STANDARDIZED CAT HAIR ALLERGENIC EXTRACT- felis catus solution
Greer Laboratories, Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION
ALLERGENIC EXTRACT STANDARDIZED - CAT HAIR, Felis catus Solution for percutaneous, intradermal, or subcutaneous administration

These highlights do not include all the information needed to use Standardized Cat Hair Allergenic Extract safely and effectively. See full prescribing information for Standardized Cat Hair Allergenic Extract.
Standardized Cat Hair Allergenic Extract (Felis catus) solution for percutaneous, intradermal, or subcutaneous administration.
Initial U.S. Approval: 1992

WARNING: SEVERE ALLERGIC REACTIONS

See full prescribing information for complete boxed warning.

- **Cat Hair allergenic extract can cause severe life-threatening systemic reactions, including anaphylaxis. (5.1)**
- **Do not administer Cat Hair allergenic extract to patients with severe, unstable or uncontrolled asthma. (4)**
- **Observe patients in the office for at least 30 minutes following treatment. Emergency measures and personnel trained in their use must be available immediately in the event of a life-threatening reaction. (5.1)**
- **Patients with extreme sensitivity, on an accelerated immunotherapy build-up, switching to another lot, or receiving high doses of Cat Hair extract, or those also exposed to similar allergens may be at increased risk of a severe allergic reaction. (5.1)**
- **Cat Hair allergenic extract may not be suitable for patients with certain underlying medical conditions that may reduce their ability to survive a systemic reaction, or who are receiving beta blockers as they may be unresponsive to epinephrine. (5.1,5.2)**
- **Cat Hair extracts with potency labeling in Bioequivalent Allergy Units/milliliter is not interchangeable with Cat Pelt extracts labeled in Bioequivalent Allergy Units/milliliter. (5.3)**

INDICATIONS AND USAGE

GREER Standardized Cat Hair Allergenic Extract is indicated for:

- Skin test diagnosis of patients with a history of allergy to cats. (1)
- Treatment of cat hair-induced allergic asthma, rhinitis and conjunctivitis when avoidance is not possible. (1)

DOSAGE AND ADMINISTRATION

For percutaneous, intradermal or subcutaneous use only.
The extract is diluted with sterile diluents when used for intradermal testing or subcutaneous immunotherapy. Dosages vary by mode of administration, and by individual response and tolerance. (2.1)

DOSAGE FORMS AND STRENGTHS

Stock concentrate vials at 10,000 and 5,000 Bioequivalent Allergy Units/milliliter. (3)

CONTRAINDICATIONS

- Severe, unstable or uncontrolled asthma. (4)
- History of any severe systemic allergic reaction or any severe local reaction to subcutaneous allergen immunotherapy. (4)

WARNINGS AND PRECAUTIONS

Severe allergic reactions have occurred following the administration of other allergenic extracts and may occur in individuals following the administration of Cat Hair allergenic extract in the following situations:

- Extreme sensitivity to cat hair, or receiving high doses of Cat Hair extract or concomitant exposure to similar environmental allergens. (5.1)
- Receiving an accelerated immunotherapy build-up schedule (e.g., “rush” immunotherapy), or changing from one allergenic lot to another. (5.1)

ADVERSE REACTIONS

The most common adverse reactions, occuring in over 25% of all patients, are local reactions at the injection site (e.g., erythema, itching, swelling, tenderness, pain). (6)

Systemic reactions, occurring in ≤ 7% of patients, include generalized skin erythema, urticaria, pruritus, angioedema, rhinitis, wheezing, laryngeal edema, and hypotension. These can be fatal. (6)

To report SUSPECTED ADVERSE REACTIONS, contact GREER Laboratories, Inc. at 1-800-438-0088 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Beta blockers may cause unresponsiveness to usual doses of epinephrine used to treat serious systemic reactions, including anaphylaxis. (7.1)
- Antihistamines and other medications that suppress histamine, including topical corticosteroids, topical anesthetics and tricyclic antidepressants can interfere with skin test results. (7.2)

USE IN SPECIFIC POPULATIONS

(18)
(18)

Revised: 10/2016

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FULL PRESCRIBING INFORMATION

