STANDARDIZED CAT HAIR - standardized cat hair injection, solution
Antigen Laboratories, Inc.

Allergenic Extract

WARNINGS

Standardized cat hair and cat pelt extracts labeled in Bioequivalent Allergy Units (BAU/ml) are not interchangeable with each other and are not interchangeable with cat extracts labeled in Allergy Units (AU/ml). Standardized Cat allergenic extract is intended for use by physicians who are experienced in the administration of allergenic extracts for diagnosis, immunotherapy and the emergency care of anaphylaxis, or for use under the guidance of an allergy specialist. This extract is not directly interchangeable with other allergenic extracts. Patients being switched from other types of extract to Antigen Laboratories' allergenic extracts should be started as though they were coming under treatment for the first time. See "WARNINGS" section. As with all allergenic extracts, severe systemic reactions may occur. In certain individuals, these life-threatening reactions may result in death. Patients should be observed for at least 20 minutes following allergenic extract injections. Treatment and emergency measures, as well as personnel trained in their use, should be immediately available in the event of a life-threatening reaction. Sensitive patients may experience severe anaphylactic reactions resulting in respiratory obstruction, shock, coma and/or death. Patients being switched from one lot of extract to another from the same manufacturer should have the dose reduced by 75%.
This product should not be injected intravenously. Deep subcutaneous routes have proven to be safe, see "WARNINGS", "PRECAUTIONS", "ADVERSE REACTIONS" and "OVERDOSAGE" sections.
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 treatment of shock. Adrenocorticosteroids may be administered parenterally or intravenously. Refer to "ADVERSE REACTIONS" section.

DESCRIPTION

The cat allergen that seems to be most important has been called cat allergen 1 (Fel d I) and is found in saliva and extracts of cat hair, dander, and pelt. Using immunofluorescence, it was shown that this allergen is present in certain sebaceous glands of the skin. It is not found in serum or bladder-puncture urine. There are significant amounts of different non-Fel d I allergens contained in cat pelt extracts that are not present, or present in minimal amounts, in cat hair extracts.

The extract is a sterile solution intended for dilution prior to skin testing and/or immunotherapy. The designation BAU/ml (bioequivalent allergy units per ml) is unitage based upon quantitative skin testing.[23] When the extract contains 10-19.9 Fel d I u/ml, quantitative skin testing indicates it contains 10,000 BAU/ml, 5,000 BAU/ml = 5.00 to 9.99 FDA units of Fel d I.

The source material is cat hair and cat washings. The extracting fluid contains Sodium Chloride 0.95%, Sodium Bicarbonate 0.24%, and Glycerine 50% v/v as a stabilizing agent and preservative. The following is a brief description of the standardized quality procedures applied to these extracts:

1. The source material is carefully selected from healthy, veterinarian inspected cats who react negative to feline leukemia tests.
2. Isoelectric focusing (IEF) comparing Antigen Laboratories' Standardized Cat Hair 10,000 BAU/ml

with the Center for Biologics Evaluation and Research Standardized Cat Hair demonstrates undetectable to minimal cat albumin.

3. Skin testing by ID_{50}EAL method.[23]
4. A ninhydrin protein analysis is completed.
5. Each lot is standardized with the Cat (Fel d I) reference standard.
6. The standardized extract is analyzed for glycerine content to insure a minimum 50% v/v glycerine for optimal stability during the entire dating period.

CLINICAL PHARMACOLOGY

As a consequence of the discovery of IgE and the development of methods to identify and quantify anti-allergen IgE levels, interest in recent years has centered around the utilization of in vivo and in vitro diagnostic procedures.[3,5]

The most clinically relevant mechanism of mast cell mediator release results from the cross-linking of plasma membrane receptor-bound IgE molecules by specific antigens. In vitro this process is temperature dependent, requires the presence of divalent cations, and also requires activation of a cell membrane-associated serine esterase. Another immunologic mechanism for mast cell degranulation is mediated by complement-derived anaphylatoxins C3a, C4a and C5a. These low molecular weight peptides presumably stimulate degranulation of mast cells by binding to distinct plasma membrane receptor(s) and are active mast cell secretagogues in human skin in vivo. Several naturally occurring and exogenous agents are also capable of degranulating and/or stimulating mast cells by nonimmunologic mechanisms that may differ from those initiated by antigen-IgE binding.

