MUCOR PLUMBEUS- mucor plumbeus liquid
OAK, CALIFORNIA MIX- quercus agrifolia/quercus kelloggii liquid
PINE MIX- pinus echinata/pinus ponderosa/pinus strobus liquid
RHIZOPUS NIGRICANS- rhizopus nigricans liquid
SMUT, BERMUDA GRASS- ustilago cynodontis injection
SMUT, WHEAT- ustilago tritici liquid
CLADOSPORIUM CLADOSPORIOIDES- cladosporium cladosporioides liquid
MAPLE, CALIFORNIA MIX- acer macrophyllum/acer negundo liquid
SACCHAROMYCES CEREVISIAE- saccharomyces cerevisiae liquid
TRICHOPHYTON RUBRUM- trichophyton rubrum liquid
SMUT, OAT- ustilago avenae liquid
ALDER MIX- alnus rhombifolia/alnus rubra/alnus rugosa liquid
ASPERGILLUS NIDULANS- aspergillus nidulans liquid
STEMPHYLIUM SOLANI- stemphylium solani liquid
TRICHOPHYTON MENTAGROPHYTES- trichophyton mentagrophytes liquid
TRICHOPHYTON MIX- trichophyton mentagrophytes/trichophyton rubrum liquid
ASPERGILLUS NIGER- aspergillus niger injection
SMUT, BARLEY- ustilago nuda liquid
Allermed Laboratories, Inc.

WARNINGS
This allergenic 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.
This allergenic extract is not directly interchangeable with other allergenic extracts. The initial dose must be based on skin testing as described in the dosage and administration section of this insert. Patients being switched from other types of extracts, such as alum precipitated extracts, should be started as though they were coming under treatment for the first time. 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 be life threatening. Patients should be observed for at least 20 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.
This product should not be injected intravenously (see Dosage and Administration). Refer also to the Warnings, Precautions, Adverse Reactions and Overdosage sections below.
Serious adverse reactions to this product should be reported to MEDWATCH, Food and Drug Administration, at 1-800-FDA-1088 or www.fda.gov/medwatch

Allergenic extract contains the aqueous extractables from allergenic source material in extracting solution containing 0.25% sodium chloride, 0.125% sodium bicarbonate, and 50% glycerol. 0.4% phenol is added as a preservative. The weight by volume value shown on the label is a measurement of extract concentration, rather than extract potency.

Positive skin tests with allergenic extract are the result of histamine release from mast cells sensitized with allergen specific IgE. The exact mechanisms by which immunotherapy relieves symptoms of allergy are still under investigation. Elevations in allergen-specific IgG antibodies and an increase in the activity of T suppressor lymphocytes appear to be some of the immunologic changes that occur from hyposensitization. [1,2,3]

Allergenic extract may be used as a diagnostic skin test reagent in persons suspected of being sensitive to the allergenic source material from which the extract is made. Skin tests should be used in

conjunction with a thorough allergic history to establish the relevance of a given allergen in the etiology of allergic disease. [4,5,6]
Immunotherapy with allergenic extract is indicated in persons suffering from allergic rhinitis, bronchitis, conjunctivitis, urticaria and asthma. The therapeutic efficacy of allergenic extract has been proven in ragweed, grass, and mountain cedar pollinosis, cat-induced asthma and hypersensitivity to hymenoptera venoms. [7-12]
Immunotherapy may be used along with or exclusive of antihistamines and other medications used to control allergic symptoms.