WARNING: SEVERE ALLERGIC REACTIONS

- **Cat Hair allergenic extract can cause severe life‐threatening systemic reactions, including anaphylaxis. (5.1)**
- **Do not administer Cat Hair allergenic extract to patients with severe, unstable, or uncontrolled asthma. (4)**
- **Observe patients in the office for at least 30 minutes following treatment. Emergency measures and personnel trained in their use must be available immediately in the event of a life-threatening reaction. (5.1)**
- **Patients with extreme sensitivity to Cat Hair allergenic extract, those on an accelerated immunotherapy build-up schedule, switching to another allergenic lot, and those receiving high doses of the Cat Hair allergenic extract or are also exposed to similar allergens may be at increased risk of a severe allergic reaction. (5.1)**
- **Cat Hair allergenic extract may not be suitable for patients with certain underlying medical conditions that may reduce their ability to survive a systemic reaction. (5.1)**
- **Cat Hair allergenic extract may not be suitable for patients who are receiving beta blockers as they may be unresponsive to epinephrine. (5.2)**
- **Standardized Cat Hair Allergenic Extract with potency labeling in Bioequivalent Allergy Units/milliliter is not interchangeable with Standardized Cat Pelt Allergenic Extracts labeled in Bioequivalent Allergy Units/milliliter. (5.3)**

1 Indications and Usage

GREER Standardized Cat Hair Allergenic Extract is indicated for:

- Skin test diagnosis of patients with a history of allergy to cats.
- Treatment of cat hair-induced allergic asthma, rhinitis and conjunctivitis. Immunotherapy is indicated when cat allergy is established and the patient cannot avoid exposure to cat allergens.

2 DOSAGE AND ADMINISTRATION

For percutaneous, intradermal or subcutaneous use only.

Stock concentrate vials are available at 10,000 and 5,000 Bioequivalent Allergy Units (BAU)/milliliter.

2.1 Preparation for Administration

Visually inspect parenteral drug products for particulate matter and discoloration prior to administration, whenever solution and container permit. GREER Standardized Cat Hair Allergenic Extract should be a clear and colorless to light yellow solution that is free of particulate matter. Discard solution if particulate matter is observed.

The extracts are diluted with sterile diluents when used for percutaneous and intradermal testing, or for subcutaneous immunotherapy.

To prepare 10-fold dilutions for percutaneous testing in highly sensitive patients, start with a 10,000 BAU/milliliter or 5,000 BAU/milliliter stock concentrate. Proceed as in Table 1. The 10-fold dilution series uses 0.5 milliliters of concentrate added to 4.5 milliliters of sterile 50% glycerin diluent. Subsequent dilutions are made in a similar manner.

To prepare 10-fold dilutions for intradermal testing or immunotherapy, start with a 10,000 BAU/milliliter or 5,000 BAU/milliliter stock concentrate. Proceed as in Table 1. The 10-fold dilution

series uses 0.5 milliliters of concentrate added to 4.5 milliliters of sterile diluent (glycerin-free diluents for intradermal testing, glycerin-free or 10% glycerin-saline diluents for immunotherapy). Subsequent dilutions are made in a similar manner.

Table 1: 10-fold Dilution Series

Dilution	Extract	Milliliters of Diluent	BAU/milliliter	BAU/milliliter
0	Concentrate		10,000	5,000
1	0.5 milliliters Concentrate	4.5	1,000	500
2	0.5 milliliters Dilution 1	4.5	100	50
3	0.5 milliliters Dilution 2	4.5	10	5
4	0.5 milliliters Dilution 3	4.5	1	0.5
5	0.5 milliliters Dilution 4	4.5	0.1	0.5
6	0.5 milliliters Dilution 5	4.5	0.01	0.005

To prepare 5-fold dilutions for percutaneous testing in highly sensitive patients, start with a 10,000 BAU/milliliter or 5,000 BAU/milliliter stock concentrate. Proceed as in Table 2. The 5-fold dilution series uses 1 milliliter of concentrate added to 4 milliliters of sterile 50% glycerin diluent. Subsequent dilutions are made in a similar manner.

