
|----------|------------------|--|--|--|

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ACACIA

acacia injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1000 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------------|
| ACACIA (UNII: 5C5403N26O) (ACACIA - UNII:5C5403N26O) | ACACIA | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1000-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1000-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ACACIA

acacia injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1001 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|-----------------|
| ACACIA (UNII: 5C5403N26O) (ACACIA - UNII:5C5403N26O) | ACACIA | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1001-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1001-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| BLA | BLA103753 | 01/01/1965 | |

AILANTHUS ALTISSIMA POLLEN

ailanthus tree of heaven injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1004 |
| Route of Administration | SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | | | |
|--|--|--|----------------------------|--------------------|
| Ingredient Name | | | Basis of Strength | Strength |
| AILANTHUS ALTISSIMA POLLEN (UNII: 2A64U81OQ3) (AILANTHUS ALTISSIMA POLLEN - UNII:2A64U81OQ3) | | | AILANTHUS ALTISSIMA POLLEN | 0.05 g in 1 mL |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | 0.5 mL in 1 mL | |
| PHENOL (UNII: 339NCG44TV) | | | 0.004 mL in 1 mL | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | 0.009 g in 1 mL | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | 0.00275 g in 1 mL | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1004-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1004-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | | 01/01/1965 | 11/30/2021 |

ALNUS INCANA SSP RUGOSA POLLEN

alder white injection, solution

| Product Information | | | |
|--|-----------------------------|-----------------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1007 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| ALNUS INCANA SUBSP. RUGOSA POLLEN (UNII: 605T96G8Y5) (ALNUS INCANA SUBSP. RUGOSA POLLEN - UNII:605T96G8Y5) | | ALNUS INCANA SUBSP. RUGOSA POLLEN | 0.10 g in 1 mL |
| Inactive Ingredients | | | |
| Ingredient Name | | Strength | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | |

| | |
|--|-------------------|
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1007-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

ALNUS INCANA SSP RUGOSA POLLEN

alder white injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1008 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------------------|----------------|
| ALNUS INCANA SUBSP. RUGOSA POLLEN (UNII: 605T96G8Y5) (ALNUS INCANA SUBSP. RUGOSA POLLEN - UNII:605T96G8Y5) | ALNUS INCANA SUBSP. RUGOSA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 | NDC:0268- | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a | | |

| | | | | |
|---|------------------|--|--|--|
| 1 | 1008-10 | Combination Product | | |
| 2 | NDC:0268-1008-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | 01/01/1965 | |

ALNUS INCANA SSP RUGOSA POLLEN

alder white injection, solution

| Product Information | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1009 |
| Route of Administration | SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | | |
|--|-----------------------------------|---------------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| ALNUS INCANA SUBSP. RUGOSA POLLEN (UNII: 605T96G8Y5) (ALNUS INCANA SUBSP. RUGOSA POLLEN - UNII:605T96G8Y5) | ALNUS INCANA SUBSP. RUGOSA POLLEN | 40000 [PNU] in 1 mL | |

| Inactive Ingredients | | |
|---------------------------------------|-------------------|--|
| Ingredient Name | Strength | |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | |

| Packaging | | | | |
|-----------|------------------|--|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1009-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

MEDICAGO SATIVA POLLEN

alfalfa injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1012 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|------------------------|----------------|
| MEDICAGO SATIVA POLLEN (UNII: G515RAI9FY) (MEDICAGO SATIVA POLLEN - UNII:G515RAI9FY) | MEDICAGO SATIVA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1012-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1012-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

MEDICAGO SATIVA POLLEN

alfalfa injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1013 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|------------------------|--------------------|
| MEDICAGO SATIVA POLLEN (UNII: G515RAI9FY) (MEDICAGO SATIVA POLLEN - UNII:G515RAI9FY) | MEDICAGO SATIVA POLLEN | 1000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1013-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

FRAXINUS VELUTINA POLLEN

ash arizona injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1016 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|----------------|
| FRAXINUS VELUTINA POLLEN (UNII: LJT6I6Z8FD) (FRAXINUS VELUTINA POLLEN - UNII:LJT6I6Z8FD) | FRAXINUS VELUTINA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------|------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |

| | |
|--|-------------------|
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1016-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

FRAXINUS VELUTINA POLLEN

ash arizona injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1017 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|----------------|
| FRAXINUS VELUTINA POLLEN (UNII: LJT6I6Z8FD) (FRAXINUS VELUTINA POLLEN - UNII:LJT6I6Z8FD) | FRAXINUS VELUTINA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1017-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

FRAXINUS VELUTINA POLLEN

ash arizona injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1018 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|---------------------|
| FRAXINUS VELUTINA POLLEN (UNII: LJT6I6Z8FD) (FRAXINUS VELUTINA POLLEN - UNII:LJT6I6Z8FD) | FRAXINUS VELUTINA POLLEN | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1018-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

FRAXINUS AMERICANA POLLEN

ash white injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1021 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------------|-----------------|
| FRAXINUS AMERICANA POLLEN (UNII: G684LX721Q) (FRAXINUS AMERICANA POLLEN - UNII:G684LX721Q) | FRAXINUS AMERICANA POLLEN | 0.001 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:0268-1021-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

FRAXINUS AMERICANA POLLEN

ash white injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1022 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------------|
| FRAXINUS AMERICANA POLLEN (UNII: G684LX721Q) (FRAXINUS AMERICANA | FRAXINUS AMERICANA | 0.10 g |

| | | | | |
|---------------------------------------|---|--|-----------------------------|---------------------------|
| POLLEN - UNII:G684LX721Q) | | POLLEN | in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| PHENOL (UNII: 339NCG44TV) | | | 0.004 mL in 1 mL | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | 0.009 g in 1 mL | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | 0.00275 g in 1 mL | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1022-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1022-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | | 01/01/1965 | |

| | | | | |
|--|-----------------------------|---------------------------|---------------------------|-----------------|
| FRAXINUS AMERICANA POLLEN | | | | |
| ash white injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1023 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | | Basis of Strength | Strength |
| FRAXINUS AMERICANA POLLEN (UNII: G684LX721Q) (FRAXINUS AMERICANA POLLEN - UNII:G684LX721Q) | | | FRAXINUS AMERICANA POLLEN | 0.05 g in 1 mL |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | 0.5 mL in 1 mL | |
| PHENOL (UNII: 339NCG44TV) | | | 0.004 mL in 1 mL | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | 0.009 g in 1 mL | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | 0.00275 g in 1 mL | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |

SODIUM HYDROXIDE (UNII: 55X04QC32I)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1023-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1023-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

FRAXINUS AMERICANA POLLEN

ash white injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1024 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------------|---------------------|
| FRAXINUS AMERICANA POLLEN (UNII: G684LX721Q) (FRAXINUS AMERICANA POLLEN - UNII:G684LX721Q) | FRAXINUS AMERICANA POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1024-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

FRAXINUS AMERICANA POLLEN

ash white injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1025 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|---------------------------|---------------------|
| FRAXINUS AMERICANA POLLEN (UNII: G684LX721Q) (FRAXINUS AMERICANA POLLEN - UNII:G684LX721Q) | FRAXINUS AMERICANA POLLEN | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1025-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

FRAXINUS AMERICANA POLLEN

ash white injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1026 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------------|---------------------|
| FRAXINUS AMERICANA POLLEN (UNII: G684LX721Q) (FRAXINUS AMERICANA POLLEN - UNII:G684LX721Q) | FRAXINUS AMERICANA POLLEN | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|-----------------------------|---------------------------|
| 1 | NDC:0268-1026-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

POPULUS TREMULOIDES POLLEN

aspen injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1029 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------------|-----------------|
| POPULUS TREMULOIDES POLLEN (UNII: 928OC2TJDA) (POPULUS TREMULOIDES POLLEN - UNII:928OC2TJDA) | POPULUS TREMULOIDES POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1029-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1029-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

POPULUS TREMULOIDES POLLEN

aspen injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1030 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------------|----------------|
| POPULUS TREMULOIDES POLLEN (UNII: 928OC2TJDA) (POPULUS TREMULOIDES POLLEN - UNII:928OC2TJDA) | POPULUS TREMULOIDES POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1030-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1030-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

PASPALUM NOTATUM POLLEN

bahia grass injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1033 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------------|-----------------|
| PASPALUM NOTATUM POLLEN (UNII: V003SHB7VK) (PASPALUM NOTATUM POLLEN - UNII:V003SHB7VK) | PASPALUM NOTATUM POLLEN | 0.001 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0268-1033-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

PASPALUM NOTATUM POLLEN

bahia grass injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1034 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------------|----------------|
| PASPALUM NOTATUM POLLEN (UNII: V003SHB7VK) (PASPALUM NOTATUM POLLEN - UNII:V003SHB7VK) | PASPALUM NOTATUM POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1034-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1034-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

PASPALUM NOTATUM POLLEN

bahia grass injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1035 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------------|----------------|
| PASPALUM NOTATUM POLLEN (UNII: V003SHB7VK) (PASPALUM NOTATUM POLLEN - UNII:V003SHB7VK) | PASPALUM NOTATUM POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1035-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1035-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

PASPALUM NOTATUM POLLEN

bahia grass injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1036 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------------|---------------------|
| PASPALUM NOTATUM POLLEN (UNII: V003SHB7VK) (PASPALUM NOTATUM POLLEN - UNII:V003SHB7VK) | PASPALUM NOTATUM POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1036-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1036-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

PASPALUM NOTATUM POLLEN

bahia grass injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1037 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------------|---------------------|
| PASPALUM NOTATUM POLLEN (UNII: V003SHB7VK) (PASPALUM NOTATUM POLLEN - UNII:V003SHB7VK) | PASPALUM NOTATUM POLLEN | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1037-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

PASPALUM NOTATUM POLLEN

bahia grass injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1038 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------------|---------------------|
| PASPALUM NOTATUM POLLEN (UNII: V003SHB7VK) (PASPALUM NOTATUM POLLEN - UNII:V003SHB7VK) | PASPALUM NOTATUM POLLEN | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1038-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

MORELLA CERIFERA POLLEN

bayberry wax myrtle injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1041 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------------|----------------|
| MORELLA CERIFERA POLLEN (UNII: LC8MEV9S89) (MORELLA CERIFERA POLLEN - UNII:LC8MEV9S89) | MORELLA CERIFERA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1041-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

MORELLA CERIFERA POLLEN

bayberry wax myrtle injection, solution

Product Information

| | | | |
|--------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1042 |
|--------------|-----------------------------|--------------------|---------------|

| | | | | |
|--|---|--|-----------------------------|---------------------------|
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| | Ingredient Name | Basis of Strength | Strength | |
| | MORELLA CERIFERA POLLEN (UNII: LC8MEV9S89) (MORELLA CERIFERA POLLEN - UNII:LC8MEV9S89) | MORELLA CERIFERA POLLEN | 0.05 g in 1 mL | |
| Inactive Ingredients | | | | |
| | Ingredient Name | Strength | | |
| | GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL | | |
| | PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL | | |
| | SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL | | |
| | SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL | | |
| | HYDROCHLORIC ACID (UNII: QTT17582CB) | | | |
| | SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1042-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1042-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | | |

| | | | |
|---|---|---------------------------|---------------------|
| MORELLA CERIFERA POLLEN | | | |
| bayberry wax myrtle injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1043 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| | Ingredient Name | Basis of Strength | Strength |
| | MORELLA CERIFERA POLLEN (UNII: LC8MEV9S89) (MORELLA CERIFERA POLLEN - UNII:LC8MEV9S89) | MORELLA CERIFERA POLLEN | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1043-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

FAGUS GRANDIFOLIA POLLEN

beech injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1046 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|----------------|
| FAGUS GRANDIFOLIA POLLEN (UNII: 34X886W1H4) (FAGUS GRANDIFOLIA POLLEN - UNII:34X886W1H4) | FAGUS GRANDIFOLIA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1046-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

FAGUS GRANDIFOLIA POLLEN

beech injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1047 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|----------------|
| FAGUS GRANDIFOLIA POLLEN (UNII: 34X886W1H4) (FAGUS GRANDIFOLIA POLLEN - UNII:34X886W1H4) | FAGUS GRANDIFOLIA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1047-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1047-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

FAGUS GRANDIFOLIA POLLEN

beech injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1048 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|---------------------|
| FAGUS GRANDIFOLIA POLLEN (UNII: 34X886W1H4) (FAGUS GRANDIFOLIA POLLEN - UNII:34X886W1H4) | FAGUS GRANDIFOLIA POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1048-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1048-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

FAGUS GRANDIFOLIA POLLEN

beech injection, solution

| Product Information | | | | |
|--|--|--|----------------------|--------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1049 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | Basis of Strength | Strength | | |
| FAGUS GRANDIFOLIA POLLEN (UNII: 34X886W1H4) (FAGUS GRANDIFOLIA POLLEN - UNII:34X886W1H4) | FAGUS GRANDIFOLIA POLLEN | 20000 [PNU] in 1 mL | | |
| Inactive Ingredients | | | | |
| Ingredient Name | Strength | | | |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL | | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1049-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 | |

| BETULA LENTA POLLEN | | | |
|--|-----------------------------|--------------------|---------------|
| birch black injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1056 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | Basis of Strength | Strength | |
| BETULA LENTA POLLEN (UNII: JQ5HI5004M) (BETULA LENTA POLLEN - UNII:JQ5HI5004M) | BETULA LENTA POLLEN | 0.10 g in 1 mL | |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1056-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

BETULA LENTA POLLEN

birch black injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1057 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|---------------------|---------------------|
| BETULA LENTA POLLEN (UNII: JQ5HI5004M) (BETULA LENTA POLLEN - UNII:JQ5HI5004M) | BETULA LENTA POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1057-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

BETULA LENTA POLLEN

birch black injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1058 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|---------------------|----------------|
| BETULA LENTA POLLEN (UNII: JQ5HI5004M) (BETULA LENTA POLLEN - UNII:JQ5HI5004M) | BETULA LENTA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1058-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
|-----------|---------------------------------|-----------------|---------------|
|-----------|---------------------------------|-----------------|---------------|

| Category | Citation | Date | Date |
|----------|-----------|------------|------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

BETULA LENTA POLLEN

birch black injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1059 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|---------------------|---------------------|
| BETULA LENTA POLLEN (UNII: JQ5HI5004M) (BETULA LENTA POLLEN - UNII:JQ5HI5004M) | BETULA LENTA POLLEN | 50000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1059-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

BETULA NIGRA POLLEN

birch river red injection, solution

Product Information

| | | | |
|--------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1062 |
|--------------|-----------------------------|--------------------|---------------|

Route of Administration SUBCUTANEOUS

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------|----------------|
| BETULA NIGRA POLLEN (UNII: 93963RFO1P) (BETULA NIGRA POLLEN - UNII:93963RFO1P) | BETULA NIGRA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1062-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

BETULA NIGRA POLLEN

birch river red injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1063 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------|----------------|
| BETULA NIGRA POLLEN (UNII: 93963RFO1P) (BETULA NIGRA POLLEN - UNII:93963RFO1P) | BETULA NIGRA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1063-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1063-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

BETULA NIGRA POLLEN

birch river red injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1064 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------|---------------------|
| BETULA NIGRA POLLEN (UNII: 93963RFO1P) (BETULA NIGRA POLLEN - UNII:93963RFO1P) | BETULA NIGRA POLLEN | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1064-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

BETULA NIGRA POLLEN

birch river red injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1065 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------|---------------------|
| BETULA NIGRA POLLEN (UNII: 93963RFO1P) (BETULA NIGRA POLLEN - UNII:93963RFO1P) | BETULA NIGRA POLLEN | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1065-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
|--------------------|--|----------------------|--------------------|

| | | | |
|-----|-----------|------------|------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |
|-----|-----------|------------|------------|

BETULA NIGRA POLLEN

birch river red injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1066 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------|---------------------|
| BETULA NIGRA POLLEN (UNII: 93963RFO1P) (BETULA NIGRA POLLEN - UNII:93963RFO1P) | BETULA NIGRA POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1066-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1066-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

BETULA LENTA POLLEN

birch white injection, solution

Product Information

| | | | |
|---------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1069 |
|---------------------|-----------------------------|---------------------------|---------------|

Route of Administration SUBCUTANEOUS

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|---------------------|----------------|
| BETULA LENTA POLLEN (UNII: JQ5HI5004M) (BETULA LENTA POLLEN - UNII:JQ5HI5004M) | BETULA LENTA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1069-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1069-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

RHODOTORULA RUBRA

rhodotorula rubra injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0940 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------------|
| RHODOTORULA RUBRA (UNII: 15W81V867R) (RHODOTORULA RUBRA - UNII:15W81V867R) | RHODOTORULA RUBRA | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0940-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

RHODOTORULA RUBRA

rhodotorula rubra injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0941 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------------|
| RHODOTORULA RUBRA (UNII: 15W81V867R) (RHODOTORULA RUBRA - UNII:15W81V867R) | RHODOTORULA RUBRA | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0941-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

RHODOTORULA RUBRA

rhodotorula rubra injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0942 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------------|
| RHODOTORULA RUBRA (UNII: 15W81V867R) (RHODOTORULA RUBRA - UNII:15W81V867R) | RHODOTORULA RUBRA | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0942-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

RHODOTORULA RUBRA

rhodotorula rubra injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0943 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------------|
| RHODOTORULA RUBRA (UNII: 15W81V867R) (RHODOTORULA RUBRA - UNII:15W81V867R) | RHODOTORULA RUBRA | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C00X) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0943-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

RHODOTORULA RUBRA

rhodotorula rubra injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0944 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------------|
| RHODOTORULA RUBRA (UNII: 15W81V867R) (RHODOTORULA RUBRA - UNII:15W81V867R) | RHODOTORULA RUBRA | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C00X) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0944-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

USTILAGO MAYDIS

corn smut injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0945 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------------|
| USTILAGO MAYDIS (UNII: 4K7Z7K7SWG) (USTILAGO MAYDIS - UNII:4K7Z7K7SWG) | USTILAGO MAYDIS | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0945-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0945-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

USTILAGO MAYDIS

corn smut injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0946 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------------|
| USTILAGO MAYDIS (UNII: 4K7Z7K7SWG) (USTILAGO MAYDIS - UNII:4K7Z7K7SWG) | USTILAGO MAYDIS | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0946-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

USTILAGO TRITICI

loose wheat smut injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0952 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| USTILAGO TRITICI (UNII: BV82OL2IZ8) (USTILAGO TRITICI - UNII:BV82OL2IZ8) | USTILAGO TRITICI | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0952-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0952-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
|-----------|---------------------------------|-----------------|---------------|
|-----------|---------------------------------|-----------------|---------------|

| Category | Citation | Date | Date |
|----------|-----------|------------|------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

STEMPHYLIUM SOLANI

stemphylium solani injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0955 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------|---------------------|
| STEMPHYLIUM SOLANI (UNII: 1IEK4UDP5M) (STEMPHYLIUM SOLANI - UNII:1IEK4UDP5M) | STEMPHYLIUM SOLANI | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0955-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0955-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

STEMPHYLIUM SOLANI

stemphylium solani injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0956 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------|---------------------|
| STEMPHYLIUM SOLANI (UNII: 1IEK4UDP5M) (STEMPHYLIUM SOLANI - UNII:1IEK4UDP5M) | STEMPHYLIUM SOLANI | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0956-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0956-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

COCHLIOBOLUS SATIVUS

helminthosporium sorokinianum injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0883 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-------------|
| COCHLIOBOLUS SATIVUS (UNII: 3LN5B70U4W) (COCHLIOBOLUS SATIVUS - | COCHLIOBOLUS | 10000 [PNU] |

| | | |
|------------------|---------|---------|
| UNII:3LN5B70U4W) | SATIVUS | in 1 mL |
|------------------|---------|---------|

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0883-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

EPICOCCUM NIGRUM

epicoccum nigrum injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0884 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------------|
| EPICOCCUM NIGRUM (UNII: 87U156LEN7) (EPICOCCUM NIGRUM - UNII:87U156LEN7) | EPICOCCUM NIGRUM | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0884-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0884-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 3 | NDC:0268-0884-30 | 30 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

EPICOCCUM NIGRUM

epicoccum nigrum injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0885 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------------|
| EPICOCCUM NIGRUM (UNII: 87U156LEN7) (EPICOCCUM NIGRUM - UNII:87U156LEN7) | EPICOCCUM NIGRUM | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0885-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| | | |
|---|------------------|--|
| 2 | NDC:0268-0885-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product |
|---|------------------|--|

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

HOUSE DUST

house dust injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0001 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|--------------------|
| HOUSE DUST (UNII: EYO007VX98) (HOUSE DUST - UNII:EYO007VX98) | HOUSE DUST | 1000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0001-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 06/30/2013 |

HOUSE DUST

house dust injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0002 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|---------------------|
| HOUSE DUST (UNII: EYO007VX98) (HOUSE DUST - UNII:EYO007VX98) | HOUSE DUST | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|-----------------------------|---------------------------|
| 1 | NDC:0268-0002-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| BLA | BLA103753 | 01/01/1965 | 06/30/2013 |

HOUSE DUST

house dust injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0003 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|---------------------|
| HOUSE DUST (UNII: EYO007VX98) (HOUSE DUST - UNII:EYO007VX98) | HOUSE DUST | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0003-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 06/30/2013 |

HOUSE DUST

house dust injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0004 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------------|
| HOUSE DUST (UNII: EYO007VX98) (HOUSE DUST - UNII:EYO007VX98) | HOUSE DUST | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0004-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0004-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 06/30/2013 |

HOUSE DUST

house dust injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0005 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------------|
| HOUSE DUST (UNII: EYO007VX98) (HOUSE DUST - UNII:EYO007VX98) | HOUSE DUST | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0005-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0005-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| | | | |

| | | | |
|-----|-----------|------------|------------|
| BLA | BLA103753 | 01/01/1965 | 06/30/2013 |
|-----|-----------|------------|------------|

HOUSE DUST

house dust injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0006 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|------------------|
| HOUSE DUST (UNII: EYO007VX98) (HOUSE DUST - UNII:EYO007VX98) | HOUSE DUST | 10 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0006-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 06/30/2013 |