Stimulation of mast cells leads to the release and generation of a variety of pharmacologically active soluble factors that produce immediate hypersensitivity reactions. These factors include both preformed substances as well as unstored mediators that are produced upon stimulation of these cells. Some mediators are rapidly liberated from mast cell granules (e.g., histamine), whereas others remain granule-associated after release from the cell (e.g., heparin). Products of arachidonic acid metabolism are rapidly produced and released from mast cells following stimulation. In addition to immediate reactions mediated by endogenous mast cell-derived pharmacologic agents, selected patients demonstrate later reactions (i.e., late-phase reactions) at sites of mast cell degranulation. These reactions begin 2 to 8 hours after mediator release and are characterized by granulocyte-rich infiltrates that are followed by accumulations of mononuclear cells. Clinically these late-phase reactions present as inflammatory, infiltrated plaques or nodules.[17]

Patients who react to a small quantity of antigen by skin testing, or have a high RAST score, can be classified as highly sensitive. Those who react only to large quantities of antigen, or have a low RAST score, can be classified as less sensitive. It would appear that there is at least a 50,000-fold range between the most and least sensitive individuals. On the other hand, certain patients who do not appear to have elevated quantities of specific anti-allergen IgE, RAST negative, do have positive skin tests and have symptoms of allergic rhinitis. These patients are considerably less sensitive than patients with detectable levels of specific IgE antibody.[6]

The mode of action of immunotherapy with allergenic extracts is still under investigation. Increasing subcutaneous injection doses of allergenic extract into patients with allergic disease have been shown to result in both humoral and cellular changes including the production of allergen specific IgG antibodies, the suppression of histamine release from target cells, decrease in circulating levels of antigen specific IgE antibody over long periods of time and suppression of peripheral blood T-lymphocyte cell responses to antigen.[10, 14, 15]

Of ten patients with clinical symptoms from exposure to cats, the ID_{50}EAL skin test results were as follows: Mean sum puncture erythema – 70.4 mm; Range 51-105 mm; Mean sum puncture wheal – 15.6 mm; Range 10-22 mm. Mean intradermal dose in BAU for 50 mm sum of erythema response BAU_{50} 0.14 BAU/ml; Range 0.06-0.19 BAU/ml. Using Histamine Phosphate, 2.75 mg/ml containing 1 mg histamine base: Mean sum puncture erythema – 48.5 mm; Range 29-70 mm.

INDICATIONS AND USAGE

Allergenic extract is indicated for diagnostic testing and for the treatment (immunotherapy) of patients whose histories indicate that upon natural exposure to cat allergen, they experience allergic symptoms. Confirmation is determined by skin testing. An orderly approach to the diagnostic use of allergenic extracts usually begins with direct skin testing.

CONTRAINDICATIONS

Do not administer in the presence of diseases characterized by bleeding diathesis. Individuals with autoimmune disease may be at risk of exacerbating symptoms, of the underlying disease, possibly due to routine immunization. Patients who have experienced a recent myocardial infarction may not be tolerant of immunotherapy. Children with nephrotic syndrome probably should not receive injections due to a variety of seemingly unrelated events, such as immunization causing exacerbation of their nephrotic disease.

This product is not intended for the treatment of patients who do not experience allergic symptoms upon natural exposure to the allergen.