To prepare 5-fold dilutions for intradermal testing or immunotherapy, start with a 10,000 BAU/milliliter or 5,000 BAU/milliliter stock concentrate. Proceed as in Table 2. The 5-fold dilution series uses 1 milliliter of concentrate added to 4 milliliters of sterile diluent (glycerin-free diluents for intradermal testing, glycerin-free or 10% glycerin-saline diluents for immunotherapy). Subsequent dilutions are made in a similar manner.

Table 2: 5-fold Dilution Series

Dilution	Extract	Milliliters of Diluent	BAU/milliliter	BAU/milliliter
0	Concentrate		10,000	5,000
1	1 milliliters Concentrate	4	2,000	1,000
2	1 milliliters Dilution 1	4	400	200
3	1 milliliters Dilution 2	4	80	40
4	1 milliliters Dilution 3	4	16	8
5	1 milliliters Dilution 4	4	3.2	1.6
6	1 milliliters Dilution 5	4	0.64	0.32

2.2 Diagnostic Testing

Diagnostic testing can be performed via percutaneous or intradermal administration of the Cat Hair allergenic extract. A positive skin test reaction must be interpreted in relation to the patient's history and known exposure to the allergen.

Percutaneous Skin Testing

Determine the patient's sensitivity to the Standardized Cat Hair Allergenic Extract.

Prick or puncture testing: use 10,000 BAU/milliliter or 5,000 BAU/milliliter extract stock concentrate.

In highly sensitive patients initiate testing with several serial 10-fold or 5-fold dilutions.

Preparation and Dose

For percutaneous testing (prick or puncture) use 10,000 or 5,000 BAU/milliliter stock concentrates. If a lower concentration is desired in highly sensitive patients, 10-fold or 5-fold dilutions of the concentrate can be tested.

Prick test: Place one drop of extract or control on the skin and with a skin test device pierce through the drop into the skin with a slight lifting motion.

Puncture test: Place one drop of extract or control on the skin and pierce the skin through the drop with a skin test device perpendicular to the skin.

Interpreting Results

When using percutaneous skin test devices, follow the directions provided with the test devices. A glycerinated histamine control solution (6 milligrams/milliliter or 1 milligram/milliliter histamine base) may be used as the positive control. A 50% glycerin saline solution may be used as the negative control.

Read skin test responses 15 to 20 minutes after exposure and measure the average diameter of the induration (wheal) and erythema (flare), or the sum of the longest diameter and the mid-point orthogonal diameters of erythema (ΣE).

An example of a commonly used scale is provided in Table 3 below. [1,2]

Table 3: Grading Sensitivity

Grade	Skin Apperarance
0	No reaction or reaction no different than negative control
1+	Erythema less than 21 milliliters
2+	Wheal less than 3 milliliters and erythema larger than 21 milliliters
3+	Wheal greater than 3 milliliters with surrounding erythema
4+	Wheals with pseudopods and surrounding erythema

Responses to positive controls should be at least 3 millimeters larger than responses to the negative controls.

Negative controls should elicit no reaction or only reactions of small diameters (less than 2 millimeters wheal, less than 5 millimeters erythema).

If either the positive or negative control response does not meet the above criteria, results for the allergenic extracts tested at the same time are invalid and must be repeated.

