345014-H07

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use STANDARDIZED MITE EXTRACT (*Dermatophagoides farinae*), STANDARDIZED MITE EXTRACT (*Dermatophagoides pteronyssinus*), and STANDARDIZED MITE MIXTURE EXTRACT (*Dermatophagoides farinae* and *Dermatophagoides pteronyssinus*) safely and effectively. See full prescribing information for STANDARDIZED MITE EXTRACT (*Dermatophagoides farinae*), STANDARDIZED MITE EXTRACT (*Dermatophagoides pteronyssinus*), and STANDARDIZED MITE MIXTURE EXTRACT (*Dermatophagoides farinae and Dermatophagoides pteronyssinus*).

STANDARDIZED MITE EXTRACT (*Dermatophagoides farinae*)
STANDARDIZED MITE EXTRACT (*Dermatophagoides pteronyssinus*)
STANDARDIZED MITE MIXTURE EXTRACT (*Dermatophagoides farinae* and *Dermatophagoides pteronyssinus*)
Injection, for percutaneous, intradermal, or subcutaneous use.
Initial U.S. Approval: 1988

WARNING: ANAPHYLAXIS

See full prescribing information for complete boxed warning.

- **Standardized Mite Extract (*Dermatophagoides farinae*), Standardized Mite Extract (*Dermatophagoides pteronyssinus*), Standardized Mite Mixture Extract (*Dermatophagoides farinae* and *Dermatophagoides pteronyssinus*) can cause anaphylaxis, including anaphylactic shock and death. (5.1 Anaphylaxis)**
- **Do not administer to individuals with severe, unstable or uncontrolled asthma, history of severe systemic reaction to the allergen extract when administered for diagnosis or treatment, or with medical conditions that reduce the ability to survive anaphylaxis. (4 CONTRAINDICATIONS)**
- **Observe individuals for at least 30 minutes following administration. Emergency measures and healthcare providers trained in their use must be available in the event of a life-threatening reaction. (5.1 Anaphylaxis)**
- **Individuals with extreme sensitivity to these products, on an accelerated immunotherapy build-up, switching to another lot, receiving high doses of these products, or exposed to excessive amounts of dust mite may be at increased risk of anaphylaxis. (5.1 Anaphylaxis)**
- **These products may not be suitable for individuals who may be unresponsive to epinephrine or inhaled bronchodilators, such as those taking beta-blockers. (5.1 Anaphylaxis)**

----------INDICATIONS AND USAGE----------

Standardized Mite Extract (*Dermatophagoides farinae*), and Standardized Mite Extract (*Dermatophagoides pteronyssinus*) are skin tests indicated for:

- Diagnosis of patients with a clinical history of allergy to dust mite allergens. (1 INDICATIONS AND USAGE)

Standardized Mite Extract (*Dermatophagoides farinae*), Standardized Mite Extract (*Dermatophagoides pteronyssinus*), Standardized Mite Mixture Extract (*Dermatophagoides farinae* and *Dermatophagoides pteronyssinus*) (standardized mite extracts) are immunotherapies indicated for:

- Mitigation of mite-induced allergic asthma, rhinitis and conjunctivitis in patients with hypersensitivity to dust mites based on clinical history and confirmation by skin or *in vitro* testing for allergen-specific IgE antibodies. (1 INDICATIONS AND USAGE)

----------DOSAGE AND ADMINISTRATION----------

For percutaneous, intradermal, or subcutaneous use only.
Administration:

- Percutaneous for diagnostic testing
- Intradermal for diagnostic testing
- Subcutaneous for immunotherapy

See full prescribing information for details on dosing and dilution preparation. (2 DOSAGE AND ADMINISTRATION)

----------DOSAGE FORMS AND STRENGTHS----------

Injection. Standardized mite extracts are labeled in Allergenic Units per milliliter (AU/mL). (11)
Refer to the vial label for the product concentration. (16)

- For percutaneous testing, standardized mite extract stock concentrates containing 30,000 AU/mL of *D. farinae* or *D. pteronyssinus* are supplied in 5 mL dropper vials. (11)
- For intradermal testing, standardized mite extract stock concentrates containing 30,000 AU/mL of *D. farinae* or *D. pteronyssinus* are supplied in 10 mL and 30 mL multi-dose vials. (11)
- For immunotherapy, standardized mite extract stock concentrates containing a total of 10,000 or 30,000 AU/mL of *D. farinae* or *D. pteronyssinus* or 5,000 or 15,000 AU/ml of an equal mixture of *D. farinae* and *D. pteronyssinus* are supplied in 10, 30, and 50 mL multiple-dose vials. (11)

----------CONTRAINDICATIONS----------

- Severe, unstable or uncontrolled asthma. (4 CONTRAINDICATIONS)
- History of any severe systemic reaction to the allergen extract when administered for diagnosis or treatment. (4 CONTRAINDICATIONS)
- Medical conditions that reduce the ability to survive anaphylaxis. (4 CONTRAINDICATIONS)

----------WARNINGS AND PRECAUTIONS----------

The risk of anaphylaxis may be increased in the following situations (5.1):

- Extreme sensitivity to standardized mite extracts.
- Receipt of an accelerated build-up schedule.
- Change from one lot of a particular standardized mite extract to another lot of the same standardized mite extract.
- Receipt of high doses of the standardized mite extracts.
- Exposure to excessive amounts of dust mite.