Extreme caution is necessary when using diagnostic skin tests or injection treatment in highly sensitive patients, who have experienced severe symptoms or anaphylaxis by natural exposure or previous skin testing or treatment. IN THESE CASES BOTH THE POTENCY FOR SKIN TESTS AND THE ESCALATION OF THE TREATMENT DOSE MUST BE ADJUSTED TO THE PATIENT'S SENSITIVITY AND TOLERANCE.

This product is not intended for treatment of patients who do not manifest immediate hypersensitivity reactions to the allergenic extract following skin testing.

WARNINGS

Allergenic extracts should be used by physicians with experience in maximal dose immunotherapy and treatment of anaphylaxis. *Patients receiving beta-blockers may not be responsive to epinephrine or inhaled bronchodilators.*

Epinephrine 1:1000 should be available. When changing from one lot to another of allergenic extract, dose adjustment, if indicated, should be based on such considerations, as the results of skin endpoint titration (see "INDICATIONS AND USAGE" section). Patient re-evaluation may be necessary. Injections should never be given intravenously. A 5/8 inch, 25 gauge needle on a sterile syringe will allow deep subcutaneous injection. Precaution of withdrawing the plunger slightly after inserting the needle is advisable to determine if a blood vessel has been entered. DO NOT INJECT INTRAVENOUSLY. Proper measurement of the dose and caution in making the injection will minimize reactions. Adverse reactions to allergenic extracts are usually apparent within 20-30 minutes following injection. Patients should be detained for 20-30 minutes after injection and advised to notify the office immediately if symptoms or reactions occur.

Patients being switched from one lot of extract to another from the same manufacturer should have the dose reduced by 75%. This extract should be temporarily withheld or dosage reduced in the following conditions: 1) flu or other infection with fever; 2) exposure to excessive amounts of allergen prior to injection; 3) rhinitis and/or asthma exhibiting severe symptoms; 4) adverse reaction to previous injection until cause of reaction has been evaluated by the physician supervising the patient's immunotherapy program.

PRECAUTIONS

General: Immunotherapy must be given under the supervision of a physician. Sterile solutions of vials, syringes, etc. should be used. Aseptic technique should be observed in making dilutions from bulk extracts, skin testing and extracts for treatment. The usual precautions in administering allergenic extracts are necessary. Disposable, sterile syringe and needle should be used for each individual patient to prevent transmission of serum hepatitis, HIV and other infectious agents from one person to another.

Refer to "OVERDOSAGE" section for a description of the treatment of anaphylactic

reactions.

Pregnancy Category C: Animal reproduction studies have not been conducted with allergenic extracts. It is not known whether allergenic extracts cause fetal harm during pregnancy or affect reproductive capacity. A systemic reaction to allergenic extracts could cause uterine contractions leading to spontaneous abortion or premature labor. Allergenic extracts should be used during pregnancy only if potential benefit justifies potential risk to fetus.[11]

Nursing Mothers: It is not known whether allergenic extracts are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when allergenic extracts are administered to a nursing woman.

Pediatric Use: Allergenic extracts have been used routinely in children and no special problems of safety or specific hazards have been found. 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 in half and administer the injection at two different sites.

Carcinogenicity: Long term studies in animals have not been conducted with cat hair allergenic extracts to evaluate carcinogenicity or mutagenicity.

Drug Interactions: Antihistamines and hydroxyzine can significantly inhibit immediate skin test reactions. This effect has been primarily documented when testing was performed within 1-2 hours after drug ingestion. Although partial inhibition of the skin test reaction has been observed for longer periods, it was minor. Epinephrine injection inhibits the immediate skin test reaction for several hours. Patients on delayed absorption antihistamine tablets should be free of such medication for 48 hours. **Maintenance dose potency must be established by the physician's clinical observation and experience.**[6, 13]

Patients with a history of severe sensitivity and markedly positive skin test to high dilutions of the allergenic extract should be started with low doses of highly diluted extract. Pregnancy or a history of prior reactions to allergen immunotherapy dictates the need to start with small quantities of antigen.