HOUSE DUST

house dust injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0007 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|-------------------|
| HOUSE DUST (UNII: EYO007VX98) (HOUSE DUST - UNII:EYO007VX98) | HOUSE DUST | 100 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0007-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0007-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 06/30/2013 |

HOUSE DUST

house dust injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0008 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|-------------------|
| HOUSE DUST (UNII: EYO007VX98) (HOUSE DUST - UNII:EYO007VX98) | HOUSE DUST | 500 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |

HYDROCHLORIC ACID (UNII: QTT17582CB)

SODIUM HYDROXIDE (UNII: 55X04QC32I)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0008-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 06/30/2013 |

HOUSE DUST

house dust injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0009 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------------|
| HOUSE DUST (UNII: EYO007VX98) (HOUSE DUST - UNII:EYO007VX98) | HOUSE DUST | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0009-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0009-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 06/30/2013 |

HOUSE DUST

house dust injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0010 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------------|
| HOUSE DUST (UNII: EYO007VX98) (HOUSE DUST - UNII:EYO007VX98) | HOUSE DUST | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0010-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 06/30/2013 |

HOUSE DUST

house dust injection, solution

| Product Information | | | | |
|--|--|--|----------------------|--------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0011 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | Basis of Strength | Strength | | |
| HOUSE DUST (UNII: EYO007VX98) (HOUSE DUST - UNII:EYO007VX98) | HOUSE DUST | 20000 [PNU] in 1 mL | | |
| Inactive Ingredients | | | | |
| Ingredient Name | Strength | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL | | | |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL | | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-0011-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0011-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 06/30/2013 | |

| HOUSE DUST | | | |
|--|-----------------------------|--------------------|---------------|
| house dust injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0012 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | Basis of Strength | Strength | |
| HOUSE DUST (UNII: EYO007VX98) (HOUSE DUST - UNII:EYO007VX98) | HOUSE DUST | 0.10 g in 1 mL | |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0012-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0012-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 06/30/2013 |

HOUSE DUST

house dust injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0013 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------------|
| HOUSE DUST (UNII: EYO007VX98) (HOUSE DUST - UNII:EYO007VX98) | HOUSE DUST | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0013-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0013-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 06/30/2013 |

BOS TAURUS SKIN

cattle epithelia injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0603 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| BOS TAURUS SKIN (UNII: 7J12CD609L) (BOS TAURUS SKIN - UNII:7J12CD609L) | BOS TAURUS SKIN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C00X) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0603-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0603-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

BOS TAURUS SKIN

cattle epithelia injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0604 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------------|
| BOS TAURUS SKIN (UNII: 7J12CD609L) (BOS TAURUS SKIN - UNII:7J12CD609L) | BOS TAURUS SKIN | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0604-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

BOS TAURUS SKIN

cattle epithelia injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0605 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|---------------------|
| BOS TAURUS SKIN (UNII: 7J12CD609L) (BOS TAURUS SKIN - UNII:7J12CD609L) | BOS TAURUS SKIN | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|-----------------------------|---------------------------|
| 1 | NDC:0268-0605-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

BOS TAURUS SKIN

cattle epithelia injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0606 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------------|
| BOS TAURUS SKIN (UNII: 7J12CD609L) (BOS TAURUS SKIN - UNII:7J12CD609L) | BOS TAURUS SKIN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0606-30 | 30 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

COTTON FIBER

cotton linters injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0609 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| COTTON FIBER (UNII: 70LDW53ROO) (COTTON FIBER - UNII:70LDW53ROO) | COTTON FIBER | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0609-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0609-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

COTTON SEED

cottonseed injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0612 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| COTTON SEED (UNII: DIOZRJ0MXN) (COTTON SEED - UNII:DIOZRJ0MXN) | COTTON SEED | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0612-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

CANIS LUPUS FAMILIARIS SKIN

dog epithelia injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0615 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------------|-------------------|
| CANIS LUPUS FAMILIARIS SKIN (UNII: X2W7CLE97T) (CANIS LUPUS FAMILIARIS SKIN - UNII:X2W7CLE97T) | CANIS LUPUS FAMILIARIS SKIN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0615-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0615-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

CANIS LUPUS FAMILIARIS SKIN

dog epithelia injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0616 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------------|--------------------|
| CANIS LUPUS FAMILIARIS SKIN (UNII: X2W7CLE97T) (CANIS LUPUS FAMILIARIS SKIN - UNII:X2W7CLE97T) | CANIS LUPUS FAMILIARIS SKIN | 1000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0616-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

CANIS LUPUS FAMILIARIS SKIN

dog epithelia injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0617 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------------|------------------|
| CANIS LUPUS FAMILIARIS SKIN (UNII: X2W7CLE97T) (CANIS LUPUS FAMILIARIS SKIN - UNII:X2W7CLE97T) | CANIS LUPUS FAMILIARIS SKIN | 10 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------|------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |

| | |
|--|-------------------|
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0617-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

CANIS LUPUS FAMILIARIS SKIN

dog epithelia injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0618 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------------|-------------------|
| CANIS LUPUS FAMILIARIS SKIN (UNII: X2W7CLE97T) (CANIS LUPUS FAMILIARIS SKIN - UNII:X2W7CLE97T) | CANIS LUPUS FAMILIARIS SKIN | 100 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0268-0618-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

CANIS LUPUS FAMILIARIS SKIN

dog epithelia injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0619 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-----------------------------|---------------------|
| CANIS LUPUS FAMILIARIS SKIN (UNII: X2W7CLE97T) (CANIS LUPUS FAMILIARIS SKIN - UNII:X2W7CLE97T) | CANIS LUPUS FAMILIARIS SKIN | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0619-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0619-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

CANIS LUPUS FAMILIARIS SKIN

dog epithelia injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0620 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------------|---------------------|
| CANIS LUPUS FAMILIARIS SKIN (UNII: X2W7CLE97T) (CANIS LUPUS FAMILIARIS SKIN - UNII:X2W7CLE97T) | CANIS LUPUS FAMILIARIS SKIN | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|-----------------------------|---------------------------|
| 1 | NDC:0268-0620-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0620-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| BLA | BLA103753 | 01/01/1965 | |

CANIS LUPUS FAMILIARIS SKIN

dog epithelia injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0621 |
| Route of Administration | SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | | | |
|--|--|--|-----------------------------|--------------------|
| Ingredient Name | | | Basis of Strength | Strength |
| CANIS LUPUS FAMILIARIS SKIN (UNII: X2W7CLE97T) (CANIS LUPUS FAMILIARIS SKIN - UNII:X2W7CLE97T) | | | CANIS LUPUS FAMILIARIS SKIN | 0.05 [PNU] in 1 mL |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | 0.5 mL in 1 mL | |
| PHENOL (UNII: 339NCG44TV) | | | 0.004 mL in 1 mL | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | 0.009 g in 1 mL | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | 0.00275 g in 1 mL | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-0621-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0621-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | | 01/01/1965 | |

| CANIS LUPUS FAMILIARIS SKIN | | | |
|--|-----------------------------|-----------------------------|-----------------|
| dog epithelia injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0622 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| CANIS LUPUS FAMILIARIS SKIN (UNII: X2W7CLE97T) (CANIS LUPUS FAMILIARIS SKIN - UNII:X2W7CLE97T) | | CANIS LUPUS FAMILIARIS SKIN | 0.005 g in 1 mL |
| Inactive Ingredients | | | |
| Ingredient Name | | Strength | |

| | |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0622-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

CANIS LUPUS FAMILIARIS SKIN

dog epithelia injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0623 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------------|------------------|
| CANIS LUPUS FAMILIARIS SKIN (UNII: X2W7CLE97T) (CANIS LUPUS FAMILIARIS SKIN - UNII:X2W7CLE97T) | CANIS LUPUS FAMILIARIS SKIN | 0.0005 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 | NDC:0268- | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a | | |

| 0623-10 | Combination Product | | |
|------------------------------|--|----------------------|--------------------|
| Marketing Information | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

CANIS LUPUS FAMILIARIS SKIN

dog epithelia injection, solution

| Product Information | | | |
|----------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0624 |
| Route of Administration | SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | | |
|--|-----------------------------|-----------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| CANIS LUPUS FAMILIARIS SKIN (UNII: X2W7CLE97T) (CANIS LUPUS FAMILIARIS SKIN - UNII:X2W7CLE97T) | CANIS LUPUS FAMILIARIS SKIN | 0.001 g in 1 mL | |

| Inactive Ingredients | | | |
|---------------------------------------|-------------------|--|--|
| Ingredient Name | Strength | | |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | |

| Packaging | | | | |
|------------------|------------------|--|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-0624-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0624-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|------------------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

CANIS LUPUS FAMILIARIS SKIN

dog epithelia injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0625 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------------|----------------|
| CANIS LUPUS FAMILIARIS SKIN (UNII: X2W7CLE97T) (CANIS LUPUS FAMILIARIS SKIN - UNII:X2W7CLE97T) | CANIS LUPUS FAMILIARIS SKIN | 0.01 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0625-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

EQUUS CABALLUS SKIN

horse epithelia injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0630 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

Basis of

| Ingredient Name | | Basis of Strength | Strength | |
|--|--|--|----------------------|--------------------|
| EQUUS CABALLUS SKIN (UNII: 88VZV9HGT4) (EQUUS CABALLUS SKIN - UNII:88VZV9HGT4) | | EQUUS CABALLUS SKIN | 20000 [PNU] in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-0630-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 | |

EQUUS CABALLUS SKIN

horse epithelia injection, solution

| Product Information | | | |
|--|-----------------------------|---------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0631 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| EQUUS CABALLUS SKIN (UNII: 88VZV9HGT4) (EQUUS CABALLUS SKIN - UNII:88VZV9HGT4) | | EQUUS CABALLUS SKIN | 0.05 g in 1 mL |
| Inactive Ingredients | | | |
| Ingredient Name | | Strength | |
| GLYCERIN (UNII: PDC6A3C0OX) | | 0.5 mL in 1 mL | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | |

| | |
|--|-------------------|
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0631-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0631-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

EQUUS CABALLUS SKIN

horse epithelia injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0632 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------|-------------------|
| EQUUS CABALLUS SKIN (UNII: 88VZV9HGT4) (EQUUS CABALLUS SKIN - UNII:88VZV9HGT4) | EQUUS CABALLUS SKIN | 100 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 | NDC:0268- | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a | | |

| 0632-10 | Combination Product | | |
|------------------------------|--|----------------------|--------------------|
| Marketing Information | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

EQUUS CABALLUS SKIN

horse epithelia injection, solution

| Product Information | | | |
|----------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0656 |
| Route of Administration | SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | |
|---|---------------------|----------------|
| Ingredient Name | Basis of Strength | Strength |
| EQUUS CABALLUS SKIN (UNII: 88VZV9HGT4) (EQUUS CABALLUS SKIN - UNII:88VZV9HGT4) | EQUUS CABALLUS SKIN | 0.10 g in 1 mL |

| Inactive Ingredients | |
|--|-------------------|
| Ingredient Name | Strength |
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

| Packaging | | | | |
|------------------|------------------|--|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-0656-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0656-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|------------------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

CEIBA PENTANDRA FIBER

kapok injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0635 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-----------------------|----------------|
| CEIBA PENTANDRA FIBER (UNII: 758Z9H9WW9) (CEIBA PENTANDRA FIBER - UNII:758Z9H9WW9) | CEIBA PENTANDRA FIBER | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0635-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0635-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

MUS MUSCULUS SKIN

mouse epithelia injection, solution

Product Information

| | | | |
|--------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0638 |
|--------------|-----------------------------|--------------------|---------------|

Route of Administration SUBCUTANEOUS

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------------|
| MUS MUSCULUS SKIN (UNII: 390AN9GB09) (MUS MUSCULUS SKIN - UNII:390AN9GB09) | MUS MUSCULUS SKIN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0638-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0638-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

MUS MUSCULUS SKIN

mouse epithelia injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0639 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|-------------------|
| MUS MUSCULUS SKIN (UNII: 390AN9GB09) (MUS MUSCULUS SKIN - UNII:390AN9GB09) | MUS MUSCULUS SKIN | 100 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0268-0639-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ORRIS

iris x germanica root injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0642 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-----------------------|----------------|
| IRIS X GERMANICA ROOT (UNII: 8N6VTJ9IWW) (IRIS X GERMANICA ROOT - UNII:8N6VTJ9IWW) | IRIS X GERMANICA ROOT | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0642-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0642-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

RABBIT

rabbit injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0649 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------------|
| RABBIT (UNII: O5V0F26RUW) (RABBIT - UNII:O5V0F26RUW) | RABBIT | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0649-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
|-----------|---------------------------------|-----------------|---------------|
|-----------|---------------------------------|-----------------|---------------|

| Category | Citation | Date | Date |
|----------|-----------|------------|------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

RABBIT

rabbit injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0650 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| RABBIT (UNII: O5V0F26RUW) (RABBIT - UNII:O5V0F26RUW) | RABBIT | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C00X) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0650-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

RABBIT

rabbit injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0651 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------------|
| RABBIT (UNII: O5V0F26RUW) (RABBIT - UNII:O5V0F26RUW) | RABBIT | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0651-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

PERIPLANETA AMERICANA

american cockroach injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0705 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------|---------------------|
| PERIPLANETA AMERICANA (UNII: 2RQ1L9N089) (PERIPLANETA AMERICANA - UNII:2RQ1L9N089) | PERIPLANETA AMERICANA | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------|----------|
|-----------------|----------|

| | |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0705-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

PERIPLANETA AMERICANA

american cockroach injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0706 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------|---------------------|
| PERIPLANETA AMERICANA (UNII: 2RQ1L9N089) (PERIPLANETA AMERICANA - UNII:2RQ1L9N089) | PERIPLANETA AMERICANA | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

| | | | | |
|---|------------------|--|--|--|
| 1 | NDC:0268-0706-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0706-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

PERIPLANETA AMERICANA

american cockroach injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0707 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-----------------------|----------------|
| PERIPLANETA AMERICANA (UNII: 2RQ1L9N089) (PERIPLANETA AMERICANA - UNII:2RQ1L9N089) | PERIPLANETA AMERICANA | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0707-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0707-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
|-----------|---------------------------------|-----------------|---------------|
|-----------|---------------------------------|-----------------|---------------|

| Category | Citation | Date | Date |
|----------|-----------|------------|------|
| BLA | BLA103753 | 01/01/1965 | |

PERIPLANETA AMERICANA

american cockroach injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0708 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------|--------------------|
| PERIPLANETA AMERICANA (UNII: 2RQ1L9N089) (PERIPLANETA AMERICANA - UNII:2RQ1L9N089) | PERIPLANETA AMERICANA | 1000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0708-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

PERIPLANETA AMERICANA

american cockroach injection, solution

Product Information

| | | | |
|---------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0709 |
|---------------------|-----------------------------|---------------------------|---------------|

Route of Administration SUBCUTANEOUS

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------|------------------|
| PERIPLANETA AMERICANA (UNII: 2RQ1L9N089) (PERIPLANETA AMERICANA - UNII:2RQ1L9N089) | PERIPLANETA AMERICANA | 10 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0709-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

PERIPLANETA AMERICANA

american cockroach injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0710 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------|-------------------|
| PERIPLANETA AMERICANA (UNII: 2RQ1L9N089) (PERIPLANETA AMERICANA - UNII:2RQ1L9N089) | PERIPLANETA AMERICANA | 100 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0710-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

PERIPLANETA AMERICANA

american cockroach injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0711 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------|-----------------|
| PERIPLANETA AMERICANA (UNII: 2RQ1L9N089) (PERIPLANETA AMERICANA - UNII:2RQ1L9N089) | PERIPLANETA AMERICANA | 0.001 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start | Marketing End |
|---|-----------|---------------------|-----------------|---------------|
|---|-----------|---------------------|-----------------|---------------|

| # | Item Code | Package Description | Date | Date |
|---|------------------|---|------|------|
| 1 | NDC:0268-0711-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

BLATELLA GERMANICA

german cockroach injection, solution

| Product Information | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0714 |
| Route of Administration | SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | |
|--|--------------------|----------------|
| Ingredient Name | Basis of Strength | Strength |
| BLATELLA GERMANICA (UNII: G9O67I0A8Q) (BLATELLA GERMANICA - UNII:G9O67I0A8Q) | BLATELLA GERMANICA | 0.05 g in 1 mL |

| Inactive Ingredients | |
|---------------------------------------|-------------------|
| Ingredient Name | Strength |
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

| Packaging | | | | |
|-----------|------------------|--|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-0714-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0714-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| | | | |

| | | | |
|-----|-----------|------------|--|
| BLA | BLA103753 | 01/01/1965 | |
|-----|-----------|------------|--|

BLATELLA GERMANICA
german cockroach injection, solution

| Product Information | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0715 |
| Route of Administration | SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | |
|--|--------------------|--------------------|
| Ingredient Name | Basis of Strength | Strength |
| BLATELLA GERMANICA (UNII: G9O67I0A8Q) (BLATELLA GERMANICA - UNII:G9O67I0A8Q) | BLATELLA GERMANICA | 1000 [PNU] in 1 mL |

| Inactive Ingredients | |
|---------------------------------------|-------------------|
| Ingredient Name | Strength |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

| Packaging | | | | |
|-----------|------------------|--|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-0715-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

BLATELLA GERMANICA
german cockroach injection, solution

| Product Information | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0715 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------|------------------|
| BLATTELLA GERMANICA (UNII: G9O67I0A8Q) (BLATTELLA GERMANICA - UNII:G9O67I0A8Q) | BLATTELLA GERMANICA | 10 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0716-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

BLATELLA GERMANICA

german cockroach injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0717 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------|-------------------|
| BLATTELLA GERMANICA (UNII: G9O67I0A8Q) (BLATTELLA GERMANICA - UNII:G9O67I0A8Q) | BLATTELLA GERMANICA | 100 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------|----------|
|-----------------|----------|

| | |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0717-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

BLATELLA GERMANICA

german cockroach injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0718 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------|---------------------|
| BLATELLA GERMANICA (UNII: G9O67I0A8Q) (BLATELLA GERMANICA - UNII:G9O67I0A8Q) | BLATELLA GERMANICA | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

| | | | | |
|----------|------------------|--|--|--|
| 1 | NDC:0268-0718-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
|----------|------------------|--|--|--|

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

BLATELLA GERMANICA

german cockroach injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0719 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------|---------------------|
| BLATELLA GERMANICA (UNII: G9O67I0A8Q) (BLATELLA GERMANICA - UNII:G9O67I0A8Q) | BLATELLA GERMANICA | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0719-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0719-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

BLATELLA GERMANICA

german cockroach injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0720 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------------|
| BLATELLA GERMANICA (UNII: G9O67I0A8Q) (BLATELLA GERMANICA - UNII:G9O67I0A8Q) | BLATELLA GERMANICA | 0.001 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:0268-0720-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

BLATELLA GERMANICA

german cockroach injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0721 |
| Route of Administration | SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | | | |
|--|--|---|----------------------|--------------------|
| Ingredient Name | | | Basis of Strength | Strength |
| BLATTELLA GERMANICA (UNII: G9O67I0A8Q) (BLATTELLA GERMANICA - UNII:G9O67I0A8Q) | | | BLATTELLA GERMANICA | 500 [PNU] in 1 mL |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| PHENOL (UNII: 339NCG44TV) | | | 0.004 mL in 1 mL | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | 0.009 g in 1 mL | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | 0.00275 g in 1 mL | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-0721-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 | |

| ACREMONIUM STRICTUM | | | |
|--|-----------------------------|----------------------|---------------------|
| sarocladium strictum injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0800 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| SAROCLADIUM STRICTUM (UNII: 3F36V0451W) (SAROCLADIUM STRICTUM - UNII:3F36V0451W) | | SAROCLADIUM STRICTUM | 20000 [PNU] in 1 mL |
| Inactive Ingredients | | | |
| Ingredient Name | | Strength | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | |

| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | | |
|--|--|--|----------------------|--------------------|
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-0800-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 | |

| ACREMONIUM STRICTUM | | | | |
|---|-----------------------------|--|----------------------|--------------------|
| sarocladium strictum injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0801 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | Basis of Strength | Strength | | |
| SAROCLADIUM STRICTUM (UNII: 3F36V0451W) (SAROCLADIUM STRICTUM - UNII:3F36V0451W) | SAROCLADIUM STRICTUM | 10000 [PNU] in 1 mL | | |
| Inactive Ingredients | | | | |
| Ingredient Name | Strength | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL | | | |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL | | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-0801-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| 2 | NDC:0268-0801-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
|-----------------------|--|--|----------------------|--------------------|
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | | 01/01/1965 | 05/18/2023 |

ACREMONIUM STRICTUM

sarocladium strictum injection, solution

| Product Information | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0802 |
| Route of Administration | SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | |
|---|----------------------|---------------------|
| Ingredient Name | Basis of Strength | Strength |
| SAROCLADIUM STRICTUM (UNII: 3F36V0451W) (SAROCLADIUM STRICTUM - UNII:3F36V0451W) | SAROCLADIUM STRICTUM | 40000 [PNU] in 1 mL |

| Inactive Ingredients | |
|--|-------------------|
| Ingredient Name | Strength |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

| Packaging | | | | |
|-----------|------------------|--|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-0802-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| Marketing Information | | | | |
|-----------------------|--|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | | 01/01/1965 | 05/18/2023 |

ACREMONIUM STRICTUM

sarocladium strictum injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0803 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------|---------------------|
| SAROCLADIUM STRICTUM (UNII: 3F36V0451W) (SAROCLADIUM STRICTUM - UNII:3F36V0451W) | SAROCLADIUM STRICTUM | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0803-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0803-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ALTERNARIA TENUIS

alternaria tenuis injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0805 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------|--------------------|
| ALTERNARIA ALTERNATA (UNII: 52B29REC7H) (ALTERNARIA ALTERNATA - UNII:52B29REC7H) | ALTERNARIA ALTERNATA | 1000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0805-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ALTERNARIA TENUIS

alternaria tenuis injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0806 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------|-------------------|
| ALTERNARIA ALTERNATA (UNII: 52B29REC7H) (ALTERNARIA ALTERNATA - UNII:52B29REC7H) | ALTERNARIA ALTERNATA | 100 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------|------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |

| | |
|--|-------------------|
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0806-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ALTERNARIA TENUIS

alternaria tenuis injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0807 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------|---------------------|
| ALTERNARIA ALTERNATA (UNII: 52B29REC7H) (ALTERNARIA ALTERNATA - UNII:52B29REC7H) | ALTERNARIA ALTERNATA | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0807-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| 2 | NDC:0268-0807-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
|-----------------------|--|--|--------------------|--|
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 | |