Allergenic extract should not be administered to a non-allergic person. However, there are no absolute contraindications to the use of allergenic extract for treatment in appropriate individuals. Relative contraindications include: EXTREME SENSITIVITY TO AN ALLERGEN - Determined from the allergic history, or from previous anaphylaxis following skin testing or subcutaneous injection; AUTOIMMUNE DISEASE - Individuals with autoimmune disease may be at risk, due to the possibility of routine immunizations exacerbating symptoms of the underlying disease; PREGNANCY - In limited controlled studies of women receiving allergenic extract during conception and throughout all trimesters of pregnancy, no evidence was found that extract is harmful to the fetus or mother. However, because of the known pharmacologic action of histamine on uterine muscle, any treatment that might result in the release of significant amounts of this mediator should be avoided if possible [13]. See Precaution #4; MYOCARDIAL INFARCTION - Patients who have experienced a recent myocardial infarction may not be able to tolerate immunotherapy. As in all of the above circumstances, the benefit to risk ratio must be carefully evaluated; BLEEDING DIATHESIS - Patients with a bleeding tendency should not be tested or treated with allergenic extract, unless the physician responsible believes that such procedures are safe to perform.
Allergenic extract should be temporarily withheld from patients if any of the following conditions exist: (1) severe symptoms of hay fever and/or asthma; (2) infection or flu accompanied by fever; and (3) exposure to excessive amounts of clinically relevant allergens prior to skin testing or immunotherapy.

The only approved method for determining hypersensitivity to Allermed Laboratories Allergenic Extracts is by diagnostic skin testing (See DOSAGE AND ADMINISTRATION — DIAGNOSIS). Physicians who administer allergenic extract should have emergency medication and equipment available to treat anaphylaxis [14]. See Precautions, Adverse Reactions and Overdosage below.
To reduce the risk of anaphylaxis, the following measures must be observed:

1. Concentrated extract must be diluted before use for intradermal skin testing and for beginning immunotherapy. It should never be injected intravenously during testing or treatment procedures.
2. Patients who are highly sensitive, determined from clinical findings and test results, may require that treatment start with a very weak concentration of extract, such as 1:10,000,000 v/v.
3. The dosage of fresh (new) extract given to a patient receiving maintenance injections must be reduced to one-fourth the amount given from the previous (old) lot (See Immunotherapy, last paragraph).
4. Patients who are transferred to standardized extract after previous treatment with unstandardized extract must be skin tested with serial dilutions, starting with a 1:100,000 v/v dilution of the standardized extract, to determine a safe, non-reacting starting dose.
5. Patients who are transferred to this extract after treatment with alum precipitated or other modified extract must re-start injections with the beginning recommended dose of this extract.

1. Extract should be stored at 2°C to 8°C since higher temperatures may adversely affect the stability of the product. Do not freeze.
2. After the needle is inserted subcutaneously, the plunger should be withdrawn slightly to check for the presence of blood in the syringe. If blood is observed, a new injection should be prepared and given at another site, observing the same precautions.
3. Treatment with beta-blocking drugs may make patients refractory to the usual dose of epinephrine, in the event epinephrine is required to control an adverse allergic reaction.
4. PREGNANCY CATEGORY C. Allergenic extract. Animal reproduction studies have not been

conducted with allergenic extract. It is also not known whether allergenic extract can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Allergenic extract should be given to a pregnant woman only if clearly needed.

5. PATIENT INSTRUCTIONS: Patients should be instructed to remain in the physician's office for at least 20 minutes after skin testing and after each treatment injection, and immediately notify the physician if symptoms of a generalized reaction or shock occur.
6. CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY: Long term studies have not been conducted with allergenic extracts to determine their potential for carcinogenesis, mutagenesis, and impairment of fertility.
7. NURSING MOTHERS: Data are not available on the secretion of allergenic extract in human milk and it is not known what affect this might have on the nursing infant.
8. PEDIATRIC USE: The dose of allergenic extract recommended for children is the same as that used for adults, except in the injection of large doses of extract for treatment. In this case, the amount of extract given to a child may be modified so that the discomfort of the injection is minimized.

Local Reactions: The occurrence of a hive 5 to 15 minutes after the subcutaneous injection of extract does not require a reduction in dosage. However, a local reaction with edema larger than 2 cm in diameter or swelling and redness that persist for several hours or longer indicates that too much extract has been given. Treatment should be altered as follows:

1. Additional injections should not be given until all evidence of the reaction has disappeared.
2. The next injection administered should be 50% of the last non-reacting dose or less, depending upon the size and severity of the local reaction.
3. Subsequent injections should be continued at the reduced dosage unless the physician responsible for treatment believes that it is safe to increase the dose, and that possible clinical improvement would result from the administration of a larger dose of extract.