ADVERSE REACTIONS

Adverse reactions include, but are not necessarily limited to urticaria, itching, edema of the extremities, respiratory wheezing or asthma, dyspnea, cyanosis, tachycardia, lacrimation, marked perspiration, flushing of the face, neck or upper chest, mild persistent clearing of the throat, hacking cough, or persistent sneezing.

1) Local Reactions

Small amounts of erythema and swelling at the site of injection are common, the extent varying with the patient. Such reactions should not be considered significant unless they persist for at least 24 hours or exceed 50 mm in diameter.

Larger local reactions are not only uncomfortable, but indicate the possibility of a systemic reaction if dosage is increased. In such cases the dosage should be reduced to the last level not causing the reaction and maintained at this level for two or three treatments before cautiously increasing again.

Large, persistent local reactions or minor exacerbations of the patient's allergic symptoms may be treated by local cold applications and/or the use of oral antihistamines, but they should be considered a warning of possible severe systemic reactions and the need for temporarily reduced dosages.

A mild burning immediately after the injection is to be expected; this usually leaves in 10-20 seconds. Prolonged pain, or pain radiating up the arm, is usually the result of intramuscular injection, making this injection route undesirable. Subcutaneous injection is the recommended route.

2) Systemic Reactions

Systemic reactions may range from mild exaggeration of the patient's allergic symptoms to anaphylactic reactions. Very sensitive patients may show a rapid response. In some instances, a severe systemic reaction with blood pressure fall and/or shock may occur. Quantitation of patient's sensitivity combined with careful early observation is essential for safe skin testing and treatment.

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.

Patients receiving beta-blockers may not be responsive to epinephrine or inhaled bronchodilators. The following are commonly prescribed beta-blockers: Levatol, Lopressor, Propanolol Intersol, Propanolol HCL, Blocadren, Propanolol, Inderal-LA, Visken, Corgard, Ipran, Tenormin, Timoptic. Ophthalmic beta-blockers: Betaxolol, Levobunolol, Timolol, Timoptic. Chemicals that are beta-blockers and may be components of other drugs: Acebutolol, Atenolol, Esmolol, Metoprolol, Nadolol, Penbutolol, Pindolol, Propanolol, Timolol, Labetalol, Carteolol.

It cannot be overemphasized that, under certain unpredictable combinations of circumstances, anaphylactic shock is always a possibility. Other possible systemic reaction symptoms are, in varying degrees of severity, fainting, pallor, bradycardia, hypotension, angioedema, cough, wheezing, conjunctivitis, rhinitis, and urticaria.[13, 14]

OVERDOSAGE

If a systemic or anaphylactic reaction does occur, oxygen by nasal cannula, mask or ambu bag should be first treatment if patient has respiratory distress or asthma. Apply a tourniquet above the site of injection and inject intramuscularly or subcutaneously 0.3 to 0.5 ml of 1:1000 epinephrine-hydrochloride into opposite arm or gluteal area. The dose may be repeated in 5-10 minutes if necessary. Loosen the tourniquet at least every 10 minutes.

The epinephrine HCL 1:1000 dose for infants to 2 years is 0.05 to 0.1 ml; for children 2 to 6 years it is 0.15 ml; for children 6 to 12 years it is 0.2 ml.

Studies on asthmatic subjects reveal that plasma concentrations of theophylline of 5 to 20 ug/ml are associated with therapeutic effects. Toxicity is particularly apparent at concentrations greater than 20 ug/ml. A loading dose of aminophylline of 5.6 mg/kg intravenously followed by 0.9 mg/kg per hour results in plasma concentrations of approximately 10 ug/ml (Mitenko and Ogilvie 1973b; Nicholson and Chick 1973).[4]

Other beta-adrenergic drugs such as isoproterenol, isoetharine, or albuterol may be used by inhalation. The usual dose to relieve broncho-constriction in asthma is 0.5 ml or the 0.5% solution for isoproterenol HCL; albuterol is longer acting than isoproterenol by any route of administration. The albuterol inhaler delivers approximately 90 mcg of albuterol from the mouthpiece. The usual dosage for adults and children would be two inhalations repeated every 4 to 6 hours. Isoetharine supplied in the Bronkometer unit delivers approximately 340 mcg isoetharine. The average adult dose is one to two inhalations.