ALTERNARIA TENUIS

alternaria tenuis injection, solution

| Product Information | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0808 |
| Route of Administration | SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | |
|--|----------------------|---------------------|
| Ingredient Name | Basis of Strength | Strength |
| ALTERNARIA ALTERNATA (UNII: 52B29REC7H) (ALTERNARIA ALTERNATA - UNII:52B29REC7H) | ALTERNARIA ALTERNATA | 20000 [PNU] in 1 mL |

| Inactive Ingredients | |
|---------------------------------------|-------------------|
| Ingredient Name | Strength |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

| Packaging | | | | |
|-----------|------------------|--|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-0808-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0808-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ALTERNARIA TENUIS

alternaria tenuis injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0809 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|----------------------|---------------------|
| ALTERNARIA ALTERNATA (UNII: 52B29REC7H) (ALTERNARIA ALTERNATA - UNII:52B29REC7H) | ALTERNARIA ALTERNATA | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0809-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0809-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ALTERNARIA TENUIS

alternaria tenuis injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0810 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------|------------------|
| ALTERNARIA ALTERNATA (UNII: 52B29REC7H) (ALTERNARIA ALTERNATA - UNII:52B29REC7H) | ALTERNARIA ALTERNATA | 10 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0810-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ALTERNARIA TENUIS

alternaria tenuis injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0811 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------|----------------|
| ALTERNARIA ALTERNATA (UNII: 52B29REC7H) (ALTERNARIA ALTERNATA - UNII:52B29REC7H) | ALTERNARIA ALTERNATA | 0.01 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------|----------|
|-----------------|----------|

| | |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0811-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ALTERNARIA TENUIS

alternaria tenuis injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0812 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------|-----------------|
| ALTERNARIA ALTERNATA (UNII: 52B29REC7H) (ALTERNARIA ALTERNATA - UNII:52B29REC7H) | ALTERNARIA ALTERNATA | 0.001 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

| | | | | |
|---|------------------|--|--|--|
| 1 | NDC:0268-0812-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0812-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

| ALTERNARIA TENUIS | | | | |
|--|--|---|----------------------|--------------------|
| alternaria tenuis injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0813 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| ALTERNARIA ALTERNATA (UNII: 52B29REC7H) (ALTERNARIA ALTERNATA - UNII:52B29REC7H) | | ALTERNARIA ALTERNATA | 0.02 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-0813-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 | |

ALTERNARIA TENUIS

alternaria tenuis injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0814 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-------------------|
| ALTERNARIA ALTERNATA (UNII: 52B29REC7H) (ALTERNARIA ALTERNATA - UNII:52B29REC7H) | ALTERNARIA ALTERNATA | 100 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:0268-0814-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ALTERNARIA TENUIS

alternaria tenuis injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0815 |
| Route of Administration | SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | | | |
|--|--|--|----------------------|---------------------|
| Ingredient Name | | | Basis of Strength | Strength |
| ALTERNARIA ALTERNATA (UNII: 52B29REC7H) (ALTERNARIA ALTERNATA - UNII:52B29REC7H) | | | ALTERNARIA ALTERNATA | 10000 [PNU] in 1 mL |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | 0.5 mL in 1 mL | |
| PHENOL (UNII: 339NCG44TV) | | | 0.004 mL in 1 mL | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | 0.009 g in 1 mL | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | 0.00275 g in 1 mL | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-0815-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0815-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | | 01/01/1965 | 05/18/2023 |

| ALTERNARIA TENUIS | | | |
|--|-----------------------------|----------------------|---------------------|
| alternaria tenuis injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0816 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| ALTERNARIA ALTERNATA (UNII: 52B29REC7H) (ALTERNARIA ALTERNATA - UNII:52B29REC7H) | | ALTERNARIA ALTERNATA | 20000 [PNU] in 1 mL |
| Inactive Ingredients | | | |

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0816-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0816-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ASPERGILLUS FUMIGATUS

aspergillus fumigatus injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0817 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------|---------------------|
| ASPERGILLUS FUMIGATUS (UNII: X88DF51T48) (ASPERGILLUS FUMIGATUS - UNII:X88DF51T48) | ASPERGILLUS FUMIGATUS | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0817-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0817-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 3 | NDC:0268-0817-30 | 30 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ASPERGILLUS FUMIGATUS

aspergillus fumigatus injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0818 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-----------------------|---------------------|
| ASPERGILLUS FUMIGATUS (UNII: X88DF51T48) (ASPERGILLUS FUMIGATUS - UNII:X88DF51T48) | ASPERGILLUS FUMIGATUS | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0818-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ASPERGILLUS FUMIGATUS

aspergillus fumigatus injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0819 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-----------------------|---------------------|
| ASPERGILLUS FUMIGATUS (UNII: X88DF51T48) (ASPERGILLUS FUMIGATUS - UNII:X88DF51T48) | ASPERGILLUS FUMIGATUS | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0819-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0819-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ASPERGILLUS FUMIGATUS

aspergillus fumigatus injection, solution

| Product Information | | | | |
|--|--|--|----------------------|--------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0820 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | Basis of Strength | Strength | | |
| ASPERGILLUS FUMIGATUS (UNII: X88DF51T48) (ASPERGILLUS FUMIGATUS - UNII:X88DF51T48) | ASPERGILLUS FUMIGATUS | 1000 [PNU] in 1 mL | | |
| Inactive Ingredients | | | | |
| Ingredient Name | Strength | | | |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL | | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-0820-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 | |

| ASPERGILLUS FUMIGATUS | | | |
|---|-----------------------------|--------------------|---------------|
| aspergillus fumigatus injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0821 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | Basis of Strength | Strength | |
| ASPERGILLUS FUMIGATUS (UNII: X88DF51T48) (ASPERGILLUS FUMIGATUS - | ASPERGILLUS | 10 [PNU] | |

| | | | | |
|---------------------------------------|---|--|-----------------------------|---------------------------|
| UNII:X88DF51T48) | | FUMIGATUS | in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| PHENOL (UNII: 339NCG44TV) | | | 0.004 mL in 1 mL | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | 0.009 g in 1 mL | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | 0.00275 g in 1 mL | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-0821-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | | 01/01/1965 | 11/30/2021 |

ASPERGILLUS FUMIGATUS

aspergillus fumigatus injection, solution

| | | | | |
|--|-----------------------------|---------------------------|-------------------|--|
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0822 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| ASPERGILLUS FUMIGATUS (UNII: X88DF51T48) (ASPERGILLUS FUMIGATUS - UNII:X88DF51T48) | | ASPERGILLUS FUMIGATUS | 100 [PNU] in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| PHENOL (UNII: 339NCG44TV) | | | 0.004 mL in 1 mL | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | 0.009 g in 1 mL | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | 0.00275 g in 1 mL | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0822-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

ASPERGILLUS FUMIGATUS

aspergillus fumigatus injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0823 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-----------------------|----------------|
| ASPERGILLUS FUMIGATUS (UNII: X88DF51T48) (ASPERGILLUS FUMIGATUS - UNII:X88DF51T48) | ASPERGILLUS FUMIGATUS | 0.02 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0268-0823-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
|-----------|---------------------------------|-----------------|---------------|
|-----------|---------------------------------|-----------------|---------------|

| Category | Citation | Date | Date |
|----------|-----------|------------|------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ASPERGILLUS FUMIGATUS

aspergillus fumigatus injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0824 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-----------------------|-----------------|
| ASPERGILLUS FUMIGATUS (UNII: X88DF51T48) (ASPERGILLUS FUMIGATUS - UNII:X88DF51T48) | ASPERGILLUS FUMIGATUS | 0.001 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0268-0824-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ASPERGILLUS FUMIGATUS

aspergillus fumigatus injection, solution

Product Information

| | | | |
|--------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0825 |
|--------------|-----------------------------|--------------------|---------------|

Route of Administration SUBCUTANEOUS

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------|---------------------|
| ASPERGILLUS FUMIGATUS (UNII: X88DF51T48) (ASPERGILLUS FUMIGATUS - UNII:X88DF51T48) | ASPERGILLUS FUMIGATUS | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0825-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0825-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ASPERGILLUS FUMIGATUS

aspergillus fumigatus injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0826 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------|---------------------|
| ASPERGILLUS FUMIGATUS (UNII: X88DF51T48) (ASPERGILLUS FUMIGATUS - UNII:X88DF51T48) | ASPERGILLUS FUMIGATUS | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0826-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0826-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ASPERGILLUS NIGER VAR NIGER

aspergillus niger injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0827 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|------------------------------|---------------------|
| ASPERGILLUS NIGER VAR. NIGER (UNII: 9IOA40ANG6) (ASPERGILLUS NIGER VAR. NIGER - UNII:9IOA40ANG6) | ASPERGILLUS NIGER VAR. NIGER | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0827-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0827-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

ASPERGILLUS NIGER VAR NIGER

aspergillus niger injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0828 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|------------------------------|---------------------|
| ASPERGILLUS NIGER VAR. NIGER (UNII: 9IOA40ANG6) (ASPERGILLUS NIGER VAR. NIGER - UNII:9IOA40ANG6) | ASPERGILLUS NIGER VAR. NIGER | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0828-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0828-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

ASPERGILLUS NIGER VAR NIGER

aspergillus niger injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0829 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|------------------------------|---------------------|
| ASPERGILLUS NIGER VAR. NIGER (UNII: 9IOA40ANG6) (ASPERGILLUS NIGER VAR. NIGER - UNII:9IOA40ANG6) | ASPERGILLUS NIGER VAR. NIGER | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0829-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ASPERGILLUS NIGER VAR NIGER

aspergillus niger injection, solution

Product Information

| | | | | |
|--|---|--|-----------------------------|---------------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0830 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| ASPERGILLUS NIGER VAR. NIGER (UNII: 9IOA40ANG6) (ASPERGILLUS NIGER VAR. NIGER - UNII:9IOA40ANG6) | | ASPERGILLUS NIGER VAR. NIGER | 20000 [PNU] in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| GLYCERIN (UNII: PDC6A3C00X) | | 0.5 mL in 1 mL | | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-0830-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0830-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 | |

AUREOBASIDIUM PULLULANS VAR PULLULANS

pullularia pullulans injection, solution

| | | | | |
|--|-----------------------------|------------------------------|---------------------|--|
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0832 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| AUREOBASIDIUM PULLULANS VAR. PULLUTANS (UNII: D1A2NG69CK) (AUREOBASIDIUM PULLULANS VAR. PULLUTANS - UNII:D1A2NG69CK) | | AUREOBASIDIUM PULLULANS VAR. | 20000 [PNU] in 1 mL | |

(AUREOBASIDIUM PULLULANS VAR. PULLUTANS - UNII:D1A2NG69CK)

PULLUTANS

III 1 mL

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0832-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0832-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 3 | NDC:0268-0832-30 | 30 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

AUREOBASIDIUM PULLULANS VAR PULLULANS

pullularia pullulans injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0833 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--|---------------------|
| AUREOBASIDIUM PULLULANS VAR. PULLUTANS (UNII: D1A2NG69CK) (AUREOBASIDIUM PULLULANS VAR. PULLUTANS - UNII:D1A2NG69CK) | AUREOBASIDIUM PULLULANS VAR. PULLUTANS | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|------------------------------------|------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |

| | |
|--|-------------------|
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0833-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0833-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

AUREOBASIDIUM PULLULANS VAR PULLULANS

pullularia pullulans injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0834 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--|---------------------|
| AUREOBASIDIUM PULLULANS VAR. PULLUTANS (UNII: D1A2NG69CK) (AUREOBASIDIUM PULLULANS VAR. PULLUTANS - UNII:D1A2NG69CK) | AUREOBASIDIUM PULLULANS VAR. PULLUTANS | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

| | | | | |
|---|------------------|--|--|--|
| 1 | NDC:0268-0834-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0834-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

AUREOBASIDIUM PULLULANS VAR PULLULANS

pullularia pullulans injection, solution

| Product Information | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0835 |
| Route of Administration | SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | |
|--|--|---------------------|
| Ingredient Name | Basis of Strength | Strength |
| AUREOBASIDIUM PULLULANS VAR. PULLUTANS (UNII: D1A2NG69CK) (AUREOBASIDIUM PULLULANS VAR. PULLUTANS - UNII:D1A2NG69CK) | AUREOBASIDIUM PULLULANS VAR. PULLUTANS | 20000 [PNU] in 1 mL |

| Inactive Ingredients | |
|--|-------------------|
| Ingredient Name | Strength |
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

| Packaging | | | | |
|-----------|------------------|--|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-0835-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0835-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|---------------------------------|-----------------|---------------|
| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
| | | | |

| Category | Citation | Date | Date |
|----------|-----------|------------|------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

AUREOBASIDIUM PULLULANS VAR PULLULANS

pullularia pullulans injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0836 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--|------------------------|
| AUREOBASIDIUM PULLULANS VAR. PULLUTANS (UNII: D1A2NG69CK) (AUREOBASIDIUM PULLULANS VAR. PULLUTANS - UNII:D1A2NG69CK) | AUREOBASIDIUM PULLULANS VAR. PULLUTANS | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0836-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0836-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

BOTRYTIS CINEREA

botrytis cinerea injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0837 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------------|
| BOTRYTIS CINEREA (UNII: TBW53313S7) (BOTRYTIS CINEREA - UNII:TBW53313S7) | BOTRYTIS CINEREA | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0837-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

BOTRYTIS CINEREA

botrytis cinerea injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0838 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------------|
| BOTRYTIS CINEREA (UNII: TBW53313S7) (BOTRYTIS CINEREA - UNII:TBW53313S7) | BOTRYTIS CINEREA | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0838-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

BOTRYTIS CINEREA

botrytis cinerea injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0839 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------------|
| BOTRYTIS CINEREA (UNII: TBW53313S7) (BOTRYTIS CINEREA - UNII:TBW53313S7) | BOTRYTIS CINEREA | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0839-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

BOTRYTIS CINEREA

botrytis cinerea injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0840 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------------|
| BOTRYTIS CINEREA (UNII: TBW53313S7) (BOTRYTIS CINEREA - UNII:TBW53313S7) | BOTRYTIS CINEREA | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W471Q8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0840-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0840-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

BOTRYTIS CINEREA

botrytis cinerea injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0841 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------------|
| BOTRYTIS CINEREA (UNII: TBW53313S7) (BOTRYTIS CINEREA - UNII:TBW53313S7) | BOTRYTIS CINEREA | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0841-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

CANDIDA ALBICANS

candida albicans injection, solution

Product Information

| | | | |
|--------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0842 |
|--------------|-----------------------------|--------------------|---------------|

| | | | | |
|--|---|--|-----------------------------|---------------------------|
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| | Ingredient Name | Basis of Strength | Strength | |
| | CANDIDA ALBICANS (UNII: 4D7G21HDBC) (CANDIDA ALBICANS - UNII:4D7G21HDBC) | CANDIDA ALBICANS | 0.01 g in 1 mL | |
| Inactive Ingredients | | | | |
| | Ingredient Name | Strength | | |
| | PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL | | |
| | SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL | | |
| | SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL | | |
| | HYDROCHLORIC ACID (UNII: QTT17582CB) | | | |
| | SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-0842-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 | |

| | | | |
|--|---|---------------------------|---------------------|
| CANDIDA ALBICANS | | | |
| candida albicans injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0843 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| | Ingredient Name | Basis of Strength | Strength |
| | CANDIDA ALBICANS (UNII: 4D7G21HDBC) (CANDIDA ALBICANS - UNII:4D7G21HDBC) | CANDIDA ALBICANS | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0843-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0843-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

CANDIDA ALBICANS

candida albicans injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0844 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------------|
| CANDIDA ALBICANS (UNII: 4D7G21HDBC) (CANDIDA ALBICANS - UNII:4D7G21HDBC) | CANDIDA ALBICANS | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0844-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0844-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

CANDIDA ALBICANS

candida albicans injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0845 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------------|
| CANDIDA ALBICANS (UNII: 4D7G21HD8C) (CANDIDA ALBICANS - UNII:4D7G21HD8C) | CANDIDA ALBICANS | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0845-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

CANDIDA ALBICANS

candida albicans injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0846 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|--------------------|
| CANDIDA ALBICANS (UNII: 4D7G21HDBC) (CANDIDA ALBICANS - UNII:4D7G21HDBC) | CANDIDA ALBICANS | 1000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0846-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

CANDIDA ALBICANS

candida albicans injection, solution

Product Information

| | | | | |
|--|---|--|-----------------------------|---------------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0847 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| CANDIDA ALBICANS (UNII: 4D7G21HDBC) (CANDIDA ALBICANS - UNII:4D7G21HDBC) | | CANDIDA ALBICANS | 100 [PNU] in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-0847-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 | |

| | | | | |
|--|-----------------------------|---------------------------|-----------------|--|
| CANDIDA ALBICANS | | | | |
| candida albicans injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0848 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| CANDIDA ALBICANS (UNII: 4D7G21HDBC) (CANDIDA ALBICANS - UNII:4D7G21HDBC) | | CANDIDA ALBICANS | 0.02 g in 1 mL | |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0268-0848-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

CANDIDA ALBICANS

candida albicans injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0849 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------------|
| CANDIDA ALBICANS (UNII: 4D7G21HDBC) (CANDIDA ALBICANS - UNII:4D7G21HDBC) | CANDIDA ALBICANS | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0849-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0849-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

CANDIDA ALBICANS

candida albicans injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0850 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------------|
| CANDIDA ALBICANS (UNII: 4D7G21HDBC) (CANDIDA ALBICANS - UNII:4D7G21HDBC) | CANDIDA ALBICANS | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0850-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

CHAETOMIUM GLOBOSUM

chaetomium globosum injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0851 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|---------------------|---------------------|
| CHAETOMIUM GLOBOSUM (UNII: 5016WB8B8A) (CHAETOMIUM GLOBOSUM - UNII:5016WB8B8A) | CHAETOMIUM GLOBOSUM | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0851-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0851-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

CHAETOMIUM GLOBOSUM

chaetomium globosum injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0852 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|---------------------|
| CHAETOMIUM GLOBOSUM (UNII: 5016WB8B8A) (CHAETOMIUM GLOBOSUM - UNII:5016WB8B8A) | CHAETOMIUM GLOBOSUM | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|-----------------------------|---------------------------|
| 1 | NDC:0268-0852-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0852-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

CHAETOMIUM GLOBOSUM

chaetomium globosum injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0853 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|------------------------|--------------------------|-----------------|
|------------------------|--------------------------|-----------------|

| | | |
|---|---------------------|---------------------|
| CHAETOMIUM GLOBOSUM (UNII: 5016WB8B8A) (CHAETOMIUM GLOBOSUM - UNII:5016WB8B8A) | CHAETOMIUM GLOBOSUM | 20000 [PNU] in 1 mL |
|---|---------------------|---------------------|

| Inactive Ingredients | |
|--|-------------------|
| Ingredient Name | Strength |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

| Packaging | | | | |
|-----------|------------------|--|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-0853-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0853-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

CLADOSPORIUM CLADOSPORIOIDES

cladosporium cladosporioides injection, solution

| Product Information | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0855 |
| Route of Administration | SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | |
|---|------------------------------|---------------------|
| Ingredient Name | Basis of Strength | Strength |
| CLADOSPORIUM CLADOSPORIOIDES (UNII: 4ZWY20GTGO) (CLADOSPORIUM CLADOSPORIOIDES - UNII:4ZWY20GTGO) | CLADOSPORIUM CLADOSPORIOIDES | 20000 [PNU] in 1 mL |

| Inactive Ingredients | |
|--|-------------------|
| Ingredient Name | Strength |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |

SODIUM HYDROXIDE (UNII: 55X04QC32I)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0855-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0855-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

CLADOSPORIUM CLADOSPORIOIDES

cladosporium cladosporioides injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0856 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|------------------------------|---------------------|
| CLADOSPORIUM CLADOSPORIOIDES (UNII: 4Z WY20GTGO) (CLADOSPORIUM CLADOSPORIOIDES - UNII:4Z WY20GTGO) | CLADOSPORIUM CLADOSPORIOIDES | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0856-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268- | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a | | |

0856-50 Combination Product

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

CLADOSPORIUM CLADOSPORIOIDES

cladosporium cladosporioides injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0857 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|------------------------------|---------------------|
| CLADOSPORIUM CLADOSPORIOIDES (UNII: 4Z WY20GTGO) (CLADOSPORIUM CLADOSPORIOIDES - UNII:4Z WY20GTGO) | CLADOSPORIUM CLADOSPORIOIDES | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0857-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0857-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

CLADOSPORIUM CLADOSPORIOIDES

cladosporium cladosporioides injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0858 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|------------------------------|-------------------|
| CLADOSPORIUM CLADOSPORIOIDES (UNII: 4ZWY20GTGO) (CLADOSPORIUM CLADOSPORIOIDES - UNII:4ZWY20GTGO) | CLADOSPORIUM CLADOSPORIOIDES | 100 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0858-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

CLADOSPORIUM CLADOSPORIOIDES

cladosporium cladosporioides injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0859 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------|-------------------|----------|
|-----------------|-------------------|----------|

| | | |
|---|------------------------------|----------------|
| CLADOSPORIUM CLADOSPORIOIDES (UNII: 4Z WY20GTGO) (CLADOSPORIUM CLADOSPORIOIDES - UNII:4Z WY20GTGO) | CLADOSPORIUM CLADOSPORIOIDES | 0.01 g in 1 mL |
|---|------------------------------|----------------|

| Inactive Ingredients | |
|--|-------------------|
| Ingredient Name | Strength |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

| Packaging | | | | |
|-----------|------------------|--|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-0859-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