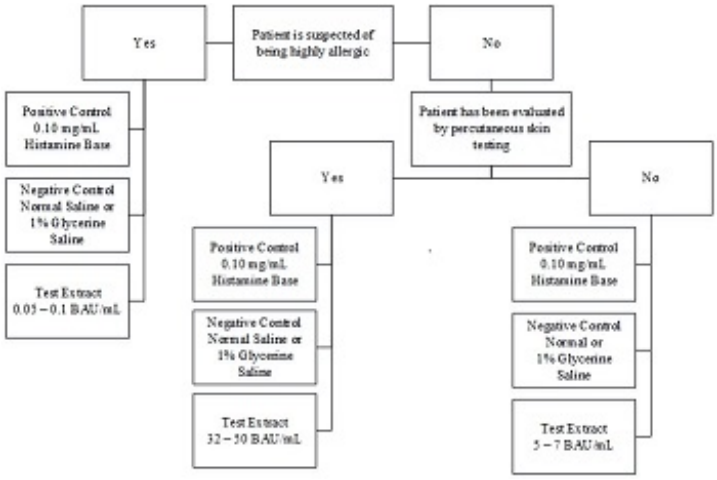
Intradermal Skin Testing

For intradermal testing, use 10,000 BAU/milliliter or 5,000 BAU/milliliter of GREER Standardized Cat Hair Allergenic Extract stock concentrate in 10, 30 or 50 milliliters multiple-dose vials. Dilute the stock concentrate with sterile diluent [see Dosage and Administration (2.1)]. Use normal or buffered saline or normal saline with human serum albumin (HSA) diluent. If the initial test dose is negative, subsequent intradermal tests using increasingly stronger doses may be performed up to the maximum recommended strength of 200 BAU/milliliter.

Preparation and Dose

Inject 0.02 milliliters of the following solutions intradermally as shown in Figure 1:

Figure 1: Conditions of Testing



2.3 Immunotherapy

For subcutaneous administration only.

Preparation and Dose

Stock concentrate of GREER Standardized Cat Hair Allergenic Extract is available at 10,000 BAU/milliliter or 5,000 BAU/milliliter in 50% glycerin saline for immunotherapy. Stock concentrates are diluted in normal saline, buffered saline, HSA saline, or 10% glycerin saline, depending on the patient's reactivity to the diluent. See Table 1 and Table 2 for dilution preparation.

Administration of Immunotherapy

Administer immunotherapy by subcutaneous injection in the lateral aspect of the upper arm or thigh. Avoid injection directly into any blood vessel.

The optimal interval between doses of allergenic extract varies among individuals. Injections are usually given 1 to 2 times per week until the maintenance dose is reached, at which time the injection interval is increased to 2, then 3, and finally 4 weeks. Dosages vary by mode of administration, and by clinical response and tolerance. The minimum course of treatment may be three to five years, depending on the clinical response.

Guidelines for Immunotherapy

The initial dose of the extract should be based on the skin test reactivity. In patients who appear to be highly sensitive by history and skin test, the initial dose of the extract should be 0.1 milliliter of a 0.005 to 0.05 BAU/milliliter extract dilution. Patients with lesser sensitivity may be started at a 0.1 milliliter of a 0.5 to 5 BAU/milliliter extract dilution.

The dose of allergenic extract is increased at each injection by no more than 50% of the previous dose, and the next increment is governed by the response to the last injection.

Select the maximum tolerated maintenance dose based on the patient's clinical response and tolerance. Doses larger than 0.2 milliliter of the stock concentrate are rarely administered because an extract in 50% glycerin can cause discomfort upon injection.

Dosage Modification Guidelines for Immunotherapy

The following conditions may indicate a need to withhold or reduce the dosage of immunotherapy.

Symptoms of rhinitis and/or asthma.

Infection accompanied by fever.

Exposure to excessive amounts of clinically relevant environmental allergen prior to a scheduled injection.

Large local reactions that persist for longer than 24 hours can be an indication for repeating the previous dose or reducing the dose at the next administration.

Any evidence of a systemic reaction is an indication for a significant reduction (at least 75%) in the subsequent dose. Repeated systemic reactions, are sufficient reason for the cessation of further attempts to increase the reaction-causing dose.

Local reactions require a decrease in the next dose by at least 50%. Proceed cautiously in subsequent dosing. In situations prompting dose reduction, once the reduced dose is tolerated, a cautious increase in dosage can be attempted.

Changing to a different lot of extract: When switching patients to different lot of extract, the first dose from the new vial should not exceed a 25% increase of the previous dose or a 75% reduction of the previous dose, assuming both extracts contain comparable amounts of allergen as measured in BAU/milliliter.

Unscheduled gaps between treatments: Patients can lose tolerance for allergen injections during prolonged periods between doses, thus increasing their risk for an adverse reaction. The duration of tolerance between injections varies from patient to patient.

During the build-up phase, when patients receive injections 1 to 2 times per week, repeat or reduce the extract dosage if there has been a substantial time interval between injections. This depends on: 1) the concentration of allergen immunotherapy extract that is to be administered; 2) a previous history of systemic reactions; and 3) the degree of variation from the prescribed interval of time, with longer intervals since the last injection leading to greater reductions in the dose to be administered. This suggested approach to dose modification, due to unscheduled gaps between treatments during the build-up phase, is not based on published evidence. The individual physician should use this or a similar protocol for the specific clinical setting.

