ALLERGENIC EXTRACT
Standardized Mite
Dermatophagoides farinae
Dermatophagoides pteronyssinus
ALLEREGO LABORATORIES, INC.
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U.S. License 467

DESCRIPTION

Mitextract is a sterile solution containing the extractables of mite whole bodies in 0.25% sodium chloride, 0.125% sodium bicarbonate, 50% glycerol by volume and 0.4% phenol as a preservative. The mites are grown on a medium of yeast and pork and are handled and cleaned in a manner to remove more than 99% of the food medium. The medium contains about one million of human serum proteins. There is no history of the scratch, prick-puncture, or intradermal methods of skin testing for diagnostic purposes and subcutaneously for therapeutic purposes as directed under Dosage and Administration.

Intradermal skin tests in patients who were puncture test positive (Sum E ≥ 40 mm) to either D. farinae or D. pteronyssinus extract were performed with 0.01 ml of the mite food medium obtained from the same supplier. The results, submitted to the FDA by several manufacturers, were as follows: 12.5% of the intradermally tested patients were skin positive (intradermal test 4+). The results were similar for D. farinae and D. pteronyssinus.

The diagnosis of mite allergy is established by the allergy history and skin testing as described in the Dosage and Administration section of this product. The initial dose must be based on skin testing as described in the dosage and administration section of this product. Patients being started on this product should be reported to the physician's office if symptoms occur. As with all allergenic extracts, severe systemic reactions may occur and in certain individuals, especially those predisposed to anaphylaxis, these reactions may be life-threatening or cause death (11). Patients should be observed for at least 60 minutes following the injection. Emergency measures, as well as personnel trained in their use should be immediately available in the event of anaphylaxis reaction to this product. This product should never be injected intravenously. See also the IMPORTANT WARNINGS and ADVERSE REACTIONS sections below. Standardized mite extract is indicated for use in the diagnosis of patients with a history of mite allergy who have established sensitivity to house dust mites. Mitextract includes several species of mites found in homes (4,5).

INDICATIONS AND USAGE

Standardized mite extract is indicated for use in the diagnosis of patients with a history of allergy to mites or dust mite allergy. The use of mite extract for the above purposes should be made only by physicians with special familiarity and knowledge of allergy as described in a standard allergy textbook (10).

CONTRAINDICATIONS

Injections of mite extract should not be administered in the presence of disseminated intravascular coagulation or by a history of dust mite allergy. Immunotherapy should not be started in patients until a specific diagnosis of Type I allergy to mites is made by a physician based on skin testing with this product. Other contraindications include:

EXTREME SENSITIVITY TO MITE: Determined from previous anaphylaxis following skin testing, immunotherapy, or natural pressure.

AUTOIMMUNE DISEASE: Individuals with autoimmune disease may be at risk, due to the possibility of routine immunizations exacerbating symptoms of the underlying disease.

WARNINGs

Concentrated mite extract must be diluted with sterile diluent prior to first use on a patient for treatment or intradermal testing. All concentrations of allergenic extract are manufactured to assure high potency and therefore have the ability to cause serious systemic reactions, including death in sensitive patients (11). Patients should be informed of this risk and precautions should be discussed prior to initiating immunotherapy (see IMPORTANT WARNINGS below)

Adverse reactions to mite extract may be temporally withdrawn from patients or the dose adjusted downward if any of the following conditions exist: 1) severe symptomatic reactions of the skin and/or respiratory system manifested by fever; 2) exposure to massive amounts of allergen extract during the administration of allergenic extracts or for use under the direction of the physician.

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DOSAGE AND ADMINISTRATION

The U.S. reference extract has been assigned a potency of 10,000 AU/mL. Mitextract with a potency of 10,000 AU/mL in the United States. Mitextract is thought to differ slightly from U.S. reference mite extract available from the Center for Biologic Evaluation and Research, U.S. Food and Drug Administration. The U.S. reference extract should never be assigned a potency of 10,000 AU/mL based on quantitative skin testing (1).