CLADOSPORIUM CLADOSPORIOIDES

cladosporium cladosporioides injection, solution

| Product Information | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0860 |
| Route of Administration | SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | |
|---|------------------------------|-----------------|
| Ingredient Name | Basis of Strength | Strength |
| CLADOSPORIUM CLADOSPORIOIDES (UNII: 4Z WY20GTGO) (CLADOSPORIUM CLADOSPORIOIDES - UNII:4Z WY20GTGO) | CLADOSPORIUM CLADOSPORIOIDES | 0.001 g in 1 mL |

| Inactive Ingredients | |
|--|-------------------|
| Ingredient Name | Strength |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0860-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

CLADOSPORIUM CLADOSPORIOIDES

cladosporium cladosporioides injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0861 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|------------------------------|---------------------|
| CLADOSPORIUM CLADOSPORIOIDES (UNII: 4ZWX20GTGO) (CLADOSPORIUM CLADOSPORIOIDES - UNII:4ZWX20GTGO) | CLADOSPORIUM CLADOSPORIOIDES | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0861-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0861-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

CLADOSPORIUM SPHAEROSPERMUM

cladosporium sphaerospermum injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0863 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-----------------------------|---------------------|
| CLADOSPORIUM SPHAEROSPERMUM (UNII: P87YCA1U8R) (CLADOSPORIUM SPHAEROSPERMUM - UNII:P87YCA1U8R) | CLADOSPORIUM SPHAEROSPERMUM | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0863-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0863-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

CLADOSPORIUM SPHAEROSPERMUM

cladosporium sphaerospermum injection, solution

| Product Information | | | | |
|--|--|--|----------------------|--------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0864 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | Basis of Strength | Strength | | |
| CLADOSPORIUM SPHAEROSPERMUM (UNII: P87YCA1U8R) (CLADOSPORIUM SPHAEROSPERMUM - UNII:P87YCA1U8R) | CLADOSPORIUM SPHAEROSPERMUM | 20000 [PNU] in 1 mL | | |
| Inactive Ingredients | | | | |
| Ingredient Name | Strength | | | |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL | | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-0864-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-0864-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 | |

| BETULA LENTA POLLEN | | | |
|---|-----------------------------|--------------------|---------------|
| birch white injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1070 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | Basis of Strength | Strength | |
| BETULA LENTA POLLEN (UNII: JQ5HI5004M) (BETULA LENTA POLLEN - | BETULA LENTA | 0.05 g | |

| | | | | |
|---------------------------------------|---|--|-----------------------------|---------------------------|
| UNII:JQ5HI5004M) | | POLLEN | in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | 0.5 mL in 1 mL | |
| PHENOL (UNII: 339NCG44TV) | | | 0.004 mL in 1 mL | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | 0.009 g in 1 mL | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | 0.00275 g in 1 mL | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1070-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1070-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | | 01/01/1965 | |

| | | | |
|--|-----------------------------|---------------------------|-----------------|
| BETULA LENTA POLLEN | | | |
| birch white injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1071 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| BETULA LENTA POLLEN (UNII: JQ5HI5004M) (BETULA LENTA POLLEN - UNII:JQ5HI5004M) | | BETULA LENTA POLLEN | 0.005 g in 1 mL |
| Inactive Ingredients | | | |
| Ingredient Name | | Strength | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | |

HYDROCHLORIC ACID (UNII: QTT17582CB)

SODIUM HYDROXIDE (UNII: 55X04QC32I)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1071-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

BETULA LENTA POLLEN

birch white injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1072 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------|------------------|
| BETULA LENTA POLLEN (UNII: JQ5HI5004M) (BETULA LENTA POLLEN - UNII:JQ5HI5004M) | BETULA LENTA POLLEN | 0.0005 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1072-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

BETULA LENTA POLLEN

birch white injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1073 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------|---------------------|
| BETULA LENTA POLLEN (UNII: JQ5HI5004M) (BETULA LENTA POLLEN - UNII:JQ5HI5004M) | BETULA LENTA POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1073-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

POA ANNUA POLLEN

bluegrass annual injection, solution

| Product Information | | | | |
|--|--|--|----------------------|--------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1076 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| POA ANNUA POLLEN (UNII: 7U437HHU5C) (POA ANNUA POLLEN - UNII:7U437HHU5C) | | POA ANNUA POLLEN | 0.10 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1076-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 | |

| POA ANNUA POLLEN | | | |
|--|-----------------------------|--------------------|----------------|
| bluegrass annual injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1077 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| POA ANNUA POLLEN (UNII: 7U437HHU5C) (POA ANNUA POLLEN - UNII:7U437HHU5C) | | POA ANNUA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1077-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ACER NEGUNDO POLLEN

box elder ash leaf maple injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1080 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|---------------------|----------------|
| ACER NEGUNDO POLLEN (UNII: P6K070AR8V) (ACER NEGUNDO POLLEN - UNII:P6K070AR8V) | ACER NEGUNDO POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1080-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1080-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

ACER NEGUNDO POLLEN

box elder ash leaf maple injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1081 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|---------------------|----------------|
| ACER NEGUNDO POLLEN (UNII: P6K070AR8V) (ACER NEGUNDO POLLEN - UNII:P6K070AR8V) | ACER NEGUNDO POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1081-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1081-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

ACER NEGUNDO POLLEN

box elder ash leaf maple injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1082 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|---------------------|---------------------|
| ACER NEGUNDO POLLEN (UNII: P6K070AR8V) (ACER NEGUNDO POLLEN - UNII:P6K070AR8V) | ACER NEGUNDO POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1082-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ACER NEGUNDO POLLEN

box elder ash leaf maple injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1083 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|---------------------|
| ACER NEGUNDO POLLEN (UNII: P6K070AR8V) (ACER NEGUNDO POLLEN - UNII:P6K070AR8V) | ACER NEGUNDO POLLEN | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|--|-----------------------------|---------------------------|
| 1 | NDC:0268-1083-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

BROMUS INERMIS POLLEN

brome grass injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1086 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------------|
| BROMUS INERMIS POLLEN (UNII: 766QT72BK6) (BROMUS INERMIS POLLEN - UNII:766QT72BK6) | BROMUS INERMIS POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1086-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1086-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

BROMUS INERMIS POLLEN

brome grass injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1087 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------|----------------|
| BROMUS INERMIS POLLEN (UNII: 766QT72BK6) (BROMUS INERMIS POLLEN - UNII:766QT72BK6) | BROMUS INERMIS POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |

SODIUM HYDROXIDE (UNII: 55X04QC32I)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1087-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1087-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

BROMUS INERMIS POLLEN

brome grass injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1089 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------|---------------------|
| BROMUS INERMIS POLLEN (UNII: 766QT72BK6) (BROMUS INERMIS POLLEN - UNII:766QT72BK6) | BROMUS INERMIS POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1089-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

AMARANTHUS PALMERI POLLEN

carelessweed injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1092 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|---------------------------|----------------|
| AMARANTHUS PALMERI POLLEN (UNII: 1GH3W23KH) (AMARANTHUS PALMERI POLLEN - UNII:1GH3W23KH) | AMARANTHUS PALMERI POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1092-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

AMARANTHUS PALMERI POLLEN

carelessweed injection, solution

| Product Information | | | | |
|--|--|--|----------------------|--------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1093 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| AMARANTHUS PALMERI POLLEN (UNII: 1GH3WW23KH) (AMARANTHUS PALMERI POLLEN - UNII:1GH3WW23KH) | | AMARANTHUS PALMERI POLLEN | 0.025 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | 0.5 mL in 1 mL | | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1093-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1093-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | | |

| AMARANTHUS PALMERI POLLEN | | | | |
|----------------------------------|-----------------------------|--------------------|---------------|--|
| carelessweed injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1094 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |

| | | |
|---|---------------------------|---------------------|
| AMARANTHUS PALMERI POLLEN (UNII: 1GH3W23KH) (AMARANTHUS PALMERI POLLEN - UNII:1GH3W23KH) | AMARANTHUS PALMERI POLLEN | 20000 [PNU] in 1 mL |
|---|---------------------------|---------------------|

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1094-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

JUNIPERUS ASHEI POLLEN

cedar mountain injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1097 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|------------------------|----------------|
| JUNIPERUS ASHEI POLLEN (UNII: 544F8MEY0Y) (JUNIPERUS ASHEI POLLEN - UNII:544F8MEY0Y) | JUNIPERUS ASHEI POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1097-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1097-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

JUNIPERUS ASHEI POLLEN

cedar mountain injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1098 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|------------------------|----------------|
| JUNIPERUS ASHEI POLLEN (UNII: 544F8MEY0Y) (JUNIPERUS ASHEI POLLEN - UNII:544F8MEY0Y) | JUNIPERUS ASHEI POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1098-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268- | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a | | |

1098-10 Combination Product

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

JUNIPERUS ASHEI POLLEN

cedar mountain injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1099 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|------------------------|---------------------|
| JUNIPERUS ASHEI POLLEN (UNII: 544F8MEY0Y) (JUNIPERUS ASHEI POLLEN - UNII:544F8MEY0Y) | JUNIPERUS ASHEI POLLEN | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1099-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

JUNIPERUS VIRGINIANA POLLEN

cedar red injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1102 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------------|-------------------|
| JUNIPERUS VIRGINIANA POLLEN (UNII: PY0JA16R2G) (JUNIPERUS VIRGINIANA POLLEN - UNII:PY0JA16R2G) | JUNIPERUS VIRGINIANA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|--|-----------------------------|---------------------------|
| 1 | NDC:0268-1102-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1102-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| BLA | BLA103753 | 01/01/1965 | |

JUNIPERUS VIRGINIANA POLLEN

cedar red injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1103 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | | Basis of Strength | Strength |
|--|--|-----------------------------|----------------|
| JUNIPERUS VIRGINIANA POLLEN (UNII: PY0JA16R2G) (JUNIPERUS VIRGINIANA POLLEN - UNII:PY0JA16R2G) | | JUNIPERUS VIRGINIANA POLLEN | 0.05 g in 1 mL |

| Inactive Ingredients | |
|---------------------------------------|-------------------|
| Ingredient Name | Strength |
| GLYCERIN (UNII: PDC6A3C00X) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

| Packaging | | | | |
|-----------|------------------|--|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1103-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1103-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

JUNIPERUS VIRGINIANA POLLEN

cedar red injection, solution

| Product Information | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1104 |
| Route of Administration | SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | | |
|--|-----------------------------|-----------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| JUNIPERUS VIRGINIANA POLLEN (UNII: PY0JA16R2G) (JUNIPERUS VIRGINIANA POLLEN - UNII:PY0JA16R2G) | JUNIPERUS VIRGINIANA POLLEN | 0.005 g in 1 mL | |

| Inactive Ingredients | |
|------------------------------------|------------------|
| Ingredient Name | Strength |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |

| | |
|--|-------------------|
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1104-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

JUNIPERUS VIRGINIANA POLLEN

cedar red injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1105 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------------|------------------|
| JUNIPERUS VIRGINIANA POLLEN (UNII: PY0JA16R2G) (JUNIPERUS VIRGINIANA POLLEN - UNII:PY0JA16R2G) | JUNIPERUS VIRGINIANA POLLEN | 0.0005 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1105-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

JUNIPERUS VIRGINIANA POLLEN

cedar red injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1106 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-----------------------------|---------------------|
| JUNIPERUS VIRGINIANA POLLEN (UNII: PY0JA16R2G) (JUNIPERUS VIRGINIANA POLLEN - UNII:PY0JA16R2G) | JUNIPERUS VIRGINIANA POLLEN | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1106-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1106-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

JUNIPERUS VIRGINIANA POLLEN

cedar red injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1107 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------------|-----------------|
| JUNIPERUS VIRGINIANA POLLEN (UNII: PY0JA16R2G) (JUNIPERUS VIRGINIANA POLLEN - UNII:PY0JA16R2G) | JUNIPERUS VIRGINIANA POLLEN | 0.001 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0268-1107-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

XANTHIUM STRUMARIUM VAR CANADENSE POLLEN

cocklebur injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1110 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|----------------|
| XANTHIUM STRUMARIUM VAR. CANADENSE POLLEN (UNII: OZ K6G3W3BI) (XANTHIUM STRUMARIUM VAR. CANADENSE POLLEN - UNII:OZ K6G3W3BI) | XANTHIUM STRUMARIUM VAR. CANADENSE POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1110-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1110-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

XANTHIUM STRUMARIUM VAR CANADENSE POLLEN

cocklebur injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1111 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--|-------------------|
| XANTHIUM STRUMARIUM VAR. CANADENSE POLLEN (UNII: 0ZK6G3W3BI) (XANTHIUM STRUMARIUM VAR. CANADENSE POLLEN - UNII:0ZK6G3W3BI) | XANTHIUM STRUMARIUM VAR. CANADENSE POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1111-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1111-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

XANTHIUM STRUMARIUM VAR CANADENSE POLLEN

cocklebur injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1112 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--|------------------------|
| XANTHIUM STRUMARIUM VAR. CANADENSE POLLEN (UNII: 0ZK6G3W3BI) (XANTHIUM STRUMARIUM VAR. CANADENSE POLLEN - UNII:0ZK6G3W3BI) | XANTHIUM STRUMARIUM VAR. CANADENSE POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1112-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1112-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

XANTHIUM STRUMARIUM VAR CANADENSE POLLEN

cocklebur injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1113 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--|-----------------------|
| XANTHIUM STRUMARIUM VAR. CANADENSE POLLEN (UNII: 0ZK6G3W3BI) (XANTHIUM STRUMARIUM VAR. CANADENSE POLLEN - UNII:0ZK6G3W3BI) | XANTHIUM STRUMARIUM VAR. CANADENSE POLLEN | 1000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1113-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

XANTHIUM STRUMARIUM VAR CANADENSE POLLEN

cocklebur injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1114 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--|---------------------|
| XANTHIUM STRUMARIUM VAR. CANADENSE POLLEN (UNII: 0ZK6G3W3BI) (XANTHIUM STRUMARIUM VAR. CANADENSE POLLEN - UNII:0ZK6G3W3BI) | XANTHIUM STRUMARIUM VAR. CANADENSE POLLEN | 10 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1114-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

XANTHIUM STRUMARIUM VAR CANADENSE POLLEN

cocklebur injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1115 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--|----------------------|
| XANTHIUM STRUMARIUM VAR. CANADENSE POLLEN (UNII: 0ZK6G3W3BI) (XANTHIUM STRUMARIUM VAR. CANADENSE POLLEN - UNII:0ZK6G3W3BI) | XANTHIUM STRUMARIUM VAR. CANADENSE POLLEN | 100 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1115-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

XANTHIUM STRUMARIUM VAR CANADENSE POLLEN

cocklebur injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1116 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|---|---------------------|
| XANTHIUM STRUMARIUM VAR. CANADENSE POLLEN (UNII: 0ZK6G3W3BI) (XANTHIUM STRUMARIUM VAR. CANADENSE POLLEN - UNII:0ZK6G3W3BI) | XANTHIUM STRUMARIUM VAR. CANADENSE POLLEN | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

| | | | | |
|---|------------------|--|--|--|
| 1 | NDC:0268-1116-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
|---|------------------|--|--|--|

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

XANTHIUM STRUMARIUM VAR CANADENSE POLLEN

cocklebur injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1117 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---------------------|
| XANTHIUM STRUMARIUM VAR. CANADENSE POLLEN (UNII: 0Z K6G3W3BI) (XANTHIUM STRUMARIUM VAR. CANADENSE POLLEN - UNII:0Z K6G3W3BI) | XANTHIUM STRUMARIUM VAR. CANADENSE POLLEN | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1117-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ZEA MAYS POLLEN

corn pollen injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1120 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|-----------------|
| ZEA MAYS POLLEN (UNII: 74PD8J616H) (ZEA MAYS POLLEN - UNII:74PD8J616H) | ZEA MAYS POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1120-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

TAXODIUM DISTICHUM POLLEN

cypress bald injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1146 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|-----------------|
| TAXODIUM DISTICHUM POLLEN (UNII: O12H03B41R) (TAXODIUM DISTICHUM | TAXODIUM DISTICHUM | 0.10 g |

| POLLEN - UNII:O12H03B41R) | | POLLEN | in 1 mL | |
|---------------------------------------|--|--|----------------------|--------------------|
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1146-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 | |

TAXODIUM DISTICHUM POLLEN

cypress bald injection, solution

| Product Information | | | |
|--|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1147 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| TAXODIUM DISTICHUM POLLEN (UNII: O12H03B41R) (TAXODIUM DISTICHUM POLLEN - UNII:O12H03B41R) | | TAXODIUM DISTICHUM POLLEN | 0.05 g in 1 mL |
| Inactive Ingredients | | | |
| Ingredient Name | | Strength | |
| GLYCERIN (UNII: PDC6A3C0OX) | | 0.5 mL in 1 mL | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1147-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1147-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

TAXODIUM DISTICHUM POLLEN

cypress bald injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1148 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|---------------------------|-----------------|
| TAXODIUM DISTICHUM POLLEN (UNII: O12H03B41R) (TAXODIUM DISTICHUM POLLEN - UNII:O12H03B41R) | TAXODIUM DISTICHUM POLLEN | 0.001 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0268-1148-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

RUMEX ACETOSELLA POLLEN

dock sour sheep sorrel injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1151 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------------|----------------|
| RUMEX ACETOSELLA POLLEN (UNII: N52MIQ81ZW) (RUMEX ACETOSELLA POLLEN - UNII:N52MIQ81ZW) | RUMEX ACETOSELLA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1151-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1151-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

RUMEX ACETOSELLA POLLEN

dock sour sheep sorrel injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1152 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------------|----------------|
| RUMEX ACETOSELLA POLLEN (UNII: N52MIQ81ZW) (RUMEX ACETOSELLA POLLEN - UNII:N52MIQ81ZW) | RUMEX ACETOSELLA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1152-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1152-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

RUMEX ACETOSELLA POLLEN

dock sour sheep sorrel injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1153 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------------|---------------------|
| RUMEX ACETOSELLA POLLEN (UNII: N52MIQ81ZW) (RUMEX ACETOSELLA POLLEN - UNII:N52MIQ81ZW) | RUMEX ACETOSELLA POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1153-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1153-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

RUMEX ACETOSELLA POLLEN

dock sour sheep sorrel injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1154 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------------|---------------------|
| RUMEX ACETOSELLA POLLEN (UNII: N52MIQ81ZW) (RUMEX ACETOSELLA POLLEN - UNII:N52MIQ81ZW) | RUMEX ACETOSELLA POLLEN | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |

SODIUM HYDROXIDE (UNII: 55X04QC32I)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1154-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

RUMEX ACETOSELLA POLLEN

dock sour sheep sorrel injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1155 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------------|---------------------|
| RUMEX ACETOSELLA POLLEN (UNII: N52MIQ81ZW) (RUMEX ACETOSELLA POLLEN - UNII:N52MIQ81ZW) | RUMEX ACETOSELLA POLLEN | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1155-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1155-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

RUMEX ACETOSELLA POLLEN

dock sour sheep sorrel injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1156 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------------|---------------------|
| RUMEX ACETOSELLA POLLEN (UNII: N52MIQ81ZW) (RUMEX ACETOSELLA POLLEN - UNII:N52MIQ81ZW) | RUMEX ACETOSELLA POLLEN | 60000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1156-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

RUMEX CRISPUS POLLEN

dock yellow injection, solution

| Product Information | | | | |
|--|--|--|----------------------|--------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1159 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | Basis of Strength | Strength | | |
| RUMEX CRISPUS POLLEN (UNII: V825XJG64G) (RUMEX CRISPUS POLLEN - UNII:V825XJG64G) | RUMEX CRISPUS POLLEN | 0.10 g in 1 mL | | |
| Inactive Ingredients | | | | |
| Ingredient Name | Strength | | | |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL | | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1159-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1159-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | | |

| RUMEX CRISPUS POLLEN | | | |
|---------------------------------|-----------------------------|--------------------|---------------|
| dock yellow injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1160 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | Basis of Strength | Strength | |

| | | |
|---|----------------------|-------------------|
| RUMEX CRISPUS POLLEN (UNII: V825XJG64G) (RUMEX CRISPUS POLLEN - UNII:V825XJG64G) | RUMEX CRISPUS POLLEN | 0.05 g in 1 mL |
|---|----------------------|-------------------|

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1160-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1160-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

RUMEX CRISPUS POLLEN

dock yellow injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1161 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------|---------------------|
| RUMEX CRISPUS POLLEN (UNII: V825XJG64G) (RUMEX CRISPUS POLLEN - UNII:V825XJG64G) | RUMEX CRISPUS POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |

| | |
|--|-------------------|
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1161-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1161-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

EUPATORIUM CAPILLIFOLIUM POLLEN

dog fennel injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1164 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------------------|----------------|
| EUPATORIUM CAPILLIFOLIUM POLLEN (UNII: B67NF86HF0) (EUPATORIUM CAPILLIFOLIUM POLLEN - UNII:B67NF86HF0) | EUPATORIUM CAPILLIFOLIUM POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1164-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

EUPATORIUM CAPILLIFOLIUM POLLEN

dog fennel non stock injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1165 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|---------------------------------|----------------|
| EUPATORIUM CAPILLIFOLIUM POLLEN (UNII: B67NF86HF0) (EUPATORIUM CAPILLIFOLIUM POLLEN - UNII:B67NF86HF0) | EUPATORIUM CAPILLIFOLIUM POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1165-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1165-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

ULMUS AMERICANA POLLEN

elm american injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1168 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|------------------------|----------------|
| ULMUS AMERICANA POLLEN (UNII: 89BAT511BD) (ULMUS AMERICANA POLLEN - UNII:89BAT511BD) | ULMUS AMERICANA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1168-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1168-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

ULMUS AMERICANA POLLEN

elm american injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1169 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|------------------------|----------------|
| ULMUS AMERICANA POLLEN (UNII: 89BAT511BD) (ULMUS AMERICANA POLLEN - UNII:89BAT511BD) | ULMUS AMERICANA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1169-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1169-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