Similarly, if large unscheduled gaps occur during maintenance therapy, it may be necessary to reduce the dosage. Devise a protocol for the specific clinical setting in determining how to modify doses of allergen immunotherapy due to unscheduled gaps in treatment.

Extract previously used from different manufacturer: Since manufacturing processes and sources of raw materials differ among manufacturers, the interchangeability of extracts from different manufacturers cannot be assured. Decrease the starting dose of the extract from a different manufacturer even if the extract is the same dilution. In general, a dose reduction of 50 to 75% of the previous dose should be adequate, but each situation must be evaluated separately considering the patient's history of sensitivity, tolerance of previous injections, and other factors. Dose intervals should not exceed one week when rebuilding dose.

Changing from non-stabilized to human serum albumin (HSA) stabilized diluents: Allergenic extracts prepared with diluents containing HSA and 0.4% phenol are more stable than those prepared with diluents that do not contain stabilizers. When switching from a non-stabilized to an HSA stabilized diluent, consider lowering the dose for immunotherapy.

3 DOSAGE FORMS AND STRENGTHS

Standardized Cat Hair Allergenic Extract is supplied as stock concentrate vials at 10,000 BAU/milliliter and 5,000 BAU/milliliter.

4 CONTRAINDICATIONS

Standardized Cat Hair Allergenic Extract is contraindicated in patients with:

- Severe, unstable or uncontrolled asthma.
- History of any severe systemic allergic reaction or any severe local reaction to subcutaneous allergen immunotherapy.

5 WARNINGS AND PRECAUTIONS

5.1 Serious Systemic Reactions

Severe allergic reactions have occurred following the administration of other allergenic extracts and may occur in individuals following the administration of Standardized Cat Hair Allergenic Extract in the following situations:

- Extreme sensitivities to Cat Hair allergenic extract.
- Receiving an accelerated immunotherapy build-up schedule (e.g., “rush” immunotherapy).
- Receiving high doses of Cat Hair allergenic extracts or concomitant exposure to similar environmental allergens.
- Changing from one allergenic lot to another allergenic lot.

High-risk patients have had fatal reactions. In addition, patients who are not high-risk, but are on beta blockers, have had fatal reactions because beta blockers interfere with beta adrenergics, such as epinephrine, used in the treatment of anaphylaxis.

Administer Cat Hair Allergenic Extract in a healthcare setting under the supervision of a physician prepared to manage a severe systemic or a severe local allergic reaction. Observe patients in the office for at least 30 minutes following administration. [3]

5.2 Patients on Beta Blockers

Patients receiving beta blockers may be unresponsive to the usual doses of epinephrine used to treat serious systemic reactions, including anaphylaxis [see Drug Interactions (7.1)].

5.3 Cross-Reactions and Dose Sensitivity

GREER Standardized Cat Hair Allergenic Extract is labeled in BAU/milliliter. This allergenic extract is not interchangeable with Standardized Cat Pelt Extract or with cat extracts labeled in Allergy Units.

Determine the initial dilution of allergenic extract, starting dose, and progression of dosage based on the patient’s history and results of skin tests [1] [see Dosage and Administration (2.2)]. Strongly positive skin tests can be an indicator for potential systemic reactions.

6 ADVERSE REACTIONS

Allergenic extracts including Standardized Cat Hair can cause local reactions at the injection site, which may include erythema, itching, swelling, tenderness and pain. [3] Additionally, systemic reactions, which may indicate anaphylaxis, can occur and may include generalized skin erythema, urticaria, pruritus, angioedema, rhinitis, wheezing, chest tightness, laryngeal edema and hypotension.

7 DRUG INTERACTIONS

7.1 Beta Adrenergic Drugs

Patients receiving beta blocker drugs may not be responsive to beta adrenergic drugs used to treat

anaphylaxis [see Warnings and Precautions (5.2)].

