ALLERGENIC EXTRACT
Instructions for Use and Dosage Schedule for Standardized Cat Hair Extract
10,000 Bioequivalent Allergy Units per mL

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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.

Standardized Cat Hair Extract is not directly interchangeable with Standardized Cat Pelt Extract or Cat Extracts labeled in Allergy Units (AU/mL). The initial dose must be based on skin testing as described in the dosage and administration section of this insert. Care must be taken in the administration of extracts because of the following:

1. The absorption of cat extract with monospecific antisera to Fel d1 causes a reduction in the allergenic activity.
2. The primary allergen of Standardized Cat Hair Extract is Fel d 1. Standardized Cat Pelt Extract contains Fel d1, as well as non-Fel d1 allergens.
3. The importance of Fel d1 as a means of standardizing the potency of cat extract is based on the following observations:
   a. The intensity of skin reactions to cat extract correlates with the Fel d1 content of the extract in most cat sensitive patients.
   b. The absorption of cat extract with monospecific antisera to Fel d1 causes a reduction in the allergenic activity of cat extract.
   c. The precipitation arc of Fel d1 extract binds most of the IgE antibody in sera obtained from cat allergic individuals.

CLINICAL PHARMACOLOGY
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 not known. Antibodies in allergen-specific IgE and an increase in the activity of T suppressor lymphocytes appear to be some of the immunologic changes that occur from hypoosensitization (4, 5, 6).

INDICATIONS AND USAGE
Studies have shown that skin tests with cat extract are useful in the diagnosis of cat allergy. As a rule, persons with cat allergy have positive skin reactions when tested with cat extract, and non-allergic individuals rarely react (7, 8, 9). However, the relationship between a positive skin test and the appearance of clinical symptoms after exposure to a cat is not absolute, i.e., some skin-test positive persons do not experience allergic symptoms after exposure (10). Failure to experience symptoms may be dose related, since it is known that cats vary significantly in the amount of Fel d1 they produce (11).

The efficacy of cat extract immunotherapy in the treatment of bronchial asthma has been shown in two studies (12, 13). A reduction in bronchial sensitivity was observed in patients with cat allergy, whereas no reduction was observed in placebo treated, cat-allergic patients.

CONTRAINDICATIONS
Standardized Cat Hair Extract should not be used for immunotherapy in persons who do not have cat related allergic symptoms and a positive skin test to the extract.

WARNINGS
Standardized Cat Hair Extract may cause local or severe life-threatening reactions when administered to highly sensitive individuals. Physicians who use this product should be familiar with the clinical use of allergenic extract and have the necessary emergency equipment and medications available to treat systemic allergic reactions. See Precautions, Adverse Reactions and Overdosage.

Standardized Cat Hair Extract should be used interchangeably with Standardized Cat Pelt Extracts or previously standardized cat extracts labeled in Allergy Units per mL. Cat hair extracts labeled in BAU/mL made by other manufacturers should be tested by blind serial skin testing before these products are used in patients who have previously received Allermed Standardized Cat Hair Extract.

The dosage of Standardized Cat Hair Extract must be reduced when starting a patient on a new lot of Standardized Cat Hair Extract containing the same amount of Fel d1 units per mL. This is necessary due to a possible loss of potency during storage in the physician’s office.

The dose of the new lot of extract should not exceed 1/4 the last dose given from the old lot of extract.

Any evidence of a strong local or systemic reaction following the administration of Standardized Cat Hair Extract requires a reduction in dosage during the initial stages of immunotherapy, as well as during maintenance therapy.

PRECAUTIONS
GENERAL: Do not inject intravenously. 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.

The extract should be stored at 2°C-8°C. Dilutions of the 10,000 BAU/mL concentrate should be made with buffered saline containing human serum albumin for maximum stability. However, regardless of diluent type, diluted extract should be checked by skin test on a known cat-allergic individual if loss of potency is suspected.

PREGNANCY CATEGORY C: Animal reproduction studies have not been conducted with Standardized Cat Hair Extract. It is not known whether allergenic extract can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Standardized Cat Hair Extract should be given to a pregnant woman only if clearly needed.

PEDIATRIC USE: The safety and effectiveness of Standardized Cat Hair Extract in children has not been established. The dose of the new lot of extract should not exceed 1/4 the last dose given from the old lot of extract. 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.

IMMUNOCORRELATES, MULTIPLE FERTILITY: Long term studies have not been conducted with Standardized Cat Hair Extract to determine their potential for carcinogenicity, mutagenesis, and impairment of fertility.

NURSING MOTHERS: Data are not available on the secretion of Standardized Cat Hair Extract in human milk and it is not known what effect this might have on the nursing infant.

PRECAUTIONS TO USE: The dose of Standardized Cat Hair 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.