ULMUS AMERICANA POLLEN

elm american injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1170 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|------------------------|---------------------|
| ULMUS AMERICANA POLLEN (UNII: 89BAT511BD) (ULMUS AMERICANA POLLEN - UNII:89BAT511BD) | ULMUS AMERICANA POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1170-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

ULMUS AMERICANA POLLEN

elm american injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1171 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|------------------------|-----------------|
| ULMUS AMERICANA POLLEN (UNII: 89BAT511BD) (ULMUS AMERICANA POLLEN - UNII:89BAT511BD) | ULMUS AMERICANA POLLEN | 0.005 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start | Marketing End |
|---|-----------|---------------------|-----------------|---------------|
|---|-----------|---------------------|-----------------|---------------|

| # | Item Code | Package Description | Date | Date |
|---|------------------|--|------|------|
| 1 | NDC:0268-1171-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

| ULMUS AMERICANA POLLEN | | | | |
|----------------------------------|--|--|----------------------|--------------------|
| elm american injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1172 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| | Ingredient Name | Basis of Strength | Strength | |
| | ULMUS AMERICANA POLLEN (UNII: 89BAT511BD) (ULMUS AMERICANA POLLEN - UNII:89BAT511BD) | ULMUS AMERICANA POLLEN | 0.0005 g in 1 mL | |
| Inactive Ingredients | | | | |
| | Ingredient Name | Strength | | |
| | PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL | | |
| | SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL | | |
| | SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL | | |
| | HYDROCHLORIC ACID (UNII: QTT17582CB) | | | |
| | SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1172-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 | |

ULMUS AMERICANA POLLEN

elm american injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1607 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|---------------------|
| ULMUS AMERICANA POLLEN (UNII: 89BAT511BD) (ULMUS AMERICANA POLLEN - UNII:89BAT511BD) | ULMUS AMERICANA POLLEN | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|--|-----------------------------|---------------------------|
| 1 | NDC:0268-1607-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ULMUS AMERICANA POLLEN

elm american injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1174 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|------------------------|-----------------|
| ULMUS AMERICANA POLLEN (UNII: 89BAT511BD) (ULMUS AMERICANA POLLEN - UNII:89BAT511BD) | ULMUS AMERICANA POLLEN | 0.001 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0268-1174-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ULMUS CRASSIFOLIA POLLEN

elm cedar injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1177 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|----------------|
| ULMUS CRASSIFOLIA POLLEN (UNII: G82398SD3I) (ULMUS CRASSIFOLIA POLLEN - UNII:G82398SD3I) | ULMUS CRASSIFOLIA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |

SODIUM HYDROXIDE (UNII: 55X04QC32I)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1177-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

ULMUS CRASSIFOLIA POLLEN

elm cedar injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1178 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|----------------|
| ULMUS CRASSIFOLIA POLLEN (UNII: G82398SD3I) (ULMUS CRASSIFOLIA POLLEN - UNII:G82398SD3I) | ULMUS CRASSIFOLIA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1178-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

ULMUS PUMILA POLLEN

elm chinese injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1181 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------|----------------|
| ULMUS PUMILA POLLEN (UNII: 030R993R8E) (ULMUS PUMILA POLLEN - UNII:030R993R8E) | ULMUS PUMILA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1181-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ULMUS PUMILA POLLEN

elm chinese injection, solution

Product Information

| | | | | |
|---|---|--|-----------------------------|---------------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1182 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | Basis of Strength | Strength | | |
| ULMUS PUMILA POLLEN (UNII: 030R993R8E) (ULMUS PUMILA POLLEN - UNII:030R993R8E) | ULMUS PUMILA POLLEN | 0.05 g in 1 mL | | |
| Inactive Ingredients | | | | |
| Ingredient Name | Strength | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL | | | |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL | | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1182-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1182-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | | |

EUCALYPTUS GLOBULUS POLLEN

eucalyptus injection, solution

| | | | |
|--|-----------------------------|---------------------------|---------------|
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1185 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | Basis of Strength | Strength | |
| EUCALYPTUS GLOBULUS POLLEN (UNII: 7XW7TB10X9) (EUCALYPTUS | EUCALYPTUS | 0.10 g | |

| GLOBULUS POLLEN - UNII:7XW7TB10X9) | | GLOBULUS POLLEN | in 1 mL | |
|---------------------------------------|--|--|----------------------|--------------------|
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1185-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | | |

EUCALYPTUS GLOBULUS POLLEN

eucalyptus injection, solution

| Product Information | | | |
|--|-----------------------------|----------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1186 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| EUCALYPTUS GLOBULUS POLLEN (UNII: 7XW7TB10X9) (EUCALYPTUS GLOBULUS POLLEN - UNII:7XW7TB10X9) | | EUCALYPTUS GLOBULUS POLLEN | 0.05 g in 1 mL |
| Inactive Ingredients | | | |
| Ingredient Name | | Strength | |
| GLYCERIN (UNII: PDC6A3C0OX) | | 0.5 mL in 1 mL | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1186-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1186-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

EUCALYPTUS GLOBULUS POLLEN

eucalyptus injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1187 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------------|---------------------|
| EUCALYPTUS GLOBULUS POLLEN (UNII: 7XW7TB10X9) (EUCALYPTUS GLOBULUS POLLEN - UNII:7XW7TB10X9) | EUCALYPTUS GLOBULUS POLLEN | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1187-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

EUCALYPTUS GLOBULUS POLLEN

eucalyptus injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1188 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------------|---------------------|
| EUCALYPTUS GLOBULUS POLLEN (UNII: 7XW7TB10X9) (EUCALYPTUS GLOBULUS POLLEN - UNII:7XW7TB10X9) | EUCALYPTUS GLOBULUS POLLEN | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1188-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

SOLIDAGO CANADENSIS POLLEN

goldenrod injection, solution

Product Information

| | | | |
|--------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1191 |
|--------------|-----------------------------|--------------------|---------------|

Route of Administration SUBCUTANEOUS

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------------|-------------------|
| SOLIDAGO CANADENSIS POLLEN (UNII: 644CZ16IR5) (SOLIDAGO CANADENSIS POLLEN - UNII:644CZ16IR5) | SOLIDAGO CANADENSIS POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1191-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

SOLIDAGO CANADENSIS POLLEN

goldenrod injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1192 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------------|-------------------|
| SOLIDAGO CANADENSIS POLLEN (UNII: 644CZ16IR5) (SOLIDAGO CANADENSIS POLLEN - UNII:644CZ16IR5) | SOLIDAGO CANADENSIS POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------|----------|
|-----------------|----------|

| | |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C00X) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1192-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1192-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

SOLIDAGO CANADENSIS POLLEN

goldenrod injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1193 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------------|---------------------|
| SOLIDAGO CANADENSIS POLLEN (UNII: 644CZ16IR5) (SOLIDAGO CANADENSIS POLLEN - UNII:644CZ16IR5) | SOLIDAGO CANADENSIS POLLEN | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1193-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

| SOLIDAGO CANADENSIS POLLEN | | | | |
|--|--|--|----------------------|--------------------|
| goldenrod injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1608 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| SOLIDAGO CANADENSIS POLLEN (UNII: 644CZ16IR5) (SOLIDAGO CANADENSIS POLLEN - UNII:644CZ16IR5) | | SOLIDAGO CANADENSIS POLLEN | 20000 [PNU] in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1608-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 | |

SOLIDAGO CANADENSIS POLLEN

goldenrod injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1195 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------------|---------------------|
| SOLIDAGO CANADENSIS POLLEN (UNII: 644CZ16IR5) (SOLIDAGO CANADENSIS POLLEN - UNII:644CZ16IR5) | SOLIDAGO CANADENSIS POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1195-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1195-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ZEA MAYS POLLEN

corn pollen injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1122 |
| Route of Administration | SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | | | |
|--|--|--|----------------------|---------------------|
| Ingredient Name | | | Basis of Strength | Strength |
| ZEA MAYS POLLEN (UNII: 74PD8J616H) (ZEA MAYS POLLEN - UNII:74PD8J616H) | | | ZEA MAYS POLLEN | 40000 [PNU] in 1 mL |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| PHENOL (UNII: 339NCG44TV) | | | 0.004 mL in 1 mL | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | 0.009 g in 1 mL | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | 0.00275 g in 1 mL | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1122-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 | |

| ZEA MAYS POLLEN | | | |
|--|-----------------------------|--------------------|-------------------|
| corn pollen injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1123 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| ZEA MAYS POLLEN (UNII: 74PD8J616H) (ZEA MAYS POLLEN - UNII:74PD8J616H) | | ZEA MAYS POLLEN | 500 [PNU] in 1 mL |
| Inactive Ingredients | | | |
| Ingredient Name | | Strength | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | |

| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | | |
|--|--|---|----------------------|--------------------|
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1123-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 | |

| POPULUS DELTOIDES POLLEN | | | | |
|---|-----------------------------|--|----------------------|--------------------|
| cottonwood eastern common injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1126 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | Basis of Strength | Strength | | |
| POPULUS DELTOIDES POLLEN (UNII: 476DVV63WP) (POPULUS DELTOIDES POLLEN - UNII:476DVV63WP) | POPULUS DELTOIDES POLLEN | 0.10 g in 1 mL | | |
| Inactive Ingredients | | | | |
| Ingredient Name | Strength | | | |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL | | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1126-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1126-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

POPULUS DELTOIDES POLLEN

cottonwood eastern common injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1127 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|----------------|
| POPULUS DELTOIDES POLLEN (UNII: 476DVV63WP) (POPULUS DELTOIDES POLLEN - UNII:476DVV63WP) | POPULUS DELTOIDES POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1127-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1127-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

POPULUS DELTOIDES POLLEN

cottonwood eastern common injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1128 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|---------------------|
| POPULUS DELTOIDES POLLEN (UNII: 476DVV63WP) (POPULUS DELTOIDES POLLEN - UNII:476DVV63WP) | POPULUS DELTOIDES POLLEN | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1128-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1128-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

POPULUS DELTOIDES POLLEN

cottonwood eastern common injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1129 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|---------------------|
| POPULUS DELTOIDES POLLEN (UNII: 476DWW63WP) (POPULUS DELTOIDES POLLEN - UNII:476DWW63WP) | POPULUS DELTOIDES POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1129-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

POPULUS DELTOIDES POLLEN

cottonwood eastern common injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1130 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------------|
| POPULUS DELTOIDES POLLEN (UNII: 476DWW63WP) (POPULUS DELTOIDES POLLEN - UNII:476DWW63WP) | POPULUS DELTOIDES POLLEN | 0.001 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |

| | |
|--|-------------------|
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0268-1130-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

POPULUS FREMONTII POLLEN

cottonwood fremont injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1133 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|----------------|
| POPULUS FREMONTII POLLEN (UNII: 426RHB4302) (POPULUS FREMONTII POLLEN - UNII:426RHB4302) | POPULUS FREMONTII POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1133-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

POPULUS FREMONTII POLLEN

cottonwood fremont injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1134 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|----------------|
| POPULUS FREMONTII POLLEN (UNII: 426RHB4302) (POPULUS FREMONTII POLLEN - UNII:426RHB4302) | POPULUS FREMONTII POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1134-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

POPULUS FREMONTII POLLEN

cottonwood fremont injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1135 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|---------------------|
| POPULUS FREMONTII POLLEN (UNII: 426RHB4302) (POPULUS FREMONTII POLLEN - UNII:426RHB4302) | POPULUS FREMONTII POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|--|-----------------------------|---------------------------|
| 1 | NDC:0268-1135-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

POPULUS DELTOIDES SSP MONILIFERA POLLEN

cottonwood western injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1138 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--|-----------------|
| POPULUS DELTOIDES SUBSP. MONILIFERA POLLEN (UNII: 5928LJ1441) (POPULUS DELTOIDES SUBSP. MONILIFERA POLLEN - UNII:5928LJ1441) | POPULUS DELTOIDES SUBSP. MONILIFERA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1138-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

POPULUS DELTOIDES SSP MONILIFERA POLLEN

cottonwood western injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1139 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--|-------------------|
| POPULUS DELTOIDES SUBSP. MONILIFERA POLLEN (UNII: 5928LJ1441) (POPULUS DELTOIDES SUBSP. MONILIFERA POLLEN - UNII:5928LJ1441) | POPULUS DELTOIDES SUBSP. MONILIFERA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1139-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

CUPRESSUS ARIZONICA POLLEN

cypress arizona injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1142 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|----------------------------|----------------|
| CUPRESSUS ARIZONICA POLLEN (UNII: 232DMH0XVF) (CUPRESSUS ARIZONICA POLLEN - UNII:232DMH0XVF) | CUPRESSUS ARIZONICA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1142-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
|--------------------|--|----------------------|--------------------|

| | | | |
|-----|-----------|------------|------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |
|-----|-----------|------------|------------|

CUPRESSUS ARIZONICA POLLEN

cypress arizona injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1143 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------------|-------------------|
| CUPRESSUS ARIZONICA POLLEN (UNII: 232DMH0XVF) (CUPRESSUS ARIZONICA POLLEN - UNII:232DMH0XVF) | CUPRESSUS ARIZONICA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1143-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1143-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

CELTIS OCCIDENTALIS POLLEN

hackberry injection, solution

Product Information

| | | | |
|---------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1198 |
|---------------------|-----------------------------|---------------------------|---------------|

| | | | | |
|--|---|--|-----------------------------|---------------------------|
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| CELTIS OCCIDENTALIS POLLEN (UNII: 68R9X9Y96X) (CELTIS OCCIDENTALIS POLLEN - UNII:68R9X9Y96X) | | CELTIS OCCIDENTALIS POLLEN | 0.10 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1198-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | | |

| | | | | |
|--|-----------------------------|----------------------------|-----------------|--|
| CELTIS OCCIDENTALIS POLLEN | | | | |
| hackberry injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1199 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| CELTIS OCCIDENTALIS POLLEN (UNII: 68R9X9Y96X) (CELTIS OCCIDENTALIS POLLEN - UNII:68R9X9Y96X) | | CELTIS OCCIDENTALIS POLLEN | 0.05 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |

| | |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C00X) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1199-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1199-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

CELTIS OCCIDENTALIS POLLEN

hackberry injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1200 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------------|-----------------|
| CELTIS OCCIDENTALIS POLLEN (UNII: 68R9X9Y96X) (CELTIS OCCIDENTALIS POLLEN - UNII:68R9X9Y96X) | CELTIS OCCIDENTALIS POLLEN | 0.001 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0268-1200-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

| CORYLUS AMERICANA POLLEN | | | | |
|--|--|--|----------------------|--------------------|
| hazelnut pollen injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1203 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| CORYLUS AMERICANA POLLEN (UNII: ZGS382Y3AV) (CORYLUS AMERICANA POLLEN - UNII:ZGS382Y3AV) | | CORYLUS AMERICANA POLLEN | 0.10 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1203-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 | |

CORYLUS AMERICANA POLLEN

hazelnut pollen injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1204 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|----------------|
| CORYLUS AMERICANA POLLEN (UNII: ZGS382Y3AV) (CORYLUS AMERICANA POLLEN - UNII:ZGS382Y3AV) | CORYLUS AMERICANA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1204-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1204-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

CORYLUS AMERICANA POLLEN

hazelnut pollen injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1205 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|---------------------|
| CORYLUS AMERICANA POLLEN (UNII: ZGS382Y3AV) (CORYLUS AMERICANA POLLEN - UNII:ZGS382Y3AV) | CORYLUS AMERICANA POLLEN | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1205-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

CORYLUS AMERICANA POLLEN

hazelnut pollen injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1206 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|---------------------|
| CORYLUS AMERICANA POLLEN (UNII: ZGS382Y3AV) (CORYLUS AMERICANA POLLEN - UNII:ZGS382Y3AV) | CORYLUS AMERICANA POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------|------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |

| | |
|--|-------------------|
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1206-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

SORGHUM HALEPENSE POLLEN

johnson grass injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1214 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|----------------|
| SORGHUM HALEPENSE POLLEN (UNII: 577VA5B4HP) (SORGHUM HALEPENSE POLLEN - UNII:577VA5B4HP) | SORGHUM HALEPENSE POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1214-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| | NDC:0268-1214-10 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| | | |
|---|------------------|--|
| 2 | NDC:0268-1214-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product |
|---|------------------|--|

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

SORGHUM HALEPENSE POLLEN

johnson grass injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1215 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|----------------|
| SORGHUM HALEPENSE POLLEN (UNII: 577VA5B4HP) (SORGHUM HALEPENSE POLLEN - UNII:577VA5B4HP) | SORGHUM HALEPENSE POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1215-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1215-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

SORGHUM HALEPENSE POLLEN

johnson grass injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1216 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|---------------------|
| SORGHUM HALEPENSE POLLEN (UNII: 577VA5B4HP) (SORGHUM HALEPENSE POLLEN - UNII:577VA5B4HP) | SORGHUM HALEPENSE POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1216-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

SORGHUM HALEPENSE POLLEN

johnson grass injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1217 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | | Basis of Strength | Strength | |
|--|--|--|----------------------|--------------------|
| SORGHUM HALEPENSE POLLEN (UNII: 577VA5B4HP) (SORGHUM HALEPENSE POLLEN - UNII:577VA5B4HP) | | SORGHUM HALEPENSE POLLEN | 0.005 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1217-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 | |

| SORGHUM HALEPENSE POLLEN | | | |
|--|-----------------------------|--------------------------|------------------|
| johnson grass injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1218 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| SORGHUM HALEPENSE POLLEN (UNII: 577VA5B4HP) (SORGHUM HALEPENSE POLLEN - UNII:577VA5B4HP) | | SORGHUM HALEPENSE POLLEN | 0.0005 g in 1 mL |
| Inactive Ingredients | | | |
| Ingredient Name | | Strength | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1218-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

SORGHUM HALEPENSE POLLEN

johnson grass injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1219 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|---------------------|
| SORGHUM HALEPENSE POLLEN (UNII: 577VA5B4HP) (SORGHUM HALEPENSE POLLEN - UNII:577VA5B4HP) | SORGHUM HALEPENSE POLLEN | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1219-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

SORGHUM HALEPENSE POLLEN

johnson grass injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1220 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|-----------------|
| SORGHUM HALEPENSE POLLEN (UNII: 577VA5B4HP) (SORGHUM HALEPENSE POLLEN - UNII:577VA5B4HP) | SORGHUM HALEPENSE POLLEN | 0.001 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0268-1220-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

JUNIPERUS CALIFORNICA POLLEN

juniper western injection, solution

Product Information

| | | | |
|--------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1223 |
|--------------|-----------------------------|--------------------|---------------|

Route of Administration SUBCUTANEOUS

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|------------------------------|----------------|
| JUNIPERUS CALIFORNICA POLLEN (UNII: 0H1V4V5V9L) (JUNIPERUS CALIFORNICA POLLEN - UNII:0H1V4V5V9L) | JUNIPERUS CALIFORNICA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1223-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

JUNIPERUS CALIFORNICA POLLEN

juniper western injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1224 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|------------------------------|----------------|
| JUNIPERUS CALIFORNICA POLLEN (UNII: 0H1V4V5V9L) (JUNIPERUS CALIFORNICA POLLEN - UNII:0H1V4V5V9L) | JUNIPERUS CALIFORNICA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------|----------|
|-----------------|----------|

| | |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C00X) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1224-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1224-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

JUNIPERUS CALIFORNICA POLLEN

juniper western injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1225 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|------------------------------|---------------------|
| JUNIPERUS CALIFORNICA POLLEN (UNII: 0H1V4V5V9L) (JUNIPERUS CALIFORNICA POLLEN - UNII:0H1V4V5V9L) | JUNIPERUS CALIFORNICA POLLEN | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1225-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1225-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

KOCHIA SCOPARIA POLLEN

kochia firebush injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1232 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|------------------------|----------------|
| BASSIA SCOPARIA POLLEN (UNII: 07A108ZKW5) (BASSIA SCOPARIA POLLEN - UNII:07A108ZKW5) | BASSIA SCOPARIA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1232-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1232-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
|-----------|---------------------------------|-----------------|---------------|
|-----------|---------------------------------|-----------------|---------------|

| Category | Citation | Date | Date |
|----------|-----------|------------|------|
| BLA | BLA103753 | 01/01/1965 | |

KOCHIA SCOPARIA POLLEN

kochia firebush injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1233 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|------------------------|----------------|
| BASSIA SCOPARIA POLLEN (UNII: 07A108ZKW5) (BASSIA SCOPARIA POLLEN - UNII:07A108ZKW5) | BASSIA SCOPARIA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1233-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1233-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

KOCHIA SCOPARIA POLLEN

kochia firebush injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1234 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|---------------------|
| BASSIA SCOPARIA POLLEN (UNII: 07A108ZKW5) (BASSIA SCOPARIA POLLEN - UNII:07A108ZKW5) | BASSIA SCOPARIA POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|--|-----------------------------|---------------------------|
| 1 | NDC:0268-1234-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| BLA | BLA103753 | 01/01/1965 | |

KOCHIA SCOPARIA POLLEN

kochia firebush injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1235 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|---------------------|
| BASSIA SCOPARIA POLLEN (UNII: 07A108ZKW5) (BASSIA SCOPARIA POLLEN - UNII:07A108ZKW5) | BASSIA SCOPARIA POLLEN | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1235-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

CHENOPODIUM ALBUM POLLEN

lambs quarters injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1238 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|----------------|
| CHENOPODIUM ALBUM POLLEN (UNII: 098LKX5NCN) (CHENOPODIUM ALBUM POLLEN - UNII:098LKX5NCN) | CHENOPODIUM ALBUM POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1238-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1238-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

CHENOPODIUM ALBUM POLLEN

lamb's quarters injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1239 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|----------------|
| CHENOPODIUM ALBUM POLLEN (UNII: 098LKX5NCN) (CHENOPODIUM ALBUM POLLEN - UNII:098LKX5NCN) | CHENOPODIUM ALBUM POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C00X) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1239-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1239-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