CLINICAL PHARMACOLOGY

The mechanism for the pharmacologic action of allergenic extracts used diagnostically is based on the liberation of histamine and other substances following skin testing or resulting from the absorption antihistamine tablets should be free of such medication for 48 hours before testing. Non-sedating antihistamines, such as terfenadine and astemizole, may variably suppress the initial stage of anaphylaxis reactions to a variety of allergens for 48 hours after ingestion. The half-life of antihistamines, such as pheniramine and chlorpheniramine, may vary from one to three days, based on the degree of antihistaminic activity. Mitextract may be administered subcutaneously for hyposensitization to children ages 5 to 14 with adverse reactions limited to local discomfort, redness and swelling for one to two days (7).

Drug Interaction: Antihistamines and hydroxyzine can significantly inhibit the immediate skin test reaction (see Drug Interactions).

INFORMATION FOR PATIENTS: Because most serious reactions following the administration of allergenic extracts occur within 20 minutes of the injection, the patient should remain under observation for this period of time. The size of the local reaction to a mite extract is variable and is usually more than 1 mm. The mite extract must be diluted with sterile diluent prior to first use on a patient for treatment or intradermal testing. All concentrations of allergenic extracts are manufactured to assure high potency and therefore have the ability to cause serious systemic reactions, including death in sensitive patients (11). Patients should be informed of this risk and precautions should be discussed prior to initiating immunotherapy (see IMPORTANT WARNINGS below).

This product is intended for use by physicians who are experienced in the administration of allergenic extracts or for use under the guidance of an allergy specialist. The initial dose must be based on skin testing as described in the dosage and administration section of this product. Patients being started on this product should be reported to the physician's office if symptoms occur. As with all allergenic extracts, severe systemic reactions may occur and in certain individuals, especially those predisposed to anaphylaxis, these reactions may be life-threatening or cause death (11). Patients should be observed for at least 60 minutes following the injection. Emergency measures, as well as personnel trained in their use should be immediately available in the event of anaphylaxis reaction to this product. This product should never be injected intravenously. See also the IMPORTANT WARNINGS and ADVERSE REACTIONS sections below. Standardized mite extract is indicated for use in the diagnosis of patients with a history of mite allergy who have established sensitivity to house dust mites. Mitextract includes several species of mites found in homes (4,5).

MOYCARDIAL INFARCTION: Patients who have experienced a recent myocardial infarction may not be able to tolerate immunotherapy. The benefit-to-risk ratio must be carefully evaluated.

CHILDREN WITH NEPHROTIC SYNDROME: Children with nephrotic syndrome require careful consideration and probably should not receive immunotherapy due to a variety of seemingly unrelated events that may cause an exacerbation of nephrotic syndrome.

ADVERSE REACTIONS

Several systemic reactions usually occur within minutes and consist primarily of allergic symptoms such as generalized skin erythema, urticaria, pruritus, angioedema, rhinitis, wheezing, laryngeal edema and
hypotension, less commonly, nausea, emesis, abdominal cramps, diarrhea and uterine contractions and occur. Severe reactions may cause shock and loss of consciousness. Fatalities have occurred rarely (1). Systemic symptoms occur with frequency in different clinics. To some extent, the reaction rate is related to the type and dose of administered antigen and the clinical sensitivity of the patient. Despite all precautions, occasional reactions are unavoidable. 

**PREPARING DILUTIONS**

To prepare dilutions for intradermal skin tests and therapeutic use as shown in the table below, make a series of ten-fold dilutions starting with the 5,000 AU/mL or 10,000 AU/mL, as follows: add 1.0 mL of the concentrate to 9.0 mL of sterile diluent to make the 1:10 dilution; add 1.0 mL of the 1:10 dilution to 9.0 mL of sterile diluent to make the 1:100 dilution. Continue making dilutions as shown in the table below until the highest desired dilution is reached. The number of allergy units per mL in each dilution is shown in the table below.