Patients who have been taking a beta-blocker may be unresponsive to epinephrine. Epinephrine or beta-adrenergic drugs (Alupent) may be ineffective. These drugs should be administered even though a beta-blocker may have been taken. The following treatment will be effective whether or not patient is taking a beta-blocker: Aminophylline IV, slow push or drip, Atrovent (Ipratropium bromide) Inhaler, 3 inhalations repeated, Atropine, 0.4 mg/ml, 0.75 to 1.5 ml IM or IV, Solu-Cortef, 100-200 mg IM or IV, Solu-Medrol, 125 mg IM or IV, Glucagon, 0.5-1 mg IM or IV, Benadryl, 50 mg IM or IV, Cimetidine, 300 mg IM or IV, Oxygen via ambu bag.

DOSAGE AND ADMINISTRATION

The current standard method of immunotherapy dates back to Noon. Therapy is begun with a low dose which has been shown to be tolerated by both experience and skin testing. The initial dilution of allergenic extract, starting dose, and progression of dosage must be carefully determined on the basis of the patient's history and results of skin tests.

The physician who undertakes immunotherapy should be concerned with the degree of sensitivity of the patient. (See "INDICATIONS AND USAGE".) Strongly positive skin tests may be risk factors for systemic reactions. Less aggressive immunotherapy schedules may be indicated for such patients.

Serial five-fold or ten-fold dilutions of the extract are used to make more dilute extract concentrations. Other concentrations can be prepared by appropriate dilution. In brief, the allergist can prepare any dilution of extract that is considered appropriate for the patient.

Prick-Puncture Testing: To identify cat sensitive individuals and as a safety precaution, it is recommended that a prick or puncture test using a drop of the 10,000 BAU/ml extract concentrate be performed prior to initiating very dilute intradermal testing. Prick (puncture) testing is performed by placing a drop of extract concentrate on the skin and puncturing the skin through the drop with a small needle such as a bifurcated vaccinating needle. The most satisfactory sites on the back for skin testing are from the posterior axillary fold to 2.5 cm from the spinal column, and from the top of the scapula to the lower rib margins. The best areas on the arms are the volar surfaces from the axilla to 2.5 or 5 cm above the wrist, skipping the anticubital space. Glycerinated extracts are recommended for prick testing using the most concentrated dilution. A positive reaction is approximately 10-15 mm erythema with 2.5 mm wheal.

A positive control using Histamine Phosphate is important to identify those patients whose skin may not be reactive due to medications, metabolic or other reasons. A diluent control, if negative, would exclude false-positive reactions due to ingredients in the diluent or patients who have dermatographism.

Smaller, less conclusive reactions may be considered positive in conjunction with a definitive history of symptoms on exposure to the allergen. The more sensitive the patient the higher the probability that he/she will have symptoms related upon natural exposure to the offending Cat allergen. Hence, the importance of good patient history. Less sensitive individuals can be tested intradermally with an appropriately diluted extract. (See Intradermal Testing.)

SERIAL DILUTIONS
APPROXIMATE BAU/ml RESULTING FROM 1:10 DILUTION
OF ALLERGENIC EXTRACT CONCENTRATE
Allergenic Extract Concentrate

DILUTUION #	DILUTION EXPONENT	10,000 BAU/ML	5,000 BAU/ML	1,000 BAU/ML
1	10^{-1}	1,000	500	100
2	10^{-2}	100	50	10
3	10^{-3}	10	5.0	1.0
4	10^{-4}	1	0.5	0.1
5	10^{-5}	0.1	0.05	0.01
6	10^{-6}	0.01	0.005	0.001
7	10^{-7}	0.001	0.0005	0.0001
8	10^{-8}	0.0001	0.00005	0.00001
9	10^{-9}	0.00001	0.000005	0.000001
10	10^{-10}	0.000001	0.0000005	0.0000001