CHENOPODIUM ALBUM POLLEN

lams quarters injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1240 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|---------------------|
| CHENOPODIUM ALBUM POLLEN (UNII: 098LKX5NCN) (CHENOPODIUM ALBUM POLLEN - UNII:098LKX5NCN) | CHENOPODIUM ALBUM POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1240-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1240-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

CHENOPODIUM ALBUM POLLEN

lams quarters injection, solution

| Product Information | | | | |
|--|--|--|----------------------|--------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1241 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| CHENOPODIUM ALBUM POLLEN (UNII: 098LKX5NCN) (CHENOPODIUM ALBUM POLLEN - UNII:098LKX5NCN) | | CHENOPODIUM ALBUM POLLEN | 10000 [PNU] in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1241-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 | |

| CHENOPODIUM ALBUM POLLEN | | | | |
|--|-----------------------------|---------------------------|---------------------|--|
| lamb's quarters injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1242 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| CHENOPODIUM ALBUM POLLEN (UNII: 098LKX5NCN) (CHENOPODIUM ALBUM POLLEN - UNII:098LKX5NCN) | | CHENOPODIUM ALBUM POLLEN | 20000 [PNU] in 1 mL | |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1242-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ROBINIA PSEUDOACACIA POLLEN

locust black non stock injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1245 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-----------------------------|----------------|
| ROBINIA PSEUDOACACIA POLLEN (UNII: 8003NOJ82F) (ROBINIA PSEUDOACACIA POLLEN - UNII:8003NOJ82F) | ROBINIA PSEUDOACACIA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1245-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ACER RUBRUM POLLEN

maple red injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1248 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------|----------------|
| ACER RUBRUM POLLEN (UNII: 700NK45C76) (ACER RUBRUM POLLEN - UNII:700NK45C76) | ACER RUBRUM POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1248-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1248-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ACER RUBRUM POLLEN

maple red injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1249 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------|----------------|
| ACER RUBRUM POLLEN (UNII: 700NK45C76) (ACER RUBRUM POLLEN - UNII:700NK45C76) | ACER RUBRUM POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1249-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1249-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

ACER SACCHARUM POLLEN

maple sugar injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1252 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------------|
| ACER SACCHARUM POLLEN (UNII: V38QUQ7861) (ACER SACCHARUM POLLEN - UNII:V38QUQ7861) | ACER SACCHARUM POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|--|-----------------------------|---------------------------|
| 1 | NDC:0268-1252-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1252-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| BLA | BLA103753 | 01/01/1965 | |

ACER SACCHARUM POLLEN

maple sugar injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1253 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | | Basis of Strength | Strength | |
|--|--|--|----------------------|--------------------|
| ACER SACCHARUM POLLEN (UNII: V38QUQ7861) (ACER SACCHARUM POLLEN - UNII:V38QUQ7861) | | ACER SACCHARUM POLLEN | 40000 [PNU] in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1253-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1253-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | | |

ACER SACCHARUM POLLEN

maple sugar injection, solution

| Product Information | | | |
|--|-----------------------------|-----------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1254 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| ACER SACCHARUM POLLEN (UNII: V38QUQ7861) (ACER SACCHARUM POLLEN - UNII:V38QUQ7861) | | ACER SACCHARUM POLLEN | 0.05 g in 1 mL |
| Inactive Ingredients | | | |
| Ingredient Name | | Strength | |
| GLYCERIN (UNII: PDC6A3C0OX) | | 0.5 mL in 1 mL | |

| | |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1254-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

ACER SACCHARUM POLLEN

maple sugar injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1255 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------|---------------------|
| ACER SACCHARUM POLLEN (UNII: V38QUQ7861) (ACER SACCHARUM POLLEN - UNII:V38QUQ7861) | ACER SACCHARUM POLLEN | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

| | | | | |
|----------|------------------|--|--|--|
| 1 | NDC:0268-1255-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
|----------|------------------|--|--|--|

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

IVA XANTHIFOLIA POLLEN

marshelder burweed injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1258 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------------|----------------|
| CYCLACHAENA XANTHIFOLIA POLLEN (UNII: V80TPZ0T6J) (CYCLACHAENA XANTHIFOLIA POLLEN - UNII:V80TPZ0T6J) | CYCLACHAENA XANTHIFOLIA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1258-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

IVA XANTHIFOLIA POLLEN

marshelder burweed injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1259 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------------|-----------------|
| CYCLACHAENA XANTHIFOLIA POLLEN (UNII: V80TPZ0T6J) (CYCLACHAENA XANTHIFOLIA POLLEN - UNII:V80TPZ0T6J) | CYCLACHAENA XANTHIFOLIA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1259-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1259-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| BLA | BLA103753 | 01/01/1965 | |

IVA XANTHIFOLIA POLLEN

marshelder burweed injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1260 |
| Route of Administration | SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | | | |
|--|--|--|--------------------------------|---------------------|
| Ingredient Name | | | Basis of Strength | Strength |
| CYCLACHAENA XANTHIFOLIA POLLEN (UNII: V80TPZ0T6J) (CYCLACHAENA XANTHIFOLIA POLLEN - UNII:V80TPZ0T6J) | | | CYCLACHAENA XANTHIFOLIA POLLEN | 40000 [PNU] in 1 mL |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| PHENOL (UNII: 339NCG44TV) | | | 0.004 mL in 1 mL | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | 0.009 g in 1 mL | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | 0.00275 g in 1 mL | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1260-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1260-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 | |

| IVA ANNUA VAR ANNUA POLLEN | | | | |
|--|-----------------------------|--------------------|-------------------|----------------|
| marshelder rough injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1263 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | | Basis of Strength | Strength |
| IVA ANNUA POLLEN (UNII: Y2U5S5PF22) (IVA ANNUA POLLEN - UNII:Y2U5S5PF22) | | | IVA ANNUA POLLEN | 0.10 g in 1 mL |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| PHENOL (UNII: 339NCG44TV) | | | 0.004 mL in 1 mL | |

| | |
|--|-------------------|
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1263-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1263-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

IVA ANNUA VAR ANNUA POLLEN

marshelder rough injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1264 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------------|
| IVA ANNUA POLLEN (UNII: Y2U5S5PF22) (IVA ANNUA POLLEN - UNII:Y2U5S5PF22) | IVA ANNUA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1264-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1264-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

IVA ANNUA VAR ANNUA POLLEN

marshelder rough injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1265 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------------|
| IVA ANNUA POLLEN (UNII: Y2U5S5PF22) (IVA ANNUA POLLEN - UNII:Y2U5S5PF22) | IVA ANNUA POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1265-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| | | | |

| | | | |
|-----|-----------|------------|--|
| BLA | BLA103753 | 01/01/1965 | |
|-----|-----------|------------|--|

ARTEMISIA VULGARIS POLLEN

mugwort common injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1297 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------------|-------------------|
| ARTEMISIA VULGARIS POLLEN (UNII: ANT994T71D) (ARTEMISIA VULGARIS POLLEN - UNII:ANT994T71D) | ARTEMISIA VULGARIS POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1297-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1297-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

ARTEMISIA VULGARIS POLLEN

mugwort common injection, solution

Product Information

| | | | |
|---------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1298 |
|---------------------|-----------------------------|---------------------------|---------------|

Route of Administration SUBCUTANEOUS

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|---------------------------|----------------|
| ARTEMISIA VULGARIS POLLEN (UNII: ANT994T71D) (ARTEMISIA VULGARIS POLLEN - UNII:ANT994T71D) | ARTEMISIA VULGARIS POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1298-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1298-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

ARTEMISIA VULGARIS POLLEN

mugwort common injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1299 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|---------------------------|---------------------|
| ARTEMISIA VULGARIS POLLEN (UNII: ANT994T71D) (ARTEMISIA VULGARIS POLLEN - UNII:ANT994T71D) | ARTEMISIA VULGARIS POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1299-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ARTEMISIA VULGARIS POLLEN

mugwort common injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1300 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|---------------------------|---------------------|
| ARTEMISIA VULGARIS POLLEN (UNII: ANT994T71D) (ARTEMISIA VULGARIS POLLEN - UNII:ANT994T71D) | ARTEMISIA VULGARIS POLLEN | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1300-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ARTEMISIA VULGARIS POLLEN

mugwort common injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1301 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|---------------------------|---------------------|
| ARTEMISIA VULGARIS POLLEN (UNII: ANT994T71D) (ARTEMISIA VULGARIS POLLEN - UNII:ANT994T71D) | ARTEMISIA VULGARIS POLLEN | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1301-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

MORUS RUBRA POLLEN

mulberry red injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1304 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------|-------------------|
| MORUS RUBRA POLLEN (UNII: 9LYI4RTZ52) (MORUS RUBRA POLLEN - UNII:9LYI4RTZ52) | MORUS RUBRA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1304-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1304-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

MORUS RUBRA POLLEN

mulberry red injection, solution

Product Information

| | | | |
|---------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1305 |
|---------------------|-----------------------------|---------------------------|---------------|

Route of Administration SUBCUTANEOUS

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------|----------------|
| MORUS RUBRA POLLEN (UNII: 9LYI4RTZ52) (MORUS RUBRA POLLEN - UNII:9LYI4RTZ52) | MORUS RUBRA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1305-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1305-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

MORUS RUBRA POLLEN

mulberry red injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1306 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------|---------------------|
| MORUS RUBRA POLLEN (UNII: 9LYI4RTZ52) (MORUS RUBRA POLLEN - UNII:9LYI4RTZ52) | MORUS RUBRA POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1306-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1306-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

MORUS RUBRA POLLEN

mulberry red injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1307 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------|-----------------|
| MORUS RUBRA POLLEN (UNII: 9LYI4RTZ52) (MORUS RUBRA POLLEN - UNII:9LYI4RTZ52) | MORUS RUBRA POLLEN | 0.001 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0268-1307-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

MORUS ALBA POLLEN

mulberry white injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1310 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| MORUS ALBA POLLEN (UNII: 3I9T68187H) (MORUS ALBA POLLEN - UNII:3I9T68187H) | MORUS ALBA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1310-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

MORUS ALBA POLLEN

mulberry white injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1311 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| MORUS ALBA POLLEN (UNII: 3I9T68187H) (MORUS ALBA POLLEN - UNII:3I9T68187H) | MORUS ALBA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1311-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1311-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

QUERCUS AGRIFOLIA POLLEN

oak california live coast injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1314 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------------|
| QUERCUS AGRIFOLIA POLLEN (UNII: VOT5MA71M7) (QUERCUS AGRIFOLIA POLLEN - UNII:VOT5MA71M7) | QUERCUS AGRIFOLIA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|-----------------------------|---------------------------|
| 1 | NDC:0268-1314-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1314-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

QUERCUS AGRIFOLIA POLLEN

oak california live coast injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1315 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------------|
| QUERCUS AGRIFOLIA POLLEN (UNII: VOT5MA71M7) (QUERCUS AGRIFOLIA POLLEN - UNII:VOT5MA71M7) | QUERCUS AGRIFOLIA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1315-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1315-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

QUERCUS RUBRA POLLEN

oak red injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1318 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------|----------------|
| QUERCUS RUBRA POLLEN (UNII: SVW19ET93C) (QUERCUS RUBRA POLLEN - UNII:SVW19ET93C) | QUERCUS RUBRA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |

SODIUM HYDROXIDE (UNII: 55X04QC32I)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1318-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1318-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

QUERCUS RUBRA POLLEN

oak red injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1319 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------|----------------|
| QUERCUS RUBRA POLLEN (UNII: SVW19ET93C) (QUERCUS RUBRA POLLEN - UNII:SVW19ET93C) | QUERCUS RUBRA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C00X) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1319-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| | | |
|---|------------------|--|
| 2 | NDC:0268-1319-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product |
|---|------------------|--|

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

QUERCUS VIRGINIANA POLLEN

oak virginia live injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1322 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|---------------------------|----------------|
| QUERCUS VIRGINIANA POLLEN (UNII: 8KDG09A4GO) (QUERCUS VIRGINIANA POLLEN - UNII:8KDG09A4GO) | QUERCUS VIRGINIANA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1322-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

QUERCUS VIRGINIANA POLLEN

oak virginia live injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1323 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------------|-----------------|
| QUERCUS VIRGINIANA POLLEN (UNII: 8KDG09A4GO) (QUERCUS VIRGINIANA POLLEN - UNII:8KDG09A4GO) | QUERCUS VIRGINIANA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1323-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1323-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| BLA | BLA103753 | 01/01/1965 | |

QUERCUS VIRGINIANA POLLEN

oak virginia live injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1324 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------------|---------------------|
| QUERCUS VIRGINIANA POLLEN (UNII: 8KDG09A4GO) (QUERCUS VIRGINIANA POLLEN - UNII:8KDG09A4GO) | QUERCUS VIRGINIANA POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1324-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

QUERCUS ALBA POLLEN

oak white injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1327 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------|----------------|
| QUERCUS ALBA POLLEN (UNII: Z4Y9ZSV4KK) (QUERCUS ALBA POLLEN - UNII:Z4Y9ZSV4KK) | QUERCUS ALBA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |

| | |
|--|-------------------|
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1327-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1327-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

QUERCUS ALBA POLLEN

oak white injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1328 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------|----------------|
| QUERCUS ALBA POLLEN (UNII: Z4Y9ZSV4KK) (QUERCUS ALBA POLLEN - UNII:Z4Y9ZSV4KK) | QUERCUS ALBA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

| | | | | |
|---|------------------|--|--|--|
| 1 | NDC:0268-1328-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1328-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | 01/01/1965 | |

| QUERCUS ALBA POLLEN | | | | |
|--|--|--|----------------------|--------------------|
| oak white injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1329 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | Basis of Strength | Strength | | |
| QUERCUS ALBA POLLEN (UNII: Z4Y9ZSV4KK) (QUERCUS ALBA POLLEN - UNII:Z4Y9ZSV4KK) | QUERCUS ALBA POLLEN | 40000 [PNU] in 1 mL | | |
| Inactive Ingredients | | | | |
| Ingredient Name | Strength | | | |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL | | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1329-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | | |

QUERCUS ALBA POLLEN

oak white injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1330 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------|---------------------|
| QUERCUS ALBA POLLEN (UNII: Z4Y9ZSV4KK) (QUERCUS ALBA POLLEN - UNII:Z4Y9ZSV4KK) | QUERCUS ALBA POLLEN | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1330-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

QUERCUS ALBA POLLEN

oak white injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1613 |
| Route of Administration | SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | | | |
|--|--|--|----------------------|---------------------|
| Ingredient Name | | | Basis of Strength | Strength |
| QUERCUS ALBA POLLEN (UNII: Z4Y9ZSV4KK) (QUERCUS ALBA POLLEN - UNII:Z4Y9ZSV4KK) | | | QUERCUS ALBA POLLEN | 20000 [PNU] in 1 mL |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| PHENOL (UNII: 339NCG44TV) | | | 0.004 mL in 1 mL | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | 0.009 g in 1 mL | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | 0.00275 g in 1 mL | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1613-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 | |

| QUERCUS ALBA POLLEN | | | |
|--|-----------------------------|---------------------|---------------------|
| oak white injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1332 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| QUERCUS ALBA POLLEN (UNII: Z4Y9ZSV4KK) (QUERCUS ALBA POLLEN - UNII:Z4Y9ZSV4KK) | | QUERCUS ALBA POLLEN | 50000 [PNU] in 1 mL |
| Inactive Ingredients | | | |
| Ingredient Name | | Strength | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | |

| | |
|--|-------------------|
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1332-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

QUERCUS ALBA POLLEN

oak white injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1333 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------|-----------------|
| QUERCUS ALBA POLLEN (UNII: Z4Y9ZSV4KK) (QUERCUS ALBA POLLEN - UNII:Z4Y9ZSV4KK) | QUERCUS ALBA POLLEN | 0.001 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0268-1333-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

QUERCUS ALBA POLLEN

oat wild pollen injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1336 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|---------------------|----------------|
| QUERCUS ALBA POLLEN (UNII: Z4Y9ZSV4KK) (QUERCUS ALBA POLLEN - UNII:Z4Y9ZSV4KK) | QUERCUS ALBA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1336-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1336-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

OLEA EUROPAEA POLLEN

olive pollen injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1339 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------|----------------|
| OLEA EUROPAEA POLLEN (UNII: 43R41XZ627) (OLEA EUROPAEA POLLEN - UNII:43R41XZ627) | OLEA EUROPAEA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1339-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1339-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

OLEA EUROPAEA POLLEN

olive pollen injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1340 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------|----------------|
| OLEA EUROPAEA POLLEN (UNII: 43R41XZ627) (OLEA EUROPAEA POLLEN - UNII:43R41XZ627) | OLEA EUROPAEA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1340-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1340-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

SYAGRUS ROMANZOFFIANA POLLEN

palm queen coco palm injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1347 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|------------------------------|----------------|
| SYAGRUS ROMANZOFFIANA POLLEN (UNII: 84ZOM591BB) (SYAGRUS ROMANZOFFIANA POLLEN - UNII:84ZOM591BB) | SYAGRUS ROMANZOFFIANA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1347-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

SYAGRUS ROMANZOFFIANA POLLEN

palm queen coco palm injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1348 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|------------------------------|----------------|
| SYAGRUS ROMANZOFFIANA POLLEN (UNII: 84ZOM591BB) (SYAGRUS ROMANZOFFIANA POLLEN - UNII:84ZOM591BB) | SYAGRUS ROMANZOFFIANA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
| | | | | |

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1348-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1348-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

CARYA ILLINOINENSIS POLLEN

pecan pollen injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1354 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------------|----------------|
| CARYA ILLINOINENSIS POLLEN (UNII: PYO4JR720Y) (CARYA ILLINOINENSIS POLLEN - UNII:PYO4JR720Y) | CARYA ILLINOINENSIS POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1354-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1354-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| | | | |

| | | | |
|-----|-----------|------------|--|
| BLA | BLA103753 | 01/01/1965 | |
|-----|-----------|------------|--|

CARYA ILLINOINENSIS POLLEN

pecan pollen injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1355 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------------|----------------|
| CARYA ILLINOINENSIS POLLEN (UNII: PYO4JR720Y) (CARYA ILLINOINENSIS POLLEN - UNII:PYO4JR720Y) | CARYA ILLINOINENSIS POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1355-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1355-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

CARYA ILLINOINENSIS POLLEN

pecan pollen injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1614 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------------|---------------------|
| CARYA ILLINOINENSIS POLLEN (UNII: PYO4JR720Y) (CARYA ILLINOINENSIS POLLEN - UNII:PYO4JR720Y) | CARYA ILLINOINENSIS POLLEN | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1614-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

CARYA ILLINOINENSIS POLLEN

pecan pollen injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1358 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------------|-----------------|
| CARYA ILLINOINENSIS POLLEN (UNII: PYO4JR720Y) (CARYA ILLINOINENSIS POLLEN - UNII:PYO4JR720Y) | CARYA ILLINOINENSIS POLLEN | 0.001 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1358-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

SCHINUS MOLLE POLLEN

pepper tree california injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1361 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|----------------------|----------------|
| SCHINUS MOLLE POLLEN (UNII: M0G28FH9K1) (SCHINUS MOLLE POLLEN - UNII:M0G28FH9K1) | SCHINUS MOLLE POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1361-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

AMARANTHUS RETROFLEXUS POLLEN

pigweed rough redroot injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1364 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------------------|----------------|
| AMARANTHUS RETROFLEXUS POLLEN (UNII: 73B14PX5FW) (AMARANTHUS RETROFLEXUS POLLEN - UNII:73B14PX5FW) | AMARANTHUS RETROFLEXUS POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1364-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1364-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
|--------------------|--|----------------------|--------------------|

| | | | |
|-----|-----------|------------|--|
| BLA | BLA103753 | 01/01/1965 | |
|-----|-----------|------------|--|

AMARANTHUS RETROFLEXUS POLLEN

pigweed rough redroot injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1365 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------------------|----------------|
| AMARANTHUS RETROFLEXUS POLLEN (UNII: 73B14PX5FW) (AMARANTHUS RETROFLEXUS POLLEN - UNII:73B14PX5FW) | AMARANTHUS RETROFLEXUS POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1365-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1365-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

AMARANTHUS RETROFLEXUS POLLEN

pigweed rough redroot injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1366 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------------------|---------------------|
| AMARANTHUS RETROFLEXUS POLLEN (UNII: 73B14PX5FW) (AMARANTHUS RETROFLEXUS POLLEN - UNII:73B14PX5FW) | AMARANTHUS RETROFLEXUS POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1366-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1366-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

AMARANTHUS RETROFLEXUS POLLEN

pigweed rough redroot injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1367 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------------------|---------------------|
| AMARANTHUS RETROFLEXUS POLLEN (UNII: 73B14PX5FW) (AMARANTHUS RETROFLEXUS POLLEN - UNII:73B14PX5FW) | AMARANTHUS RETROFLEXUS POLLEN | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1367-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

AMARANTHUS RETROFLEXUS POLLEN

pigweed rough redroot injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1368 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------------------|-----------------|
| AMARANTHUS RETROFLEXUS POLLEN (UNII: 73B14PX5FW) (AMARANTHUS RETROFLEXUS POLLEN - UNII:73B14PX5FW) | AMARANTHUS RETROFLEXUS POLLEN | 0.001 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0268-1368-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

| AMARANTHUS SPINOSUS POLLEN | | | | |
|--|--|--|----------------------|--------------------|
| pigweed spiny injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1371 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| AMARANTHUS SPINOSUS POLLEN (UNII: 380W4HYR6N) (AMARANTHUS SPINOSUS POLLEN - UNII:380W4HYR6N) | | AMARANTHUS SPINOSUS POLLEN | 0.10 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1371-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | | |

AMARANTHUS SPINOSUS POLLEN

pigweed spiny injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1372 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------------|-------------------|
| AMARANTHUS SPINOSUS POLLEN (UNII: 380W4HYR6N) (AMARANTHUS SPINOSUS POLLEN - UNII:380W4HYR6N) | AMARANTHUS SPINOSUS POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1372-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