Systemic Reactions: Systemic (generalized) reactions may range from a mild exacerbation of the patient's allergic symptoms to hives, anaphylactic shock, or even death from anaphylaxis. The reaction usually occurs 5 to 20 minutes after injection. As a rule, the more quickly a reaction develops, the more serious it is likely to become. Symptoms may include sneezing, coughing, itching, shortness of breath, abdominal cramps, vomiting, diarrhea, tachycardia, hypotension and respiratory failure in severe cases. The reaction is usually stopped by the subcutaneous injection of Epinephrine HCL 1:1,000 (See Overdosage below). The oral administration of antihistamines and the placement of a tourniquet proximal to the injection site are helpful adjuncts. In the event that additional measures are required, it may be necessary to treat the patient for BRONCHOSPASM with intravenous aminophylline, intravenous fluids and corticosteroids; for HYPOTENSION with vasopressors, volume repletion, isoproterenol and corticosteroids; for LARYNGEAL OBSTRUCTION with oxygen and tracheostomy; and for CARDIAC ARREST with cardiopulmonary resuscitation and other appropriate measures. Immunotherapy after anaphylaxis should only be continued if the cause of the reaction can be identified and appropriate precautions taken to insure that a subsequent reaction does not occur.

A strong local reaction to the injection of extract may be treated with oral antihistamines and the local application of a cold compress. The dosage must be reduced and additional extract must not be given until all evidence of the reaction has disappeared.

A systemic reaction following the injection of extract must be treated immediately as follows (Ref. #4, vol. 2, p. 888):

1. 0.01 mL/kg up to 0.2 mL of aqueous epinephrine HCL 1:1000 subcutaneously at the injection site of antigen.
2. 0.01 mL/kg up to 0.3 mL of aqueous epinephrine HCL 1:1000 subcutaneously at another site.
3. Diphenhydramine intravenously or intramuscularly, 1.25 mg/kg up to 50 mg.
4. Tourniquet above the injection site of antigen.
5. Specific reactions:

a. Brochospasm: intravenous aminophylline 4 mg/kg up to 500 mg given over 10 to 15 minutes, aqueous hydrocortisone 5 mg/kg up to 200 mg, oxygen.

b. Laryngeal edema: oxygen, intubation, tracheostomy.

c. Hypotension: vasopressors, fluids, corticosteroids.

d. Cardiac arrest: resuscitation, sodium bicarbonate, defibrillation, antiarrhythmia medications.

Diagnosis: Concentrated extract may be used for scratch or prick testing. Provided that the patient is not extremely sensitive, concentrated extract may be used for scratch or prick testing. In the case of extreme sensitivity, the extract should be diluted 10 fold before a scratch or prick test is performed. Extract for intradermal testing must be used as follows:
a. Patients with positive scratch or prick tests: It is not advisable to perform an intradermal skin test if the patient has a positive scratch or prick test.
b. Patients with a negative scratch or prick test: Patients who do not react who do not react to a valid scratch or prick test should be tested intradermally with 0.05 mL of a 1:1000 v/v dilution of the concentrate. If the test is negative, a second test should be performed with 0.05 mL of a 1:100 v/v dilution or concentrate.
c. Patients tested only by the intradermal method: Patients suspected of being highly allergic should be tested with 0.05 mL of a 1:100,000 v/v dilution of the concentrate. A negative test should be followed by repeat tests using 10 fold stronger concentrations until the maximum dose of 0.05 mL of a 1:100 v/v dilution is reached.

Interpretation of Results
Scratch and Prick Test
A negative test shows only a slight red area at the site of scarification or prick penetration. Positive tests are scored as follows:
1+ Erythema with 5 mm wheal
2+ Erythema with a 5-10 mm wheal
3+ Erythema with a 10-15 mm wheal
4+ Erythema with a wheal 15 mm (or larger) with pseudopodia

Intradermal Test
A negative test shows no change in the appearance and size of the 5 mm wheal created by the I.D. injection of 0.05 mL of extract. Positive tests are scored as follows:
1+ Erythema 10-20 mm with a 5-10 mm wheal
2+ Erythema 20-30 mm with a 5-10 mm wheal
3+ Erythema 30-40 mm with a 10-15 mm wheal
4+ Erythema greater than 40 mm with a 15 mm wheal (or larger) with pseudopodia