**OVERDOSAGE**

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 or additional extract must not be given until all evidence of the reaction has disappeared. A systemic reaction following the injection of extract should be treated immediately with Epinephrine hydrochloride 1:1,000 aqueous, in an adult dose of 0.3 - 0.5 mL (or 0.01 mL per kg for children) administered subcutaneously. If the opposite arm is the immediate treatment of choice. A tourniquet should be placed above the site of the extract injection if the injection was given on the extremities. Antihistamines may offer relief of urticaria, associated skin reactions and gastrointestinal symptoms. Persistent wheezing may necessitate intravenous antimophylline treatment. For profound shock and hypotension intravenous fluids, vasopressors and oxygen also may be needed. Maintenance of an open airway is critical if upper airway obstruction is present. Corticosteroids may provide benefit if symptoms are prolonged or recurrent.

**DOSAGE AND ADMINISTRATION**

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. The product should be discarded if discoloration or particles are observed.

**DIAGNOSTIC USE**:

**Percutaneous Tests**:

The skin test concentration of 10,000 AU/mL in dropper vials is used for scratch or prick-puncture testing. Puncture tests performed with D. farinae extract on 5 persons sensitive to mite showed a mean diameter wheal of 7.8 mm ± 4.1 mm and mean diameter erythema of 33.7 mm ± 12.0 mm. Intradermal tests: Extract for intradermal testing should be prepared by diluting the 10,000 AU/mL stock concentrate in bulk vials with sterile saline with or without human serum albumin. Intradermal skin tests (0.05 mL) in persons highly sensitive to mite showed the following results:

**Table 1**

<table>
<thead>
<tr>
<th>ALLERGEN</th>
<th>NO. OF PERSONS</th>
<th>MEAN</th>
<th>RANGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>D. farinae</td>
<td>5</td>
<td>0.0040</td>
<td>0.0015-0.0124</td>
</tr>
<tr>
<td>D. pteronyssinus</td>
<td>10</td>
<td>0.0031</td>
<td>0.0001-0.1416</td>
</tr>
</tbody>
</table>

Intradermal tests should only be performed after a scratch or prick-puncture test has been administered with a negative result. Patients who do not react to a valid scratch or prick-puncture test should be tested intradermally with 0.02 mL of a 10 AU/mL (7.1000 v/v dilution of the 10,000 AU/mL concentrate). If this test is negative, a second intradermal test may be performed using a 100 AU/mL (7.1000 v/v dilution of the 10,000 AU/mL concentrate).

Skin tests are graded on the basis of the wheal and erythema response noted at 15 to 20 minutes. Wheal and erythema size may be recorded by actual measurement of the extent of both responses.

**THERAPEUTIC USE**:

The dosage of mite extract administered by subcutaneous injection is highly individualized and varies according to the degree of sensitivity of the patient, his clinical response and tolerance to the extract administered during the early phases of an injection regimen. In patients who appear to be highly sensitive by history and skin test, the initial injection of 0.05 mL of a 0.1 AU/mL dilution or an established by skin test titration. The amount of allergenic extract is increased in steps of not more than 50% - 100% of the previous amount, and the next increment is governed by the response to the last injection. Large local reactions which persist for longer than 24 hours are generally considered an indication for retesting the previous dose or reducing the dose. Any evidence of systemic reaction is an indication for a significant reduction (at least 50%) in the subsequent dose. The upper limits of doses are the same as previously described; however, doses larger than 0.2 mL of the concentrate may be painful due to the glycogen content of the extract. The optimal interval between doses of mite extract has not been definitely established. However, as is customarily practiced, injections are given one or two times per week until the maintenance dose of extract is reached.

The usual duration of treatment has not been established. A period of three to five years of injection therapy constitutes a common course of treatment. Children and older age patients appear to tolerate injections of allergen extract well, and no special recommendations need to be made for these groups.

**HOW SUPPLIED**

Extract of D. farinae and D. pteronyssinus containing 5,000 and 10,000 Allergy Units per mL is supplied in 50% glycerol v/v in 10 mL, 30 mL and 50 mL vials. Extract containing 10,000 Allergy Units per mL is supplied in 50% glycerol v/v in 5 mL dropper vials for scratch or prick-puncture testing. A 1:100 AU/mL vial size at a concentration of 2,500 AU/mL or 5,000 AU/mL for each vial. See DESCRIPTION above for the complete list of the active and inactive ingredients of this product.

**STORAGE AND HANDLING**

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

**REFERENCES**


**Date of Revision:** February 2013  C-10A