AMARANTHUS SPINOSUS POLLEN

pigweed spiny injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1373 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | | Basis of Strength | Strength | |
|--|--|--|----------------------|--------------------|
| AMARANTHUS SPINOSUS POLLEN (UNII: 380W4HYR6N) (AMARANTHUS SPINOSUS POLLEN - UNII:380W4HYR6N) | | AMARANTHUS SPINOSUS POLLEN | 40000 [PNU] in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1373-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 | |

| CASUARINA EQUISETIFOLIA POLLEN | | | |
|--|-----------------------------|--------------------------------|----------------|
| pine australian beefwood injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1376 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| CASUARINA EQUISETIFOLIA POLLEN (UNII: OZJ4OE173N) (CASUARINA EQUISETIFOLIA POLLEN - UNII:OZJ4OE173N) | | CASUARINA EQUISETIFOLIA POLLEN | 0.10 g in 1 mL |
| Inactive Ingredients | | | |
| Ingredient Name | | Strength | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1376-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

CASUARINA EQUISETIFOLIA POLLEN

pine australian beefwood injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1377 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------------|----------------|
| CASUARINA EQUISETIFOLIA POLLEN (UNII: OZJ4OE173N) (CASUARINA EQUISETIFOLIA POLLEN - UNII:OZJ4OE173N) | CASUARINA EQUISETIFOLIA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1377-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1377-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

CASUARINA EQUISETIFOLIA POLLEN

pine australian beefwood injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1378 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------------|---------------------|
| CASUARINA EQUISETIFOLIA POLLEN (UNII: OZJ4OE173N) (CASUARINA EQUISETIFOLIA POLLEN - UNII:OZJ4OE173N) | CASUARINA EQUISETIFOLIA POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1378-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

CASUARINA EQUISETIFOLIA POLLEN

pine australian beefwood injection, solution

Product Information

| | | | | |
|--|---|--|-----------------------------|---------------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1379 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| | Ingredient Name | Basis of Strength | Strength | |
| | CASUARINA EQUISETIFOLIA POLLEN (UNII: OZJ4OE173N) (CASUARINA EQUISETIFOLIA POLLEN - UNII:OZJ4OE173N) | CASUARINA EQUISETIFOLIA POLLEN | 50000 [PNU] in 1 mL | |
| Inactive Ingredients | | | | |
| | Ingredient Name | Strength | | |
| | PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL | | |
| | SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL | | |
| | SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL | | |
| | HYDROCHLORIC ACID (UNII: QTT17582CB) | | | |
| | SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1379-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 | |

| | | | |
|--|---|---------------------------|-----------------|
| PINUS STROBUS POLLEN | | | |
| pine white injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1382 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| | Ingredient Name | Basis of Strength | Strength |
| | PINUS STROBUS POLLEN (UNII: TX1ER5UV3T) (PINUS STROBUS POLLEN - UNII:TX1ER5UV3T) | PINUS STROBUS POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1382-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

PINUS STROBUS POLLEN

pine white injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1383 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------|----------------|
| PINUS STROBUS POLLEN (UNII: TX1ER5UV3T) (PINUS STROBUS POLLEN - UNII:TX1ER5UV3T) | PINUS STROBUS POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1383-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1383-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

PINUS STROBUS POLLEN

pine white injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1384 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------|---------------------|
| PINUS STROBUS POLLEN (UNII: TX1ER5UV3T) (PINUS STROBUS POLLEN - UNII:TX1ER5UV3T) | PINUS STROBUS POLLEN | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1384-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
|-----------|---------------------------------|-----------------|---------------|
|-----------|---------------------------------|-----------------|---------------|

| Category | Citation | Date | Date |
|----------|-----------|------------|------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

PINUS STROBUS POLLEN

pine white injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1385 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------|---------------------|
| PINUS STROBUS POLLEN (UNII: TX1ER5UV3T) (PINUS STROBUS POLLEN - UNII:TX1ER5UV3T) | PINUS STROBUS POLLEN | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1385-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

PINUS STROBUS POLLEN

pine white injection, solution

Product Information

| | | | |
|---------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1386 |
|---------------------|-----------------------------|---------------------------|---------------|

Route of Administration SUBCUTANEOUS

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------|-------------------|
| PINUS STROBUS POLLEN (UNII: TX1ER5UV3T) (PINUS STROBUS POLLEN - UNII:TX1ER5UV3T) | PINUS STROBUS POLLEN | 500 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0268-1386-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

PINUS ECHINATA POLLEN

pine yellow injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1389 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------|----------------|
| PINUS ECHINATA POLLEN (UNII: 96LRW14765) (PINUS ECHINATA POLLEN - UNII:96LRW14765) | PINUS ECHINATA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1389-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1389-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

PINUS ECHINATA POLLEN

pine yellow injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1390 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------|----------------|
| PINUS ECHINATA POLLEN (UNII: 96LRW14765) (PINUS ECHINATA POLLEN - UNII:96LRW14765) | PINUS ECHINATA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1390-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

PLANTAGO LANCEOLATA POLLEN

plantain english injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1394 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|----------------------------|----------------|
| PLANTAGO LANCEOLATA POLLEN (UNII: DO87T1U2CI) (PLANTAGO LANCEOLATA POLLEN - UNII:DO87T1U2CI) | PLANTAGO LANCEOLATA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1394-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1394-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
|-----------|---------------------------------|-----------------|---------------|
|-----------|---------------------------------|-----------------|---------------|

| Category | Citation | Date | Date |
|----------|-----------|------------|------|
| BLA | BLA103753 | 01/01/1965 | |

PLANTAGO LANCEOLATA POLLEN

plantain english injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1395 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------------|----------------|
| PLANTAGO LANCEOLATA POLLEN (UNII: DO87T1U2CI) (PLANTAGO LANCEOLATA POLLEN - UNII:DO87T1U2CI) | PLANTAGO LANCEOLATA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1395-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1395-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

PLANTAGO LANCEOLATA POLLEN

plantain english injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1396 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------------|--------------------|
| PLANTAGO LANCEOLATA POLLEN (UNII: DO87T1U2CI) (PLANTAGO LANCEOLATA POLLEN - UNII:DO87T1U2CI) | PLANTAGO LANCEOLATA POLLEN | 1000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1396-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

PLANTAGO LANCEOLATA POLLEN

plantain english injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1397 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------------|-------------------|
| PLANTAGO LANCEOLATA POLLEN (UNII: DO87T1U2CI) (PLANTAGO LANCEOLATA POLLEN - UNII:DO87T1U2CI) | PLANTAGO LANCEOLATA POLLEN | 100 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1397-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1397-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

PLANTAGO LANCEOLATA POLLEN

plantain english injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1616 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------------|---------------------|
| PLANTAGO LANCEOLATA POLLEN (UNII: DO87T1U2CI) (PLANTAGO LANCEOLATA POLLEN - UNII:DO87T1U2CI) | PLANTAGO LANCEOLATA POLLEN | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
| | | | | |

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1616-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

| PLANTAGO LANCEOLATA POLLEN | | | | |
|--|--|--|----------------------|--------------------|
| plantain english injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1399 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | Basis of Strength | Strength | | |
| PLANTAGO LANCEOLATA POLLEN (UNII: DO87T1U2CI) (PLANTAGO LANCEOLATA POLLEN - UNII:DO87T1U2CI) | PLANTAGO LANCEOLATA POLLEN | 20000 [PNU] in 1 mL | | |
| Inactive Ingredients | | | | |
| Ingredient Name | Strength | | | |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL | | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1399-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 | |

PLANTAGO LANCEOLATA POLLEN

plantain english injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1400 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------------|---------------------|
| PLANTAGO LANCEOLATA POLLEN (UNII: DO87T1U2CI) (PLANTAGO LANCEOLATA POLLEN - UNII:DO87T1U2CI) | PLANTAGO LANCEOLATA POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1400-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1400-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

PLANTAGO LANCEOLATA POLLEN

plantain english injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1401 |
| Route of Administration | SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | | | |
|--|--|--|----------------------------|------------------|
| Ingredient Name | | | Basis of Strength | Strength |
| PLANTAGO LANCEOLATA POLLEN (UNII: DO87T1U2CI) (PLANTAGO LANCEOLATA POLLEN - UNII:DO87T1U2CI) | | | PLANTAGO LANCEOLATA POLLEN | 10 [PNU] in 1 mL |

| Inactive Ingredients | |
|---------------------------------------|-------------------|
| Ingredient Name | Strength |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

| Packaging | | | | |
|-----------|------------------|--|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1401-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| Marketing Information | | | | |
|-----------------------|--|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 | |

| PLANTAGO LANCEOLATA POLLEN | | | | |
|--------------------------------------|-----------------------------|--------------------|---------------|--|
| plantain english injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1402 | |
| Route of Administration | SUBCUTANEOUS | | | |

| Active Ingredient/Active Moiety | | | |
|--|--|----------------------------|-----------------|
| Ingredient Name | | Basis of Strength | Strength |
| PLANTAGO LANCEOLATA POLLEN (UNII: DO87T1U2CI) (PLANTAGO LANCEOLATA POLLEN - UNII:DO87T1U2CI) | | PLANTAGO LANCEOLATA POLLEN | 0.001 g in 1 mL |

| Inactive Ingredients | |
|---------------------------------------|-------------------|
| Ingredient Name | Strength |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |

HYDROCHLORIC ACID (UNII: QTT17582CB)

SODIUM HYDROXIDE (UNII: 55X04QC32I)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0268-1402-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

POPULUS ALBA POLLEN

poplar white injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1405 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------|----------------|
| POPULUS ALBA POLLEN (UNII: VU8C8SB23P) (POPULUS ALBA POLLEN - UNII:VU8C8SB23P) | POPULUS ALBA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1405-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

POPULUS ALBA POLLEN

poplar white injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1406 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|---------------------|----------------|
| POPULUS ALBA POLLEN (UNII: VU8C8SB23P) (POPULUS ALBA POLLEN - UNII:VU8C8SB23P) | POPULUS ALBA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1406-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1406-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

POPULUS ALBA POLLEN

poplar white injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1407 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------|---------------------|
| POPULUS ALBA POLLEN (UNII: VU8C8SB23P) (POPULUS ALBA POLLEN - UNII:VU8C8SB23P) | POPULUS ALBA POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1407-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

POPULUS ALBA POLLEN

poplar white injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1408 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of | Strength |
|-----------------|----------|----------|
|-----------------|----------|----------|

| Ingredient Name | | Strength | Strength | |
|--|--|--|----------------------|--------------------|
| POPULUS ALBA POLLEN (UNII: VU8C8SB23P) (POPULUS ALBA POLLEN - UNII:VU8C8SB23P) | | POPULUS ALBA POLLEN | 0.005 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1408-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 | |

| POPULUS ALBA POLLEN | | | |
|--|-----------------------------|---------------------|------------------|
| poplar white injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1409 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| POPULUS ALBA POLLEN (UNII: VU8C8SB23P) (POPULUS ALBA POLLEN - UNII:VU8C8SB23P) | | POPULUS ALBA POLLEN | 0.0005 g in 1 mL |
| Inactive Ingredients | | | |
| Ingredient Name | | Strength | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | |

SODIUM HYDROXIDE (UNII: 55X04QC32I)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1409-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

LIGUSTRUM VULGARE POLLEN

privet injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1412 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|----------------|
| LIGUSTRUM VULGARE POLLEN (UNII: Y3FRX92Z0E) (LIGUSTRUM VULGARE POLLEN - UNII:Y3FRX92Z0E) | LIGUSTRUM VULGARE POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1412-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

LIGUSTRUM VULGARE POLLEN

privet injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1413 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|----------------|
| LIGUSTRUM VULGARE POLLEN (UNII: Y3FRX92Z0E) (LIGUSTRUM VULGARE POLLEN - UNII:Y3FRX92Z0E) | LIGUSTRUM VULGARE POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1413-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1413-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

LIGUSTRUM VULGARE POLLEN

privet injection, solution

| Product Information | | | | |
|--|--|--|--------------------------|---------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | | Item Code (Source) | NDC:0268-1414 |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | | Basis of Strength | Strength |
| LIGUSTRUM VULGARE POLLEN (UNII: Y3FRX92Z0E) (LIGUSTRUM VULGARE POLLEN - UNII:Y3FRX92Z0E) | | | LIGUSTRUM VULGARE POLLEN | 10000 [PNU] in 1 mL |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| GLYCERIN (UNII: PDC6A3C00X) | | | 0.5 mL in 1 mL | |
| PHENOL (UNII: 339NCG44TV) | | | 0.004 mL in 1 mL | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | 0.009 g in 1 mL | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | 0.00275 g in 1 mL | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1414-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | | 01/01/1965 | 05/18/2023 |

| LIGUSTRUM VULGARE POLLEN | | | | |
|--|-----------------------------|--|--------------------------|-----------------|
| privet injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | | Item Code (Source) | NDC:0268-1415 |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | | Basis of Strength | Strength |
| LIGUSTRUM VULGARE POLLEN (UNII: Y3FRX92Z0E) (LIGUSTRUM VULGARE POLLEN - UNII:Y3FRX92Z0E) | | | LIGUSTRUM VULGARE POLLEN | 0.001 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0268-1415-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 08/01/2017 |

ELYMUS REPENS POLLEN

quack grass injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1418 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------|----------------|
| ELYMUS REPENS POLLEN (UNII: ON2T85TA2O) (ELYMUS REPENS POLLEN - UNII:ON2T85TA2O) | ELYMUS REPENS POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1418-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

ELYMUS REPENS POLLEN

quack grass injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1419 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|----------------------|----------------|
| ELYMUS REPENS POLLEN (UNII: ON2T85TA2O) (ELYMUS REPENS POLLEN - UNII:ON2T85TA2O) | ELYMUS REPENS POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1419-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ELYMUS REPENS POLLEN

quack grass injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1420 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|----------------------|---------------------|
| ELYMUS REPENS POLLEN (UNII: ON2T85TA2O) (ELYMUS REPENS POLLEN - UNII:ON2T85TA2O) | ELYMUS REPENS POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1420-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

AMBROSIA ACANTHICARPA POLLEN

ragweed false bur injection, solution

Product Information

| | | | |
|--------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1423 |
|--------------|-----------------------------|--------------------|---------------|

| | | | | |
|--|---|--|-----------------------------|---------------------------|
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| | Ingredient Name | Basis of Strength | Strength | |
| | AMBROSIA ACANTHICARPA POLLEN (UNII: U2AI3H2J5Y) (AMBROSIA ACANTHICARPA POLLEN - UNII:U2AI3H2J5Y) | AMBROSIA ACANTHICARPA POLLEN | 0.10 g in 1 mL | |
| Inactive Ingredients | | | | |
| | Ingredient Name | Strength | | |
| | PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL | | |
| | SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL | | |
| | SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL | | |
| | HYDROCHLORIC ACID (UNII: QTT17582CB) | | | |
| | SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1423-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 | |

| | | | |
|--|---|------------------------------|-----------------|
| AMBROSIA ACANTHICARPA POLLEN | | | |
| ragweed false bur injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1424 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| | Ingredient Name | Basis of Strength | Strength |
| | AMBROSIA ACANTHICARPA POLLEN (UNII: U2AI3H2J5Y) (AMBROSIA ACANTHICARPA POLLEN - UNII:U2AI3H2J5Y) | AMBROSIA ACANTHICARPA POLLEN | 0.05 g in 1 mL |
| Inactive Ingredients | | | |
| | Ingredient Name | Strength | |

| | |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C00X) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1424-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1424-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

AMBROSIA TENUIFOLIA POLLEN

ragweed slender injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1431 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------------|----------------|
| AMBROSIA TENUIFOLIA POLLEN (UNII: 57W5SO585B) (AMBROSIA TENUIFOLIA POLLEN - UNII:57W5SO585B) | AMBROSIA TENUIFOLIA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1431-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

| AMBROSIA TENUIFOLIA POLLEN | | | | |
|--|--|--|----------------------|--------------------|
| ragweed slender injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1432 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| AMBROSIA TENUIFOLIA POLLEN (UNII: 57W5SO585B) (AMBROSIA TENUIFOLIA POLLEN - UNII:57W5SO585B) | | AMBROSIA TENUIFOLIA POLLEN | 0.05 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| GLYCERIN (UNII: PDC6A3C00X) | | 0.5 mL in 1 mL | | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1432-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 | |

AMBROSIA BIDENTATA POLLEN

ragweed southern injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1435 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------------|----------------|
| AMBROSIA BIDENTATA POLLEN (UNII: M3S672G75O) (AMBROSIA BIDENTATA POLLEN - UNII:M3S672G75O) | AMBROSIA BIDENTATA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1435-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1435-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

AMBROSIA BIDENTATA POLLEN

ragweed southern injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1436 |
| Route of Administration | SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | | | |
|--|--|--|---------------------------|--------------------|
| Ingredient Name | | | Basis of Strength | Strength |
| AMBROSIA BIDENTATA POLLEN (UNII: M3S672G75O) (AMBROSIA BIDENTATA POLLEN - UNII:M3S672G75O) | | | AMBROSIA BIDENTATA POLLEN | 0.05 g in 1 mL |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | 0.5 mL in 1 mL | |
| PHENOL (UNII: 339NCG44TV) | | | 0.004 mL in 1 mL | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | 0.009 g in 1 mL | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | 0.00275 g in 1 mL | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1436-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1436-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | | 01/01/1965 | 11/30/2021 |

| AMBROSIA ARTEMISIIFOLIA POLLEN | | | |
|--|-----------------------------|--------------------------------|----------------|
| ragweed short injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1531 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| AMBROSIA ARTEMISIIFOLIA POLLEN (UNII: K20Y81ACO3) (AMBROSIA ARTEMISIIFOLIA POLLEN - UNII:K20Y81ACO3) | | AMBROSIA ARTEMISIIFOLIA POLLEN | 0.10 g in 1 mL |
| Inactive Ingredients | | | |
| Ingredient Name | | Strength | |

| | |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1531-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1531-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

AMBROSIA ARTEMISIIFOLIA POLLEN

ragweed short injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1532 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------------|----------------|
| AMBROSIA ARTEMISIIFOLIA POLLEN (UNII: K20Y81ACO3) (AMBROSIA ARTEMISIIFOLIA POLLEN - UNII:K20Y81ACO3) | AMBROSIA ARTEMISIIFOLIA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1532-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1532-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

AMBROSIA ARTEMISIIFOLIA POLLEN

ragweed short injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1533 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------------|---------------------|
| AMBROSIA ARTEMISIIFOLIA POLLEN (UNII: K20Y81ACO3) (AMBROSIA ARTEMISIIFOLIA POLLEN - UNII:K20Y81ACO3) | AMBROSIA ARTEMISIIFOLIA POLLEN | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1533-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

AMBROSIA ARTEMISIIFOLIA POLLEN

ragweed short injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1534 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------------------|------------------------|
| AMBROSIA ARTEMISIIFOLIA POLLEN (UNII: K20Y81ACO3) (AMBROSIA ARTEMISIIFOLIA POLLEN - UNII:K20Y81ACO3) | AMBROSIA ARTEMISIIFOLIA POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1534-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1534-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

AMBROSIA TRIFIDA POLLEN

ragweed tall giant injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1439 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------------|----------------|
| AMBROSIA TRIFIDA POLLEN (UNII: KU1V1898XX) (AMBROSIA TRIFIDA POLLEN - UNII:KU1V1898XX) | AMBROSIA TRIFIDA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1439-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

AMBROSIA TRIFIDA POLLEN

ragweed tall giant injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1440 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------------|----------------|
| AMBROSIA TRIFIDA POLLEN (UNII: KU1V1898XX) (AMBROSIA TRIFIDA POLLEN - UNII:KU1V1898XX) | AMBROSIA TRIFIDA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|------------------------------------|----------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |

| | |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1440-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1440-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

AMBROSIA TRIFIDA POLLEN

ragweed tall giant injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1441 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------------|---------------------|
| AMBROSIA TRIFIDA POLLEN (UNII: KU1V1898XX) (AMBROSIA TRIFIDA POLLEN - UNII:KU1V1898XX) | AMBROSIA TRIFIDA POLLEN | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1441-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

| AMBROSIA TRIFIDA POLLEN | | | | |
|--|--|--|----------------------|--------------------|
| ragweed tall giant injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1442 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| | Ingredient Name | Basis of Strength | Strength | |
| | AMBROSIA TRIFIDA POLLEN (UNII: KU1V1898XX) (AMBROSIA TRIFIDA POLLEN - UNII:KU1V1898XX) | AMBROSIA TRIFIDA POLLEN | 40000 [PNU] in 1 mL | |
| Inactive Ingredients | | | | |
| | Ingredient Name | Strength | | |
| | PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL | | |
| | SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL | | |
| | SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL | | |
| | HYDROCHLORIC ACID (UNII: QTT17582CB) | | | |
| | SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1442-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 | |

AMBROSIA PSILOSTACHYA POLLEN

ragweed western injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1445 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------------------|-------------------|
| AMBROSIA PSILOSTACHYA POLLEN (UNII: RX18M46K8L) (AMBROSIA PSILOSTACHYA POLLEN - UNII:RX18M46K8L) | AMBROSIA PSILOSTACHYA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1445-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

AMBROSIA PSILOSTACHYA POLLEN

ragweed western injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1446 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | | Basis of Strength | Strength | |
|--|--|--|----------------------|--------------------|
| AMBROSIA PSILOSTACHYA POLLEN (UNII: RX18M46K8L) (AMBROSIA PSILOSTACHYA POLLEN - UNII:RX18M46K8L) | | AMBROSIA PSILOSTACHYA POLLEN | 0.05 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| GLYCERIN (UNII: PDC6A3C00X) | | 0.5 mL in 1 mL | | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1446-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1446-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | | |

| SALSOLA KALI POLLEN | | | |
|--|-----------------------------|------------------------|-------------------|
| russian thistle injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1453 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| SALSOLA KALI POLLEN (UNII: 2MH135KC6G) (SALSOLA KALI POLLEN - UNII:2MH135KC6G) | | SALSOLA KALI POLLEN | 0.10 g in 1 mL |
| Inactive Ingredients | | | |
| Ingredient Name | | Strength | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | |

| | |
|--|-------------------|
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1453-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1453-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