Immunotherapy
Allergenic extract should be administered subcutaneously in the outer aspect of the upper arm using a sterile tuberculin syringe and needle. The skin should be cleaned with 70% alcohol and aseptic technique should be observed in removing the extract from the vial. Care must be taken to avoid injecting the extract into a blood vessel because of the risk of anaphylaxis.
Concentrated extract must be diluted before administration to new patients. A 1:100,000 v/v dilution of concentrate is usually satisfactory to start treatment. However, as a precaution against overdose, a skin test with the intended starting dose should be done to help evaluate the patient's sensitivity to the product. If the skin response is larger than 5 mm edema/15 mm erythema, the extract is too strong and must be diluted before it is given subcutaneously. The doses shown in the Suggested Dosage Schedule below are recommended unless the patient's skin test response and allergic history indicates that more dilute extract should be used.
Little is known about the required accumulated dosage of allergen that is needed to relieve symptoms.

However, studies have shown that high dose immunotherapy is efficacious in the treatment of allergic rhinitis and asthma. For this reason, treatment with extract from Vial #5 is recommended, providing the patient can tolerate the extract without experiencing local or systemic reactions. Treatment with Vial #6 may be used for patients who have not had adverse reactions to extract in Vial #5 and who require more concentrated extract to control or relieve symptoms.
Patients who have received allergenic extract for maintenance therapy SHOULD NOT be given the same dose from a fresh vial of extract. IT IS ADVISABLE TO REDUCE THE DOSAGE OF FRESH EXTRACT TO ONE-FOURTH THE AMOUNT GIVEN FROM A PREVIOUS LOT OF EXTRACT MADE AT THE SAME CONCENTRATION AND BY THE SAME FORMULA.

Suggested Dosage Schedule

No.	Vial #1 1:100,000 w/v frequency twice weekly mL	Vial #2 1:10,000 w/v frequency twice weekly mL	Vial #3 1:1,000 w/v frequency once weekly mL	Vial #4 1:100 w/v frequency once weekly mL	Vial #5 1:10 w/v frequency every two-four weeks mL	Vial #6 Concentrate frequency every two-four weeks mL
1	0.025	0.025	0.025	0.025	0.025	0.025
2	0.05	0.05	0.05	0.05	0.05	0.05
3	0.10	0.10	0.10	0.10	0.10	0.10
4	0.15	0.15	0.15	0.15	0.15	0.15
5	0.20	0.20	0.20	0.20	0.20	0.20
6	0.25	0.25	0.25	0.25	0.25	0.25
7	0.30	0.30	0.30	0.30	0.30	0.30

Allergenic extract is supplied in 5 mL dropper vials for scratch or prick testing and in 10, 30, and 50 mL vials for bulk use.

Storage and Handling

Extract should be stored at 2-8°C since higher temperatures may adversely affect stability. Do not freeze.

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4. Middleton, Elliott, Jr., C.E. Reed and E.F. Ellis (Eds.) Allergy, Principles and Practice Vols. 1&2, C.V. Mosby 1978.
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6. Nelson, H.S. Diagnostic procedures in allergy. I. Allergy skin testing. Ann. Allergy. 51:411, 1983.
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8. Milner, F.H. and E.C. Tees. Specific sensitivity to individual grass pollens in some hay fever patients. Clinical Allergy. 2:83, 1972.
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MUCOR PLUMBEUS

mucor plumbeus liquid

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:49643-166
Route of Administration	SUBCUTANEOUS, PERCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MUCOR PLUMBEUS (UNII: D7401PWY6E) (MUCOR PLUMBEUS - UNII:D7401PWY6E)	MUCOR PLUMBEUS	0.1 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.0025 g in 1 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.5 g in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.00125 g in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49643-166-05	5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
2	NDC:49643-166-10	10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
3	NDC:49643-166-30	30 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
4	NDC:49643-166-50	50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102211	03/12/1974	