7.2 Antihistamines

Do not perform skin testing with allergenic extracts within 3 to 10 days of use of first-generation H_1-histamine receptor blockers (e.g., clemastine, diphenhydramine) and second-generation antihistamines (e.g., loratadine, terfenadine), except for astemizole, which requires an interval of 30 to 60 days between use and allergenic extract exposure. These products suppress histamine skin test reactions and could mask a positive response. [1]

7.3 Topical Corticosteroids and Topical Anesthetics

Topical corticosteroids can suppress skin reactivity; therefore, discontinue use at the skin test site for 2 to 3 weeks before skin testing. Avoid use of topical local anesthetics at skin test sites as they can suppress flare responses. [1]

7.4 Tricyclic Antidepressants

Tricyclic antidepressants can have potent antihistamine effects that can affect skin testing. If tricyclic medication has been recently discontinued allow 7 to 14 days before initiating skin testing.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C: Animal reproduction studies have not been conducted with GREER Standardized Cat Hair Allergenic Extract. It is not known whether allergenic extracts can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Standardized Cat Hair Allergenic Extract should be given to a pregnant woman only if clearly needed. Immunotherapy is typically not initiated during pregnancy due to the risks associated with systemic reactions and their treatment. [3]

8.2 Labor and Delivery

Safety and effectiveness of allergenic extracts in labor and delivery have not been established.

8.3 Nursing Mothers

It is not known whether allergenic extracts or their antigens are excreted in human milk. Because many drugs are excreted in human milk, exercise caution when administering Standardized Cat Hair Allergenic Extract to a nursing woman.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use

Safety and effectiveness of GREER Standardized Cat Hair Allergenic Extract have not been established in patients > 65 years of age.

8.6 Autoimmune Disease

For patients with existing immunologic diseases, give immunotherapy only if the risk from exposure to the allergens is greater than the risk of exacerbating the underlying disorder. [3]

11 DESCRIPTION

GREER Standardized Cat Hair Allergenic Extract is a sterile solution of extracted cat pelt and cat dander. Each vial contains sterile Standardized Cat Hair Allergenic Extract at 10,000 BAU/milliliter or 5,000 BAU/milliliter, 50% glycerin volume/volume, and 0.4% phenol volume/volume (preservative). Inactive ingredients include 0.5% sodium chloride for isotonicity and 0.25% sodium bicarbonate as a buffer.

GREER Standardized Cat Hair Allergenic Extract is labeled in BAU/milliliter. This allergenic extract is not interchangeable with Standardized Cat Pelt Extract or with cat extracts labeled in Allergy Units. The extract is standardized by comparing potency of cat allergen (Fel d 1) units by radial immunodiffusion against a reference standard from the Center for Biologics Evaluation and Research (CBER) of the U.S. Food and Drug Administration (FDA). [4,5] An extract with 10.0 to 19.9 Fel d 1 units per milliliter is designated as 10,000 BAU/milliliter by the FDA based on quantitative skin testing. [4,5]

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The precise mechanisms of action of allergy immunotherapy are not known.

The allergic reaction is dependent upon the presence of antigen-specific IgE antibodies that are bound to specific receptors on mast cells and basophils and has been demonstrated for cat-allergic individuals. [6] The presence of IgE antibodies on mast cells and basophils sensitizes these cells and upon interaction with the appropriate allergen-histamine and other mediators are released. [7] In the skin these mediators are responsible for the characteristic wheal and flare reaction. [8] An increase in cat antigen-specific IgG antibodies has been demonstrated as a result of immunotherapy. [9,10]

14 CLINICAL STUDIES

The efficacy of immunotherapy for Type I hypersensitivity (i.e. allergy) to airborne allergens [3] including cat hair/dander has been well established. Specifically, immunotherapy for allergic sensitivity to cat hair allergens has been addressed in a 2003 Cochrane meta-analysis which included 10 randomized controlled trials of immunotherapy [11], which expanded on prior meta-analyses of the effectiveness of allergy immunotherapy in asthma. [12,13] In addition, efficacy for immunotherapy for rush or cluster protocols, in which dose escalation is compressed over days or weeks, has also been demonstrated. [14]

15 REFERENCES

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16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