SERIAL DILUTIONS
APPROXIMATE BAU/ml RESULTING FROM 1:5 DILUTION
OF ALLERGENIC EXTRACT CONCENTRATE
Allergenic Extract Concentrate

DILUTION #	DILUTION EXPONENT	10,000 BAU/ML	5,000 BAU/ML	1,000 BAU/ML
1	5^{-1}	2,000	1,000	200
2	5^{-2}	400	200	40
3	5^{-3}	80	40	8.0
4	5^{-4}	16	8.0	1.6
5	5^{-5}	3.2	1.6	0.32
6	5^{-6}	0.64	0.32	0.064
7	5^{-7}	0.128	0.064	0.0128

8	5^{-8}	0.0256	0.0128	0.00256
9	5^{-9}	0.00512	0.00256	0.000512
10	5^{-10}	0.001024	0.000512	0.0001024

Intradermal testing: The surface of the upper and lower arm is the usual location for skin testing. It is important that a new sterile, disposable syringe and needle be used for each extract tested. Intracutaneous test dilutions should be made with aqueous diluent. Three-fold, five-fold or ten-fold dilutions may be prepared from stock concentrate extract. (1) Start testing with the most dilute allergenic extract concentration. (2) A volume of 0.01-0.02 ml should be injected slowly into the superficial skin layers making a small bleb (superficial wheal). (3) For patients with a suspected cat sensitivity an allergenic extract dilution of 5^{-10} (0.005 BAU/ml) or 10^{-7} (0.001 BAU/ml) dilution should be used for initial skin testing. Sensitivity of the patient can be expressed only if the minimum concentration required for a 1+ or 2+ reaction (see chart below) is determined by performing a skin test titration. The reaction should be read after fifteen minutes.

EVALUATION OF SKIN REACTIONS

GRADE	**mm ERYTHEMA**	**mm WHEAL**
0	less than 5	less than 5
+/-	5-10	5-10
1+	11-20	5-10
2+	21-30	5-10
3+	31-40	10-15 or with pseudopods
4+	greater than 40	greater than 15 or with many pseudopods

If after 20 minutes no skin reaction is obtained, continue the testing using increments in the concentration until a reaction of 5-10 mm wheal and 10-30 mm erythema is obtained, or until the concentration of 5^{-2} or 10^{-1} has been tested. As a negative control the diluent, a concentration of less than 0.5% glycerine (5^{-3} or 10^{-3}), does not produce positive skin wheal and erythema. The diluent should be tested and included in the interpretation of the skin reactions.[17]

INTRADERMAL TESTING--SKIN ENDPOINT TITRATION

The allergenic extract to which the patient is sensitive, the patient's degree of sensitivity and the initial dose of allergen to be used in immunotherapy can be quantitated using five-fold dilutions of allergenic extract for intracutaneous testing. The critical variable is the size of the wheal and erythema produced by the intracutaneous injection of 0.01-0.02 ml of the test allergen producing a 4 mm diameter superficial wheal. For initial screening 5^{-10} (0.005 BAU/ml) is a safe dilution. When a sequence of five-fold or ten-fold dilutions of an allergen are injected, the endpoint is detected by noting the dilution that first produces a wheal and erythema (15 minutes after injection) that is 2 mm larger than wheals with erythema produced by weaker, non-reacting dilutions (5 mm negative wheal). The endpoint dilution is used as a starting dose concentration for immunotherapy.

Normally, immunotherapy with allergenic extracts can be started with 0.15 ml of the endpoint of reaction. In any allergic patient, a safe starting dose can be determined by finding the first dose by intradermal skin testing producing a 1+ reaction or the dilution producing the skin endpoint.