SALSOLA KALI POLLEN

russian thistle injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1454 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------|----------------|
| SALSOLA KALI POLLEN (UNII: 2MH135KC6G) (SALSOLA KALI POLLEN - UNII:2MH135KC6G) | SALSOLA KALI POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1454-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1454-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

SALSOLA KALI POLLEN

russian thistle injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1455 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------|---------------------|
| SALSOLA KALI POLLEN (UNII: 2MH135KC6G) (SALSOLA KALI POLLEN - UNII:2MH135KC6G) | SALSOLA KALI POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1455-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1455-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
|-----------|---------------------------------|-----------------|---------------|
|-----------|---------------------------------|-----------------|---------------|

| Category | Citation | Date | Date |
|----------|-----------|------------|------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

SALSOLA KALI POLLEN

russian thistle injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1456 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------|---------------------|
| SALSOLA KALI POLLEN (UNII: 2MH135KC6G) (SALSOLA KALI POLLEN - UNII:2MH135KC6G) | SALSOLA KALI POLLEN | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1456-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

SALSOLA KALI POLLEN

russian thistle injection, solution

Product Information

| | | | |
|---------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1457 |
|---------------------|-----------------------------|---------------------------|---------------|

Route of Administration SUBCUTANEOUS

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------|-----------------|
| SALSOLA KALI POLLEN (UNII: 2MH135KC6G) (SALSOLA KALI POLLEN - UNII:2MH135KC6G) | SALSOLA KALI POLLEN | 0.001 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0268-1457-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

LOLIUM PERENNE SSP MULTIFLORUM POLLEN

rye grass italian injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1460 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------------|----------------|
| LOLIUM MULTIFLORUM POLLEN (UNII: VJ10WKK736) (LOLIUM MULTIFLORUM POLLEN - UNII:VJ10WKK736) | LOLIUM MULTIFLORUM POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C00X) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1460-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ARTEMISIA FRIGIDA POLLEN

sage prairie injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1467 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|----------------|
| ARTEMISIA FRIGIDA POLLEN (UNII: 5AN5LR8L3F) (ARTEMISIA FRIGIDA POLLEN - UNII:5AN5LR8L3F) | ARTEMISIA FRIGIDA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1467-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

| ARTEMISIA FRIGIDA POLLEN | | | |
|--|-----------------------------|--------------------|---------------|
| sage prairie injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1468 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | Basis of Strength | Strength | |
| ARTEMISIA FRIGIDA POLLEN (UNII: 5AN5LR8L3F) (ARTEMISIA FRIGIDA POLLEN - UNII:5AN5LR8L3F) | ARTEMISIA FRIGIDA POLLEN | 0.05 g in 1 mL | |
| Inactive Ingredients | | | |
| Ingredient Name | Strength | | |
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL | | |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | |

| Packaging | | | | |
|-----------|------------------|--|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1468-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1468-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|---------------------------------|-----------------|---------------|
| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
| | | | |

| Category | Citation | Date | Date |
|----------|-----------|------------|------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

ARTEMISIA TRIDENTATA POLLEN

sagebrush common injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1471 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------------|-------------------|
| ARTEMISIA TRIDENTATA POLLEN (UNII: YI19RB8YFD) (ARTEMISIA TRIDENTATA POLLEN - UNII:YI19RB8YFD) | ARTEMISIA TRIDENTATA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1471-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1471-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

ARTEMISIA TRIDENTATA POLLEN

sagebrush common injection, solution

Product Information

| | | | |
|---------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1472 |
|---------------------|-----------------------------|---------------------------|---------------|

| | | | | |
|--|--|--|-----------------------------|---------------------------|
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| | Ingredient Name | Basis of Strength | Strength | |
| | ARTEMISIA TRIDENTATA POLLEN (UNII: YI19RB8YFD) (ARTEMISIA TRIDENTATA POLLEN - UNII:YI19RB8YFD) | ARTEMISIA TRIDENTATA POLLEN | 0.05 g in 1 mL | |
| Inactive Ingredients | | | | |
| | Ingredient Name | Strength | | |
| | GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL | | |
| | PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL | | |
| | SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL | | |
| | SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL | | |
| | HYDROCHLORIC ACID (UNII: QTT17582CB) | | | |
| | SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1472-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1472-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | | |

| | | | |
|--|--|-----------------------------|---------------------|
| ARTEMISIA TRIDENTATA POLLEN | | | |
| sagebrush common injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1473 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| | Ingredient Name | Basis of Strength | Strength |
| | ARTEMISIA TRIDENTATA POLLEN (UNII: YI19RB8YFD) (ARTEMISIA TRIDENTATA POLLEN - UNII:YI19RB8YFD) | ARTEMISIA TRIDENTATA POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1473-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

DISTICHLIS SPICATA POLLEN

salt grass injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1476 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------------|----------------|
| DISTICHLIS SPICATA POLLEN (UNII: GOA51670YV) (DISTICHLIS SPICATA POLLEN - UNII:GOA51670YV) | DISTICHLIS SPICATA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1476-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1476-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

DISTICHLIS SPICATA POLLEN

salt grass injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1477 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|---------------------------|----------------|
| DISTICHLIS SPICATA POLLEN (UNII: GOA51670YV) (DISTICHLIS SPICATA POLLEN - UNII:GOA51670YV) | DISTICHLIS SPICATA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1477-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1477-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ATRIPLEX WRIGHTII POLLEN

saltbush annual atriplex injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1480 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|----------------|
| ATRIPLEX WRIGHTII POLLEN (UNII: YB1308W43O) (ATRIPLEX WRIGHTII POLLEN - UNII:YB1308W43O) | ATRIPLEX WRIGHTII POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1480-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1480-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ATRIPLEX WRIGHTII POLLEN

saltbush annual atriplex injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1481 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------------|
| ATRIPLEX WRIGHTII POLLEN (UNII: YB1308W43O) (ATRIPLEX WRIGHTII POLLEN - UNII:YB1308W43O) | ATRIPLEX WRIGHTII POLLEN | 0.025 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C00X) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|--|-----------------------------|---------------------------|
| 1 | NDC:0268-1481-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

LIQUIDAMBAR STYRACIFLUA POLLEN

sweetgum injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1493 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------------|-----------------|
| LIQUIDAMBAR STYRACIFLUA POLLEN (UNII: 5Q246DS5BS) (LIQUIDAMBAR STYRACIFLUA POLLEN - UNII:5Q246DS5BS) | LIQUIDAMBAR STYRACIFLUA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1493-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

LIQUIDAMBAR STYRACIFLUA POLLEN

sweetgum injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1494 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------------|----------------|
| LIQUIDAMBAR STYRACIFLUA POLLEN (UNII: 5Q246DS5BS) (LIQUIDAMBAR STYRACIFLUA POLLEN - UNII:5Q246DS5BS) | LIQUIDAMBAR STYRACIFLUA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1494-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1494-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

LIQUIDAMBAR STYRACIFLUA POLLEN

sweetgum injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1495 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------------|-----------------|
| LIQUIDAMBAR STYRACIFLUA POLLEN (UNII: 5Q246DS5BS) (LIQUIDAMBAR STYRACIFLUA POLLEN - UNII:5Q246DS5BS) | LIQUIDAMBAR STYRACIFLUA POLLEN | 0.005 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1495-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
|-----------|---------------------------------|-----------------|---------------|
|-----------|---------------------------------|-----------------|---------------|

| Category | Citation | Date | Date |
|----------|-----------|------------|------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

LIQUIDAMBAR STYRACIFLUA POLLEN

sweetgum injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1496 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------------|------------------|
| LIQUIDAMBAR STYRACIFLUA POLLEN (UNII: 5Q246DS5BS) (LIQUIDAMBAR STYRACIFLUA POLLEN - UNII:5Q246DS5BS) | LIQUIDAMBAR STYRACIFLUA POLLEN | 0.0005 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1496-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

LIQUIDAMBAR STYRACIFLUA POLLEN

sweetgum injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1497 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------------|---------------------|
| LIQUIDAMBAR STYRACIFLUA POLLEN (UNII: 5Q246DS5BS) (LIQUIDAMBAR STYRACIFLUA POLLEN - UNII:5Q246DS5BS) | LIQUIDAMBAR STYRACIFLUA POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1497-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

LIQUIDAMBAR STYRACIFLUA POLLEN

sweetgum injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1498 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------------|-------------------|
| LIQUIDAMBAR STYRACIFLUA POLLEN (UNII: 5Q246DS5BS) (LIQUIDAMBAR STYRACIFLUA POLLEN - UNII:5Q246DS5BS) | LIQUIDAMBAR STYRACIFLUA POLLEN | 500 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------|------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |

| | |
|--|-------------------|
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0268-1498-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

PLATANUS OCCIDENTALIS POLLEN

sycamore american injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1501 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|------------------------------|----------------|
| PLATANUS OCCIDENTALIS POLLEN (UNII: E03U1K03LK) (PLATANUS OCCIDENTALIS POLLEN - UNII:E03U1K03LK) | PLATANUS OCCIDENTALIS POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1501-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| | NDC:0268-1501-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a | | |

| 2 | NDC:0268-1501-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
|-----------------------|--|--|--------------------|--|
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | | |

PLATANUS OCCIDENTALIS POLLEN

sycamore american injection, solution

| Product Information | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1502 |
| Route of Administration | SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | |
|--|------------------------------|----------------|
| Ingredient Name | Basis of Strength | Strength |
| PLATANUS OCCIDENTALIS POLLEN (UNII: E03U1K03LK) (PLATANUS OCCIDENTALIS POLLEN - UNII:E03U1K03LK) | PLATANUS OCCIDENTALIS POLLEN | 0.05 g in 1 mL |

| Inactive Ingredients | |
|---------------------------------------|-------------------|
| Ingredient Name | Strength |
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

| Packaging | | | | |
|-----------|------------------|--|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1502-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1502-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103753 | 01/01/1965 | |

PLATANUS OCCIDENTALIS POLLEN

sycamore american injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1503 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|------------------------------|---------------------|
| PLATANUS OCCIDENTALIS POLLEN (UNII: E03U1K03LK) (PLATANUS OCCIDENTALIS POLLEN - UNII:E03U1K03LK) | PLATANUS OCCIDENTALIS POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1503-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

PLATANUS OCCIDENTALIS POLLEN

sycamore american injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1504 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | | Basis of Strength | Strength | |
|--|--|--|----------------------|--------------------|
| PLATANUS OCCIDENTALIS POLLEN (UNII: E03U1K03LK) (PLATANUS OCCIDENTALIS POLLEN - UNII:E03U1K03LK) | | PLATANUS OCCIDENTALIS POLLEN | 10000 [PNU] in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1504-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 | |

| PLATANUS OCCIDENTALIS POLLEN | | | |
|--|-----------------------------|------------------------------|-----------------|
| sycamore american injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1505 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| PLATANUS OCCIDENTALIS POLLEN (UNII: E03U1K03LK) (PLATANUS OCCIDENTALIS POLLEN - UNII:E03U1K03LK) | | PLATANUS OCCIDENTALIS POLLEN | 0.001 g in 1 mL |
| Inactive Ingredients | | | |
| Ingredient Name | | Strength | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0268-1505-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

HOLCUS LANATUS POLLEN

velvet grass injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1510 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-----------------------|----------------|
| HOLCUS LANATUS POLLEN (UNII: 7001TP6H01) (HOLCUS LANATUS POLLEN - UNII:7001TP6H01) | HOLCUS LANATUS POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1510-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1510-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

HOLCUS LANATUS POLLEN

velvet grass injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1511 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------|----------------|
| HOLCUS LANATUS POLLEN (UNII: 70O1TP6H01) (HOLCUS LANATUS POLLEN - UNII:70O1TP6H01) | HOLCUS LANATUS POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1511-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

JUGLANS NIGRA POLLEN

walnut black pollen injection, solution

| Product Information | | | | |
|--|--|--|----------------------|--------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1512 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | Basis of Strength | Strength | | |
| JUGLANS NIGRA POLLEN (UNII: 1BV28146ZR) (JUGLANS NIGRA POLLEN - UNII:1BV28146ZR) | JUGLANS NIGRA POLLEN | 0.10 g in 1 mL | | |
| Inactive Ingredients | | | | |
| Ingredient Name | Strength | | | |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL | | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1512-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1512-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | | |

| JUGLANS NIGRA POLLEN | | | |
|---|-----------------------------|--------------------|---------------|
| walnut black pollen injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1513 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | Basis of Strength | Strength | |

| | | |
|---|----------------------|----------------|
| JUGLANS NIGRA POLLEN (UNII: 1BV28146ZR) (JUGLANS NIGRA POLLEN - UNII:1BV28146ZR) | JUGLANS NIGRA POLLEN | 0.05 g in 1 mL |
|---|----------------------|----------------|

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1513-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1513-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

JUGLANS NIGRA POLLEN

walnut black pollen injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1514 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------|---------------------|
| JUGLANS NIGRA POLLEN (UNII: 1BV28146ZR) (JUGLANS NIGRA POLLEN - UNII:1BV28146ZR) | JUGLANS NIGRA POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |

| | |
|--|-------------------|
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1514-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1514-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

JUGLANS NIGRA POLLEN

walnut california black pollen injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1515 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------|----------------|
| JUGLANS NIGRA POLLEN (UNII: 1BV28146ZR) (JUGLANS NIGRA POLLEN - UNII:1BV28146ZR) | JUGLANS NIGRA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

| | | | | |
|----------|------------------|--|--|--|
| 1 | NDC:0268-1515-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
|----------|------------------|--|--|--|

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

JUGLANS REGIA POLLEN

walnut english pollen injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1516 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------|----------------|
| JUGLANS REGIA POLLEN (UNII: ARW4308711) (JUGLANS REGIA POLLEN - UNII:ARW4308711) | JUGLANS REGIA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1516-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

JUGLANS REGIA POLLEN

walnut english pollen injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1517 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------|----------------|
| JUGLANS REGIA POLLEN (UNII: ARW43087I1) (JUGLANS REGIA POLLEN - UNII:ARW43087I1) | JUGLANS REGIA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1517-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1517-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

AMARANTHUS TUBERCULATUS POLLEN

water hemp injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1518 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------------|-------------------|
| AMARANTHUS TUBERCULATUS POLLEN (UNII: 92N6W6KO2G) (AMARANTHUS TUBERCULATUS POLLEN - UNII:92N6W6KO2G) | AMARANTHUS TUBERCULATUS POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1518-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1518-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

AMARANTHUS TUBERCULATUS POLLEN

water hemp injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1519 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------------|--------------------|
| AMARANTHUS TUBERCULATUS POLLEN (UNII: 92N6W6KO2G) (AMARANTHUS TUBERCULATUS POLLEN - UNII:92N6W6KO2G) | AMARANTHUS TUBERCULATUS POLLEN | 0.025 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------------------|----------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |

| | |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1519-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1519-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

AMARANTHUS TUBERCULATUS POLLEN

water hemp injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1520 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------------|---------------------|
| AMARANTHUS TUBERCULATUS POLLEN (UNII: 92N6W6KO2G) (AMARANTHUS TUBERCULATUS POLLEN - UNII:92N6W6KO2G) | AMARANTHUS TUBERCULATUS POLLEN | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start | Marketing End |
|---|-----------|---------------------|-----------------|---------------|
|---|-----------|---------------------|-----------------|---------------|

| # | Item Code | Package Description | Date | Date |
|---|------------------|--|------|------|
| 1 | NDC:0268-1520-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1520-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

AMARANTHUS TUBERCULATUS POLLEN

water hemp injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1521 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------------|---------------------|
| AMARANTHUS TUBERCULATUS POLLEN (UNII: 92N6W6KO2G) (AMARANTHUS TUBERCULATUS POLLEN - UNII:92N6W6KO2G) | AMARANTHUS TUBERCULATUS POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1521-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

TRITICUM AESTIVUM POLLEN

wheat pollen injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1522 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|----------------|
| TRITICUM AESTIVUM POLLEN (UNII: F1KAH8374D) (TRITICUM AESTIVUM POLLEN - UNII:F1KAH8374D) | TRITICUM AESTIVUM POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1522-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1522-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

TRITICUM AESTIVUM POLLEN

wheat pollen injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1523 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|----------------|
| TRITICUM AESTIVUM POLLEN (UNII: F1KAH8374D) (TRITICUM AESTIVUM POLLEN - UNII:F1KAH8374D) | TRITICUM AESTIVUM POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1523-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1523-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

SALIX NIGRA POLLEN

willow black injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1524 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------|----------------|
| SALIX NIGRA POLLEN (UNII: 6M2JIH93ZN) (SALIX NIGRA POLLEN - UNII:6M2JIH93ZN) | SALIX NIGRA POLLEN | 0.10 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1524-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1524-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

SALIX NIGRA POLLEN

willow black injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1525 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------|----------------|
| SALIX NIGRA POLLEN (UNII: 6M2JIH93ZN) (SALIX NIGRA POLLEN - UNII:6M2JIH93ZN) | SALIX NIGRA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1525-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1525-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

SALIX NIGRA POLLEN

willow black injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1526 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------|----------------|
| SALIX NIGRA POLLEN (UNII: 6M2JIH93ZN) (SALIX NIGRA POLLEN - UNII:6M2JIH93ZN) | SALIX NIGRA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1526-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1526-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

SALIX NIGRA POLLEN

willow black injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1527 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------|---------------------|
| SALIX NIGRA POLLEN (UNII: 6M2JIH93ZN) (SALIX NIGRA POLLEN - UNII:6M2JIH93ZN) | SALIX NIGRA POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1527-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

SALIX NIGRA POLLEN

willow black injection, solution

Product Information

| | | | | |
|--|---|---|-----------------------------|---------------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1528 | |
| Route of Administration | SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| SALIX NIGRA POLLEN (UNII: 6M2JIH93ZN) (SALIX NIGRA POLLEN - UNII:6M2JIH93ZN) | | SALIX NIGRA POLLEN | 0.001 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1528-05 | 5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 | |

| | | | |
|--|-----------------------------|---------------------------|---------------------|
| SALIX NIGRA POLLEN | | | |
| willow black injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1529 |
| Route of Administration | SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| SALIX NIGRA POLLEN (UNII: 6M2JIH93ZN) (SALIX NIGRA POLLEN - UNII:6M2JIH93ZN) | | SALIX NIGRA POLLEN | 10000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1529-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ARTEMISIA ANNUA POLLEN

wormwood common annual injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1530 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------|----------------|
| SALIX NIGRA POLLEN (UNII: 6M2JIH93ZN) (SALIX NIGRA POLLEN - UNII:6M2JIH93ZN) | SALIX NIGRA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1530-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1530-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 |

EQUUS CABALLUS SKIN

horse epithelia injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1601 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------|----------------|
| EQUUS CABALLUS SKIN (UNII: 88VZV9HGT4) (EQUUS CABALLUS SKIN - UNII:88VZV9HGT4) | EQUUS CABALLUS SKIN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1601-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

RABBIT

rabbit injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-0652 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------------|
| RABBIT (UNII: O5V0F26RUW) (RABBIT - UNII:O5V0F26RUW) | RABBIT | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-0652-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

JUNIPERUS ASHEI POLLEN

cedar mountain injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1602 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|------------------------|----------------|
| JUNIPERUS ASHEI POLLEN (UNII: 544F8MEY0Y) (JUNIPERUS ASHEI POLLEN - UNII:544F8MEY0Y) | JUNIPERUS ASHEI POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1602-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

JUNIPERUS VIRGINIANA POLLEN

cedar red injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1603 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------------|----------------|
| JUNIPERUS VIRGINIANA POLLEN (UNII: PY0JA16R2G) (JUNIPERUS VIRGINIANA POLLEN - UNII:PY0JA16R2G) | JUNIPERUS VIRGINIANA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------|------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |

| | |
|--|-------------------|
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1603-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:0268-1603-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | |

JUNIPERUS VIRGINIANA POLLEN

cedar red injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1604 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------------|----------------|
| JUNIPERUS VIRGINIANA POLLEN (UNII: PY0JA16R2G) (JUNIPERUS VIRGINIANA POLLEN - UNII:PY0JA16R2G) | JUNIPERUS VIRGINIANA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

| | | | | |
|----------|------------------|--|--|--|
| 1 | NDC:0268-1604-50 | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
|----------|------------------|--|--|--|

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 02/27/2020 |

POPULUS DELTOIDES POLLEN

cottonwood eastern common injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1605 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|----------------|
| POPULUS DELTOIDES POLLEN (UNII: 476DVV63WP) (POPULUS DELTOIDES POLLEN - UNII:476DVV63WP) | POPULUS DELTOIDES POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|--|----------------------|--------------------|
| 1 | NDC:0268-1605-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

RUMEX ACETOSELLA POLLEN

dock sour sheep sorrel injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1606 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|---------------------|
| RUMEX ACETOSELLA POLLEN (UNII: N52MIQ81ZW) (RUMEX ACETOSELLA POLLEN - UNII:N52MIQ81ZW) | RUMEX ACETOSELLA POLLEN | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 1 mL |
| PHENOL (UNII: 339NCG44TV) | 0.004 mL in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.009 g in 1 mL |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | 0.00275 g in 1 mL |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|-----------------------------|---------------------------|
| 1 | NDC:0268-1606-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| BLA | BLA103753 | 01/01/1965 | 05/18/2023 |

ULMUS AMERICANA POLLEN

elm american injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|---------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:0268-1173 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

Basis of

| Ingredient Name | | Basis of Strength | Strength | |
|--|--|--|----------------------|--------------------|
| ULMUS AMERICANA POLLEN (UNII: 89BAT511BD) (ULMUS AMERICANA POLLEN - UNII:89BAT511BD) | | ULMUS AMERICANA POLLEN | 20000 [PNU] in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| GLYCERIN (UNII: PDC6A3C00X) | | 0.5 mL in 1 mL | | |
| PHENOL (UNII: 339NCG44TV) | | 0.004 mL in 1 mL | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | 0.009 g in 1 mL | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | 0.00275 g in 1 mL | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0268-1173-10 | 10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103753 | 01/01/1965 | 11/30/2021 | |

Labeler - ALK-Abello, Inc. (809998847)

Revised: 5/2023

ALK-Abello, Inc.