----------ADVERSE REACTIONS----------

Common adverse reactions reported for standardized mite extracts are:

- Local adverse reactions, occurring in 26 to 82 % of all patients who receive subcutaneous immunotherapy (e.g., erythema, swelling, pruritus, tenderness and pain at the injection site). (6 ADVERSE REACTIONS)
- Systemic adverse reactions, occurring in ≤ 7 % of patients who receive subcutaneous immunotherapy (e.g., generalized skin erythema, urticaria, pruritus, angioedema, rhinitis, wheezing, laryngeal edema, hypotension, and shock). Systemic reactions may be fatal. (6 ADVERSE REACTIONS)

To report SUSPECTED ADVERSE REACTIONS, contact Jubilant HollisterStier at 1-800-495-7437 or Adverse.Reactions@jubl.com; or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------DRUG INTERACTIONS----------

Certain medications may decrease skin test wheal and erythema responses, including antihistamines (7.1 ***Antihistamines***), topical corticosteroids/topical anesthetics (7.2 ***Topical Corticosteroids and Topical Anesthetics***), tricyclic antidepressants (7.3 ***Tricyclic Antidepressants***).

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 02/2024

FULL PRESCRIBING INFORMATION: CONTENTS

Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

WARNING: ANAPHYLAXIS

- Standardized Mite Extract (*Dermatophagoides farinae*), Standardized Mite Extract (*Dermatophagoides pteronyssinus*), Standardized Mite Mixture Extract (*Dermatophagoides farinae* and *Dermatophagoides pteronyssinus*) can cause anaphylaxis, including anaphylactic shock and death.[1] (5.1 **Anaphylaxis**)
- Do not administer to individuals with:
  - severe, unstable or uncontrolled asthma;
  - history of severe systemic reaction to the allergen extract when administered for diagnosis or treatment;
  - medical conditions that reduce the ability to survive anaphylaxis. (4 **CONTRAINDICATIONS**)
- Observe individuals for at least 30 minutes following administration. Emergency measures and healthcare providers trained in their use must be available in the event of a life-threatening reaction. (5.1 **Anaphylaxis**)
- Individuals with extreme sensitivity to these products, on an accelerated immunotherapy build-up, switching to another lot, receiving high doses of these products, or exposed to similar allergens may be at increased risk of anaphylaxis. (5.1 **Anaphylaxis**)
- These products may not be suitable for individuals who may be unresponsive to epinephrine or inhaled bronchodilators,

1 INDICATIONS AND USAGE

Standardized Mite Extract (*Dermatophagoides farinae*), and Standardized Mite Extract (*Dermatophagoides pteronyssinus*) are skin tests indicated for:

- Diagnosis of patients with a clinical history of allergy to dust mite allergens.[8, 9, 10, 13]

Standardized Mite Extract (*Dermatophagoides farinae*), Standardized Mite Extract (*Dermatophagoides pteronyssinus*), Standardized Mite Mixture Extract (*Dermatophagoides farinae* and *Dermatophagoides pteronyssinus*) are immunotherapies indicated for:

- Mitigation of mite-induced allergic asthma, rhinitis and conjunctivitis in patients with hypersensitivity to dust mites based on clinical history and confirmation by skin or *in vitro* testing for allergen-specific IgE antibodies.[11, 12]

2 DOSAGE AND ADMINISTRATION

2.1 Preparation for Administration

Appearance is clear to slightly opalescent. Standardized mite extracts should be a yellowish to light brown solution. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Discard solution if either of these conditions exist.

Standardized mite extracts diluted with Albumin Saline with Phenol (0.4 %) (stabilized diluent) may be more potent than standardized mite extracts diluted with diluents that do not contain albumin. When switching from non-stabilized to stabilized diluent, consider less concentrated initial dilutions for both intradermal testing and immunotherapy.

Different formulations, preparations, or new lots of standardized mite extracts are not interchangeable. Dosage should be adjusted appropriately when formulations, preparations, or lots of standardized mite extracts are changed [see *Immunotherapy (2.3* Immunotherapy*)* and *Dosage Forms and Strengths (3* DOSAGE FORMS AND STRENGTHS*)*].

Standardized mite extracts may be prepared for intradermal (diagnosis) or subcutaneous (immunotherapy) administration by diluting stock concentrates.

- For diluent, use sterile albumin saline with phenol or sterile normal saline with phenol.
- Dilute stock concentrates by a minimum of 100-fold for intradermal testing. Dilutions of 1,000-fold or greater are appropriate starting points for patients with a clinical history of adverse reaction.

To prepare dilutions for intradermal testing and immunotherapy, start with a stock concentrate, and prepare a ten-fold (1:10) dilution by adding 0.5 mL of concentrate to 4.5 mL of sterile aqueous diluent. Prepare subsequent dilutions in a similar manner (see Table 1).