DRUG INTERACTION: The skin test response to Standardized Cat Hair Extract in sensitive persons may be suppressed by previous treatment with antihistamines and drugs with antiadrenergic activity. Treatment with beta-blocking drugs may lower the adrenal response to the usual dose of epinephrine, in the event epinephrine is required to control an adverse allergic reaction.

Caution should be observed in the following circumstances:

EXTREME SENSITIVITY TO CATS: Determined from previous anaphylaxis following skin testing or natural exposure.

AUTOIMMUNE DISEASE: Individuals with autoimmune disease may be at risk, due to the potential for routine immunization with allergens to sensitize or provoke an autoimmune response.

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.
Intradermal tests with serial three-fold dilution of the 10,000 BAU/mL showed the following results:

<table>
<thead>
<tr>
<th>Serial 3-Fold Dilutions of 10,000 BAU/mL Extract</th>
<th>Vial #1</th>
<th>Vial #2</th>
<th>Vial #3</th>
<th>Vial #4</th>
<th>Vial #5</th>
<th>Vial #6</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.00 BAU</td>
<td>0.05</td>
<td>0.05</td>
<td>0.05</td>
<td>0.05</td>
<td>0.05</td>
<td>0.05</td>
</tr>
<tr>
<td>0.5  BAU</td>
<td>0.1</td>
<td>0.1</td>
<td>0.1</td>
<td>0.1</td>
<td>0.1</td>
<td>0.1</td>
</tr>
<tr>
<td>0.2  BAU</td>
<td>0.2</td>
<td>0.2</td>
<td>0.2</td>
<td>0.2</td>
<td>0.2</td>
<td>0.2</td>
</tr>
<tr>
<td>0.1  BAU</td>
<td>0.3</td>
<td>0.3</td>
<td>0.3</td>
<td>0.3</td>
<td>0.3</td>
<td>0.3</td>
</tr>
<tr>
<td>0.05 BAU</td>
<td>0.4</td>
<td>0.4</td>
<td>0.4</td>
<td>0.4</td>
<td>0.4</td>
<td>0.4</td>
</tr>
</tbody>
</table>

The mean three-fold dilution eliciting a response of 50 mm sum of erythema diameters was 11.120 (S.D. 2.38). The number of BAU/mL required to elicit this response was 0.05 (range 0.0005 to 9.24 BAU/mL). This concentration is approximately a 1:200,000 v/v dilution of the 10,000 BAU/mL extract.

Extract for intradermal testing should be used as follows:

- a. Patients with a positive scratch or prick test to Standardized Cat Hair Extract. It is not advisable to perform an intradermal skin test in these patients.
- b. Patients with a negative scratch or prick test to Standardized Cat Hair Extract. Patients who do not react to a scratch or prick test with the 10,000 BAU/mL concentrate may be tested intradermally with 0.05 mL of a 1:2,000 v/v dilution of the concentrate (5 BAU/mL). If the test is negative, a second test should be performed with 0.05 mL of a 1:20,000 v/v dilution of concentrate (0.05 BAU/mL). A negative test should be followed by repeat tests using 10 fold stronger concentrations until the maximum dose of 0.05 mL of a 1:200 v/v dilution (50 BAU/mL) is reached.

**Interpretation Of Skin Tests**

The interpretation of skin tests should be based on the size of the erythema and wheal response to the allergen compared to a negative saline control. A suggested method of scoring skin tests is shown below. Measurements refer to the longest (single) diameter of erythema and wheal response.

**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 a 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 5mm wheal created by the 1.0 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**

Allergic 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 potential hazard of anaphylaxis.

Standardized Cat Hair Extract must be diluted before administration to new patients. 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 5/15 mm (edema/erythema), the extract should be diluted before it is given subcutaneously. The doses shown in the Dosage Schedule may be followed unless the patient's skin test response and allergy history indicate that more dilute extract should be used.

**References**


**Dosage Schedule for Standardized Cat Hair Extract**

(The safety and efficacy of this schedule has not been determined by well-controlled clinical trials.)

| BAU Bioequivalent Allergy Units per mL |
|---------------------------------------|--------|--------|--------|--------|--------|
| Vial #1 | Vial #2 | Vial #3 | Vial #4 | Vial #5 | Vial #6 |
| 0.05 BAU | 0.05 BAU | 0.05 BAU | 0.05 BAU | 0.05 BAU | 0.05 BAU |
| 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| 0.2 | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 |
| 0.3 | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 |
| 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 |

**How Supplied**

Standardized Cat Hair Extract containing 10,000 BAU per mL is supplied in 5 mL dropper vials for scratch or prick testing and in 10 mL, 30 mL and 50 mL vials as concentrate.

**Storage and Handling**

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

**Date of Revision:** April 2010  C-9