2.1.1 Percutaneous Skin Testing

For percutaneous (scratch, prick, or puncture) testing, use 10,000 Allergy Units/mL Greer Standardized Mite Extract stock concentrate in dropper vials (2.2). If a patient is suspected of being highly allergic, initial testing should be performed using histamine phosphate. To certain foods and drugs, initiate percutaneous testing with several serial dilutions of the usual test concentration.

- For scratch tests, scratch the skin, and then apply one drop of the extract to the scratch.
- For prick tests, one drop of extract on the skin and pierce through the drop into the skin with a slight lifting motion.
- For puncture tests, place one drop of extract on the skin and penetrate the epidermis with a 25-gauge needle.

When using percutaneous test devices, follow the directions provided with the device used.

Include a positive control to detect false negative responses to skin testing, which may occur if serum levels of histamines remain from prior medication administration [see Drug Interactions (7.2)]. A glycinated histamine phosphate diluted to 0.1 mg/mL (histamine base) may be used as the positive control.

Include a negative control to detect false positive responses, which can occur when the patient has a non-specific reaction to the diluent. A 50% glycine-containing solution may be used as the negative control.

Read skin tests 15-20 minutes after exposure. Record the indentation (swelling) and erythema (redness) noting the longest diameter of each, or by the sum of the longest erythema diameter and the mid-point orthogonal diameters of erythema. Because immediate systemic reactions are more common with intradermal testing, pretesting with percutaneous testing is a practical safety measure.²

Dilute the stock concentrate with sterile saline. Use saline with known pH for subsequent dilutions. Do not use saline with pH greater than 7.2 or histamine phosphate solution with diluents with dialysis that can not stabilize allergens.

If switching from a non-standardized to an HSA stabilized diluent, administer the allergen immunotherapy extract that is to be administered, 2) a mixture of extracts, and 3) the allergen immunotherapy extract that is to be administered, and 4) a mixture of extracts.

Changing from non-standardized to human serum albumin (HSA) stabilized allergens: Allergic extracts diluted with HSA and 0.4% phenol are more resistant to potential bacterial contamination than allergens diluted with diluents that cannot stabilize allergens.

2.1.2 Intradermal Skin Testing

Intradermal tests are conducted when the reaction to percutaneous testing is negative or equivocal but the patient has a strong clinical history of allergy. It is the preferred method for determining the degree of variation from the prescribed interval of time, with other factors. Pre-testing with the allergenic extract with diluents included with the device used. This test may be used in conjunction with a percutaneous test to determine the degree of variation from the prescribed interval of time, with other factors.

Some loss of potency occurs even during storage conditions. The individual physician should use this or a similar protocol as a standard operating procedure for testing new allergen immunotherapy products.

The extract previously used is from another manufacturer: Since many allergenic extracts differ in terms of chemical composition, allergenic extracts of different manufacturers, the interchangeability of extracts from different manufacturers cannot be assured. The start dose of the extract from a different manufacturer on the background of previous treatment should be used only if the extract is the same formula and dilution. In general, a dose reduction of 50-75% 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 increments should not exceed one week when rebuiling dose.

The previous extract has expired or is near expiry: The dating period for allergen extracts indicates that only those that can be expected to retain potency under ideal storage conditions (2°C - 8°C) [see How Supplied/Storage and Handling (16)]. Some loss of potency occurs even when stored under ideal conditions, therefore extract should not be stored beyond the expiration date. For a new lot should be used (see “Changing to a different lot of extract,” above).

Changing from non-standardized to human serum albumin (HSA) stabilized allergens: Allergic extracts diluted with HSA and 0.4% phenol are more resistant to potential bacterial contamination than allergens diluted with diluents that cannot stabilize allergens.

If switching from a non-standardized to a HSA stabilized diluent, follow the allergen immunotherapy extract that is to be administered, and 4) a mixture of extracted allergens.

2.2. Administration of Immunotherapy

Administer immunotherapy by subcutaneous injection in the lateral aspect of the arm. The optimal interval between doses of allergen extracts varies among individuals. Inspections are usually given 1-2 times per week during the maintenance phase, at which time the injection interval is increased to 2.5 and 4 weeks. Because most adverse reactions occur within 30 minutes after injection, patients should be kept under observation for at least 20 minutes following injection. If patients 30 minutes of observation may not be sufficient.

2.2.1 Diagnostic Testing

For diagnosis of a patient with a suspected allergy to either of the specific skin tests, the skin test results may be used to confirm or rule out the diagnosis.

2.3 IMMUNOTHERAPY

Subcutaneous injection only. Subcutaneous immunotherapy should be performed by dilution of stock concentrate based on patient’s reaction. Stock concentrations of Greer Standardized Mite Extract are available in 5,000 Allergy Units/mL, 10,000 Allergy Units/mL, or 30,000 Allergy Units/mL for Immunotherapy. See Table 2 for dilution preparation. Also see Dosage Modifications for Immunotherapy.

- The initial dose of the extract should be based on the percutaneous test reaction. In patients who appear to be highly sensitive by history and skin test, the initial dose of the extract should be 0.1 mL of a 0.005 to 0.05 mL of a 50 Allergy Units/mL extract dilution.
- Patients suspected of being highly allergic should first receive a test dose of 0.02 to 0.05 mL of a 0.005 Allergy Units/mL extract dilution.
- If the initial dose is negative, the subsequent treatment dose should be increased up to the maximum recommended strength of 200 Allergy Units/mL.