If the first injection of the initial dilution of extract is tolerated without significant local reaction, increasing doses by 5-20% increments of that dilution may be administered. The rate of increase in dosage in the early stages of treatment with highly diluted extracts is usually more rapid than the rate of increase possible with more concentrated extracts. This schedule is intended only as a guide and must

be modified according to the reactivity of the individual patient. Needless to say, the physician must proceed cautiously in the treatment of the highly sensitive patient who develops large local or systemic reactions.

Some patients may tolerate larger doses of the allergenic extract depending on patient response.[7] Because dilute extracts tend to lose activity on storage, the first dose from a more concentrated vial should be the same or less than the previous dose.[8, 12]

Dosages progressively increase thereafter according to the tolerance of the patient at intervals of one to seven days until, (1) the patient achieves relief of symptoms, (2) induration at the site of injection is no larger than 50 mm in 36 to 48 hours, (3) a maintenance dose, the largest dose tolerated by the patient short of aggravating existing symptoms, systemic symptoms, or anaphylaxis, or patient demonstrates untoward reactions that indicate the dose to be excessive. This maintenance dose may be continued at regular intervals perennially. It may be necessary to adjust the progression of dosage downward to avoid local and constitutional reactions.

HOW SUPPLIED

Standardized Cat allergenic extract is expressed in BAU/ml. It is supplied in 10,000 BAU/ml, 5,000 BAU/ml and 1,000 BAU/ml in 5, 10, 30 and 50 ml containers. Extracts in 5 ml dropper bottles are available for prick-puncture testing. To insure maximum potency for the entire dating period, all stock concentrates contain 50% v/v glycerine.

STORAGE

Store all stock concentrates and dilutions at 2-8 degrees C. Keep at this temperature during office use. The expiration date of allergenic extract is listed on the container label. Dilutions of the allergenic extract concentration containing less than 50% v/v glycerine are less stable and, if loss of potency is suspected, it can be checked by skin testing with equal concentrations of a freshly prepared dilution of allergenic extract on known sensitive individuals.

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STANDARDIZED CAT HAIR

standardized cat hair injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49288-0121
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FELIS CATUS HAIR (UNII: 1564HD0N96) (FELIS CATUS HAIR - UNII:1564HD0N96)	FELIS CATUS HAIR	10000 [BAU] in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Glycerin (UNII: PDC6A3C0OX)	0.525 mL in 1 mL
Water (UNII: 059QF0KO0R)	
Sodium Chloride (UNII: 451W47IQ8X)	0.0095 g in 1 mL
Sodium Bicarbonate (UNII: 8MDF5V39QO)	0.0024 g in 1 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:49288-0121-2	5 mL in 1 VIAL, MULTI-DOSE		
2	NDC:49288-0121-3	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:49288-0121-4	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:49288-0121-5	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA103368	10/21/1992	

STANDARDIZED CAT HAIR

standardized cat hair injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49288-0122
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FELIS CATUS HAIR (UNII: 1564HD0N96) (FELIS CATUS HAIR - UNII:1564HD0N96)	FELIS CATUS HAIR	5000 [BAU] in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Glycerin (UNII: PDC6A3C0OX)	0.525 mL in 1 mL
Water (UNII: 059QF0KO0R)	
Sodium Chloride (UNII: 451W47IQ8X)	0.0095 g in 1 mL
Sodium Bicarbonate (UNII: 8MDF5V39QO)	0.0024 g in 1 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:49288-0122-2	5 mL in 1 VIAL, MULTI-DOSE		

2	NDC:49288-0122-3	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:49288-0122-4	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:49288-0122-5	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA103368	10/21/1992	

Labeler - Antigen Laboratories, Inc. (030705628)

Establishment

Name	Address	ID/FEI	Business Operations
Antigen Laboratories, Inc.		030705628	manufacture

Revised: 8/2009 Antigen Laboratories, Inc.