OAK, CALIFORNIA MIX

quercus agrifolia/quercus kelloggii liquid

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:49643-264
Route of Administration	PERCUTANEOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
QUERCUS AGRIFOLIA POLLEN (UNII: VOT5MA71M7) (QUERCUS AGRIFOLIA POLLEN - UNII:VOT5MA71M7)	QUERCUS AGRIFOLIA POLLEN	0.025 g in 1 mL
QUERCUS KELLOGGII POLLEN (UNII: 02RVY6X9EC) (QUERCUS KELLOGGII POLLEN - UNII:02RVY6X9EC)	QUERCUS KELLOGGII POLLEN	0.025 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PHENOL (UNII: 339NCG44TV)	0.004 g in 1 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.5 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.00125 g in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.0025 g in 1 mL

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49643-264-05	5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
2	NDC:49643-264-10	10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
3	NDC:49643-264-30	30 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
4	NDC:49643-264-50	50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102211	03/12/1974	

PINE MIX

pinus echinata/pinus ponderosa/pinus strobus liquid

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:49643-524
Route of Administration	PERCUTANEOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
PINUS ECHINATA POLLEN (UNII: 96LRW14765) (PINUS ECHINATA POLLEN - UNII:96LRW14765)	PINUS ECHINATA POLLEN	0.0167 g in 1 mL
PINUS PONDEROSA POLLEN (UNII: 042SUA2DS9) (PINUS PONDEROSA POLLEN - UNII:042SUA2DS9)	PINUS PONDEROSA POLLEN	0.0167 g in 1 mL
PINUS STROBUS POLLEN (UNII: TX1ER5UV3T) (PINUS STROBUS POLLEN - UNII:TX1ER5UV3T)	PINUS STROBUS POLLEN	0.0167 g in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
PHENOL (UNII: 339NCG44TV)	0.004 g in 1 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.5 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.00125 g in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.0025 g in 1 mL

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:49643-524-05	5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
2	NDC:49643-524-10	10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
3	NDC:49643-524-30	30 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
4	NDC:49643-524-50	50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102211	03/12/1974	

RHIZOPUS NIGRICANS

rhizopus nigricans liquid

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:49643-170
Route of Administration	PERCUTANEOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RHIZOPUS STOLONIFER (UNII: FEE198DK4Q) (RHIZOPUS STOLONIFER - UNII:FEE198DK4Q)	RHIZOPUS STOLONIFER	0.1 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	0.5 g in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.00125 g in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.0025 g in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49643-170-05	5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
2	NDC:49643-170-10	10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
3	NDC:49643-170-30	30 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
4	NDC:49643-170-50	50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102211	03/12/1974	

SMUT, BERMUDA GRASS

ustilago cynodontis injection

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:49643-172
Route of Administration	SUBCUTANEOUS, PERCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
USTILAGO CYNODONTIS (UNII: 0V3J4YEX2W) (USTILAGO CYNODONTIS - UNII:0V3J4YEX2W)	USTILAGO CYNODONTIS	0.05 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.0025 g in 1 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.5 g in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.00125 g in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49643-172-05	5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
2	NDC:49643-172-10	10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
3	NDC:49643-172-30	30 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
4	NDC:49643-172-50	50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102211	03/12/1974	

SMUT, WHEAT

ustilago tritici liquid

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:49643-177
Route of Administration	SUBCUTANEOUS, PERCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
USTILAGO TRITICI (UNII: BV82OL2IZ8) (USTILAGO TRITICI - UNII:BV82OL2IZ8)	USTILAGO TRITICI	0.033 g in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.0025 g in 1 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.5 g in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.00125 g in 1 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:49643-177-05	5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
2	NDC:49643-177-10	10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
3	NDC:49643-177-30	30 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
4	NDC:49643-177-50	50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102211	03/12/1974	

CLADOSPORIUM CLADOSPORIOIDES

cladosporium cladosporioides liquid

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:49643-178
Route of Administration	PERCUTANEOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