GREER Standardized Cat Hair Allergenic Extract is supplied as stock concentrate at 10,000 BAU/milliliter and 5,000 BAU/milliliter in 50% glycerin for use in percutaneous skin testing, intradermal testing, and subcutaneous immunotherapy. The 10,000 BAU/milliliter stock concentrate is available in 5, 10, 30 and 50 milliliter vials and the 5,000 BAU/milliliter in 10, 30 and 50 milliliter vials. GREER Standardized Cat Hair Allergenic Extract containing 10,000 BAU/milliliter and 5,000 BAU/milliliter in 50% Glycerin solution is supplied as follows:

NDC Number	**Strength/Container**
NDC 22840-0101-5	10,000 BAU/mL 5 mL dropper vial for prick testing
NDC 22840-0101-2	10,000 BAU/mL 10 mL multiple-dose vial
NDC 22840-0101-3	10,000 BAU/mL 30 mL multiple-dose vial
NDC 22840-0101-4	10,000 BAU/mL 50 mL multiple-dose vial
NDC 22840-0100-2	5,000 BAU/mL 10 mL multiple-dose vial
NDC 22840-0100-3	5,000 BAU/mL 30 mL multiple-dose vial
NDC 22840-0100-4	5,000 BAU/mL 50 mL multiple-dose vial

16.2 Storage and Handling

Maintain at 2 to 8 °C (36 to 46 °F) during storage and use.

Dilutions of concentrated extract result in a glycerin content of less than 50%, which can result in reduced stability. Extract dilutions at 1:100 v/v dilution of 10,000 BAU/milliliter Standardized Cat Hair Allergenic Extract stock concentrates should be kept no longer than a month, and more dilute solutions

no more than a week. The potency of a dilution can be checked by skin test comparison to a fresh dilution of the extract on a known cat hair allergic patient.

17 PATIENT COUNSELING INFORMATION

Instruct patient to remain under observation in the office for 30 minutes or longer after an injection.

Caution patient that reactions can occur more than 30 minutes after skin testing or an injection.

Instruct patient to recognize the following symptoms as adverse reactions and to immediately return to the office or immediately seek other medical attention if any of these symptoms occur following skin testing or an injection:

- Unusual swelling and/or tenderness at the injection site
- Hives or itching of the skin
- Swelling of face and/or mouth
- Sneezing, coughing or wheezing
- Shortness of breath
- Nausea
- Dizziness or faintness

Manufacturer:
GREER Laboratories, Inc.
Lenoir, NC 28645 U.S.A.

16001015

STANDARDIZED CAT HAIR ALLERGENIC EXTRACT

felis catus solution

Product Information			
Product Type	STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:22840-0100

Route of Administration	PERCUTANEOUS, SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FELIS CATUS DANDER (UNII: ZDN2AC0L08) (FELIS CATUS DANDER - UNII:ZDN2AC0L08)	FELIS CATUS DANDER	5000 [BAU] in 1 mL
FELIS CATUS SKIN (UNII: 5308ED00EL) (FELIS CATUS SKIN - UNII:5308ED00EL)	FELIS CATUS SKIN	5000 [BAU] in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:22840-0100-2	10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
2	NDC:22840-0100-3	30 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
3	NDC:22840-0100-4	50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA103397	09/24/1992	

STANDARDIZED CAT HAIR ALLERGENIC EXTRACT

felis catus solution

Product Information			
Product Type	STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:22840-0101
Route of Administration	PERCUTANEOUS, SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FELIS CATUS DANDER (UNII: ZDN2AC0L08) (FELIS CATUS DANDER -	FELIS CATUS	10000 [BAU]

UNII:ZDN2AC0L08)	DANDER	in 1 mL
FELIS CATUS SKIN (UNII: 5308ED00EL) (FELIS CATUS SKIN - UNII:5308ED00EL)	FELIS CATUS SKIN	10000 [BAU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOL (UNII: 339NCG44TV)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:22840-0101-2	10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
2	NDC:22840-0101-3	30 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
3	NDC:22840-0101-4	50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
4	NDC:22840-0101-5	5 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA103397	09/24/1992	

Labeler - Greer Laboratories, Inc. (024671414)

Registrant - Greer Laboratories, Inc. (024671414)

Establishment

Name	Address	ID/FEI	Business Operations
Greer Laboratories, Inc.		024671414	manufacture(22840-0100, 22840-0101)

Revised: 10/2019 Greer Laboratories, Inc.