Table 1. Intradermal Reactivity to Mite Allergens

<table>
<thead>
<tr>
<th>Allergen</th>
<th>Number of Patients</th>
<th>Dose to Elicit 50 mm Sum of Diameter Erythema Reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>D. farinae</td>
<td>46</td>
<td>0.00856</td>
</tr>
<tr>
<td>D. pteronyssinus</td>
<td>37</td>
<td>0.00571</td>
</tr>
</tbody>
</table>

³ Allergy Units/mL extract are not available on file with Greer.

2.3 IMMUNOTHERAPY

Subcutaneous injection only. Subcutaneous immunotherapy should be performed by dilution of stock concentrate based on patient’s reaction. Stock concentrations of Greer Standardized Mite Extract are available in 5,000 Allergy Units/mL, 10,000 Allergy Units/mL, or 30,000 Allergy Units/mL for Immunotherapy. See Table 2 for dilution preparation. Also see Dosage Modifications for Immunotherapy.

- The initial dose of the extract should be based on the percutaneous test reaction. In patients who appear to be highly sensitive by history and skin test, the initial dose of the extract should be 0.1 mL of a 0.005 to 0.05 mL of a 50 Allergy Units/mL extract dilution. Patients suspected of being highly allergic should first receive a test dose of 0.02 to 0.05 mL of a 0.005 Allergy Units/mL extract dilution.
- If the initial dose is negative, the subsequent treatment dose should be increased up to the maximum recommended strength of 200 Allergy Units/mL.
- If percutaneous skin testing was not performed, include a positive control to detect false negative responses to the skin test. A 1% solution of 1% histamine phosphate is recommended. The individual physician should use this or a similar protocol as a standard operating procedure for testing new allergen immunotherapy products.
- Include a negative control to detect false positive responses, which can occur when the patient has a non-specific reaction to the diluent. A 1% solution of 1% histamine phosphate is recommended. The individual physician should use this or a similar protocol as a standard operating procedure for testing new allergen immunotherapy products.
- Measure the mean of the swellings and erythemas. The mean dose of Greer dust mite allergen required to elicit a positive intradermal test result (EZ) of 50 mm in a total of 83 mm diameter test patch (EZ = 20 mm) is shown in Table 1.

1 INDICATIONS AND USAGE

Greer Standardized Mite Extracts are allergenic extracts indicated for use in the following indications:

- Diagnosis of skin test reactivity to dust mite allergen (1)
- Treatment of mite-induced allergic asthma, rhinitis and conjunctivitis in patients who have symptoms based on published evidence. The individual physician should use this or a similar protocol as a standard operating procedure for testing new allergen immunotherapy products.
Table 2: Hold-Dilution Series for Intradermal testing and immunotherapy

<table>
<thead>
<tr>
<th>Dilution</th>
<th>Extract</th>
<th>Diluent</th>
<th>AU/mL</th>
<th>AU/mL</th>
<th>AU/mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>1:10,000</td>
<td>Concentrate</td>
<td>AU/mL</td>
<td>5,000</td>
<td>10,000</td>
<td>20,000</td>
</tr>
<tr>
<td>1:5,000</td>
<td>Concentrate</td>
<td>AU/mL</td>
<td>4,500</td>
<td>1,000</td>
<td>1,000</td>
</tr>
<tr>
<td>1:2,500</td>
<td>Concentrate</td>
<td>AU/mL</td>
<td>4,50</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1:50</td>
<td>Dilute 1</td>
<td>AU/mL</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>1:50</td>
<td>Dilute 2</td>
<td>AU/mL</td>
<td>0.8</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>1:50</td>
<td>Dilute 3</td>
<td>AU/mL</td>
<td>0.6</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>1:50</td>
<td>Dilute 4</td>
<td>AU/mL</td>
<td>0.5</td>
<td>0.1</td>
<td>0.3</td>
</tr>
<tr>
<td>1:50</td>
<td>Dilute 5</td>
<td>AU/mL</td>
<td>0.5</td>
<td>0.001</td>
<td>0.003</td>
</tr>
</tbody>
</table>

*aAU = Allergy Unit*

**10. OVERDOSE**

For all allergics the therapeutic dose varies per individual. If a dose exceeds the window for a particular patient this may be considered an overdose, with appropriate measures to prevent anaphylaxis. Systemic reactions are uncommon after injection, but if the patient receives more than can be tolerated at that particular time, and begins to experience immediate hypersensitivity anaphylaxis, institute emergency treatment by trained personnel.

**11. DESCRIPTION**

Greer Standardized Mites (Dermatophagoides farinae and/or D. pteronyssinus) extracts are sterile solutions used for intradermal testing or subcutaneous immunotherapy. Each vial contains 5,000, 10,000, 30,000, or 50,000 Allergy Units/mL of sterile mite extracts (D. farinae and/or D. pteronyssinus), 50% glycerol, v/v, and 0.4% phenol (preservative). Inert ingredients include 0.50% sodium chloride for isotonicity and 1.0% buffered saline for stability.

For immunotherapy, concentrated extracts are dispensed in normal saline, buffered saline, alum/saline or 10% glycerol. Based on patient’s risk, the extract should be reconstituted with diluent such as buffered saline, albumin saline or 10% glycerol. For immunotherapy, extracts may be dispensed in normal saline, buffered saline, alum/saline or 10% glycerol. For immunotherapy, extracts may be discarded if there is anaphylaxis or other allergic reaction.

**12. CLINICAL PHARMACOLOGY**

Dust mites belong to the genus Dermatophagoides and are indoor allergens that can be found in many local environments. D. farinae and D. pteronyssinus occur widely with most homes in the United States contaminated by both species.¹²