CLADOSPORIUM CLADOSPORIOIDES (UNII: 4ZWY20GTGO) (CLADOSPORIUM CLADOSPORIOIDES - UNII:4ZWY20GTGO)	CLADOSPORIUM CLADOSPORIOIDES	0.1 g in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	0.5 g in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.00125 g in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.0025 g in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49643-178-05	5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
2	NDC:49643-178-10	10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
3	NDC:49643-178-30	30 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
4	NDC:49643-178-50	50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102211	03/12/1974	

MAPLE, CALIFORNIA MIX

acer macrophyllum/acer negundo liquid

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:49643-520
Route of Administration	PERCUTANEOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACER NEGUNDO POLLEN (UNII: P6K070AR8V) (ACER NEGUNDO POLLEN - UNII:P6K070AR8V)	ACER NEGUNDO POLLEN	0.025 g in 1 mL
ACER MACROPHYLLUM POLLEN (UNII: E4CG5Q55M1) (ACER MACROPHYLLUM POLLEN - UNII:E4CG5Q55M1)	ACER MACROPHYLLUM POLLEN	0.025 g in 1 mL

Inactive Ingredients

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

GLYCERIN (UNII: PDC6A3C0OX)	0.5 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.00125 g in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.0025 g in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49643-520-05	5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
2	NDC:49643-520-10	10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
3	NDC:49643-520-30	30 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
4	NDC:49643-520-50	50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102211	03/12/1974	

SACCHAROMYCES CEREVISIAE

saccharomyces cerevisiae liquid

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:49643-168
Route of Administration	SUBCUTANEOUS, PERCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SACCHAROMYCES CEREVISIAE (UNII: 978D8U419H) (SACCHAROMYCES CEREVISIAE - UNII:978D8U419H)	SACCHAROMYCES CEREVISIAE	0.1 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.0025 g in 1 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.5 g in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.00125 g in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:49643-168-05	5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
2	NDC:49643-168-10	10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
3	NDC:49643-168-30	30 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
4	NDC:49643-168-50	50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102211	03/12/1974	

TRICHOPHYTON RUBRUM

trichophyton rubrum liquid

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:49643-175
Route of Administration	SUBCUTANEOUS, PERCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICHOPHYTON RUBRUM (UNII: 2ZAU32517N) (TRICHOPHYTON RUBRUM - UNII:2ZAU32517N)	TRICHOPHYTON RUBRUM	0.1 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	0.5 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.00125 g in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.0025 g in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 g in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49643-175-05	5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
2	NDC:49643-175-10	10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
3	NDC:49643-175-30	30 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
4	NDC:49643-175-50	50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102211	03/12/1974	

SMUT, OAT

ustilago avenae liquid

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:49643-176
Route of Administration	SUBCUTANEOUS, PERCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
USTILAGO AVENAE (UNII: YIH315U1TU) (USTILAGO AVENAE - UNII:YIH315U1TU)	USTILAGO AVENAE	0.05 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.0025 g in 1 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.5 g in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.00125 g in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49643-176-05	5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
2	NDC:49643-176-10	10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
3	NDC:49643-176-30	30 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
4	NDC:49643-176-50	50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102211	03/12/1974	

ALDER MIX

alnus rhombifolia/alnus rubra/alnus rugosa liquid

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:49643-501
Route of Administration	PERCUTANEOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALNUS RHOMBIFOLIA POLLEN (UNII: 7X8HL8GRTM) (ALNUS RHOMBIFOLIA POLLEN - UNII:7X8HL8GRTM)	ALNUS RHOMBIFOLIA POLLEN	0.0167 g in 1 mL
ALNUS RUBRA POLLEN (UNII: Z0F2YK1B7H) (ALNUS RUBRA POLLEN - UNII:Z0F2YK1B7H)	ALNUS RUBRA POLLEN	0.0167 g in 1 mL
ALNUS INCANA SUBSP. RUGOSA POLLEN (UNII: 605T96G8Y5) (ALNUS INCANA SUBSP. RUGOSA POLLEN - UNII:605T96G8Y5)	ALNUS INCANA SUBSP. RUGOSA POLLEN	0.0167 g in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
PHENOL (UNII: 339NCG44TV)	0.004 g in 1 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.5 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.00125 g in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.0025 g in 1 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:49643-501-05	5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
2	NDC:49643-501-10	10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
3	NDC:49643-501-30	30 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
4	NDC:49643-501-50	50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102211	03/12/1974	

ASPERGILLUS NIDULANS

aspergillus nidulans liquid

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:49643-161
Route of Administration	PERCUTANEOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ASPERGILLUS NIDULANS (UNII: 242A53RB80) (ASPERGILLUS NIDULANS - UNII:242A53RB80)	ASPERGILLUS NIDULANS	0.1 g in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.0025 g in 1 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.5 g in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.00125 g in 1 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:49643-161-05	5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
2	NDC:49643-161-10	10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
3	NDC:49643-161-30	30 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
4	NDC:49643-161-50	50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102211	03/12/1974	

STEMPHYLIUM SOLANI

stemphylium solani liquid

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:49643-173
Route of Administration	PERCUTANEOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
STEMPHYLIUM SOLANI (UNII: 1IEK4UDP5M) (STEMPHYLIUM SOLANI - UNII:1IEK4UDP5M)	STEMPHYLIUM SOLANI	0.1 g in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**

GLYCERIN (UNII: PDC6A3C0OX)	0.5 g in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.00125 g in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.0025 g in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49643-173-05	5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
2	NDC:49643-173-10	10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
3	NDC:49643-173-30	30 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
4	NDC:49643-173-50	50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102211	03/12/1974	

TRICHOPHYTON MENTAGROPHYTES

trichophyton mentagrophytes liquid

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:49643-174
Route of Administration	PERCUTANEOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICHOPHYTON MENTAGROPHYTES (UNII: 199I7J3JIV) (TRICHOPHYTON MENTAGROPHYTES - UNII:199I7J3JIV)	TRICHOPHYTON MENTAGROPHYTES	0.1 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PHENOL (UNII: 339NCG44TV)	0.004 g in 1 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.5 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.00125 g in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.0025 g in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49643-174-05	5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
2	NDC:49643-174-10	10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
3	NDC:49643-174-30	30 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
4	NDC:49643-174-50	50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102211	03/12/1974	

TRICHOPHYTON MIX

trichophyton mentagrophytes/trichophyton rubrum liquid

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:49643-802
Route of Administration	PERCUTANEOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICHOPHYTON RUBRUM (UNII: 2ZAU32517N) (TRICHOPHYTON RUBRUM - UNII:2ZAU32517N)	TRICHOPHYTON RUBRUM	0.005 g in 1 mL
TRICHOPHYTON MENTAGROPHYTES (UNII: 199I7J3JIV) (TRICHOPHYTON MENTAGROPHYTES - UNII:199I7J3JIV)	TRICHOPHYTON MENTAGROPHYTES	0.0005 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PHENOL (UNII: 339NCG44TV)	0.004 g in 1 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.5 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.00125 g in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.0025 g in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49643-802-04	4 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102211	03/12/1974	

ASPERGILLUS NIGER

aspergillus niger injection

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:49643-162
Route of Administration	SUBCUTANEOUS, PERCUTANEOUS		

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	0.1 g in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.0025 g in 1 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.5 g in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.00125 g in 1 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:49643-162-05	5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
2	NDC:49643-162-10	10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
3	NDC:49643-162-30	30 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
4	NDC:49643-162-50	50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102211	03/12/1974	

SMUT, BARLEY

ustilago nuda liquid

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:49643-171
Route of Administration	PERCUTANEOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
USTILAGO NUDA (UNII: 9Y53ZS6I82) (USTILAGO NUDA - UNII:9Y53ZS6I82)	USTILAGO NUDA	0.05 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.0025 g in 1 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.5 g in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.00125 g in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49643-171-05	5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
2	NDC:49643-171-10	10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
3	NDC:49643-171-30	30 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
4	NDC:49643-171-50	50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102211	03/12/1974	

Labeler - Allermed Laboratories, Inc. (073364531)

Registrant - Allermed Laboratories, Inc. (073364531)

Establishment

Name	Address	ID/FEI	Business Operations
Allermed Laboratories, Inc.		073364531	manufacture(49643-0161)

Revised: 9/2019 Allermed Laboratories, Inc.