Table 1: 10-fold Dilution Series for Standardized Mite Extracts Labeled 10,000 AU*/mL and 30,000 AU*/mL

Dilution**	Extract	Milliliters of Diluent	Dilution Strength AU/mL	Dilution Strength AU/mL
0	Concentrate	0	10,000	30,000
1	0.5 mL Concentrate	4.5	1,000	3,000
2	0.5 mL Dilution 1	4.5	100	300
3	0.5 mL Dilution 2	4.5	10	30
4	0.5 mL Dilution 3	4.5	1	3
5	0.5 mL Dilution 4	4.5	0.1	0.3
6	0.5 mL Dilution 5	4.5	0.01	0.03
7	0.5 mL Dilution 6	4.5	0.001	0.003

* Allergy Units

** Store extract dilutions at 2 °C to 8 °C (36 °F to 46 °F).

2.2 Diagnostic Testing

For percutaneous and intradermal use only.

Use Standardized Mite Extract (*Dermatophagoides farinae)* or Standardized Mite Extract *(Dermatophagoides pteronyssinus*) to identify patients who exhibit an allergic response to either species of dust mite (*D. farinae* or *D. pteronyssinus*). False positive reactions may occur. A positive skin test reaction must be interpreted in the context of the individual's clinical history and known exposure to the allergen.

- Administer percutaneous tests prior to administration of intradermal tests.
- Do not use Standardized Mite Mixture Extract (*Dermatophagoides farinae* and *Dermatophagoides pteronyssinus*) for diagnostic testing because a positive reaction would not permit identification of the specific mite allergen that elicited the reaction. In addition, a negative reaction would fail to indicate whether an individual component allergen would have elicited a positive reaction at full strength.

Percutaneous Skin Testing

Dose

Unless an individual is suspected to be at greater risk for anaphylaxis, the initial starting dose is 1 drop (approximately 0.05 mL) of concentrated standardized mite extract (30,000 AU/mL). For individuals suspected to be at greater risk for anaphylaxis (for example, as indicated by a history of allergen-induced anaphylaxis), initiate percutaneous testing with 1 drop of a diluted standardized mite extract, if negative retest with the next higher concentration(s). Doses should be administered 15-20 minutes apart [see *Preparation for Administration (2.1* Preparation for Administration*)*].

Administration

Place one drop (approximately 0.05 mL) of standardized mite extract on the skin and using a skin test device, such as a sterile needle, lancet, or bifurcated needle, pierce through the drop into the skin with a slight lifting motion.

For self-loading devices refer to the manufacturer's product instructions.

Include a positive histamine skin test control to identify patients whose recent use of drugs with antihistamine activity may result in a false negative skin test. [see *Drug Interactions (7* DRUG INTERACTIONS*.1)*].

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

Interpreting Results

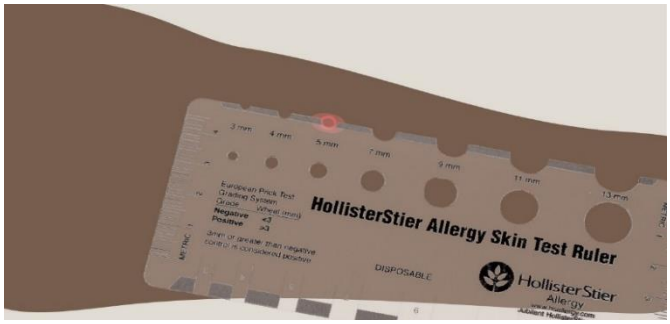
Measure and record skin test responses 15-20 minutes after exposure.[22] Individual patient reactivity can vary with time, allergen potency, and/or immunotherapy, as well as testing technique. The most reliable method of recording a skin test reaction is to measure the largest diameter of both wheal and erythema. While some correlation exists between the size of the skin test reaction and the degree of sensitivity, other factors should be considered in the diagnosis of allergy to specific allergens (see Figure 1).

- The negative control (50 % glycerin solution) response should measure < 3 mm wheal and ≤ 10 mm flare.
- Response to the positive control should be at least 3 millimeters larger than the response to the negative control.

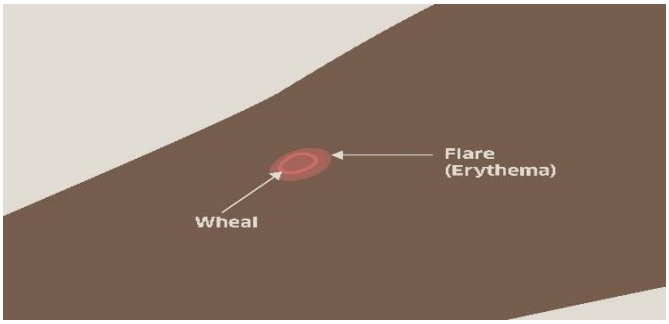
- If either the response to the histamine positive control or to the negative control do not meet the criteria above for acceptable wheal size, the results for the allergenic extracts tested at the same time should be considered invalid and be repeated.

Figure 1: Measurement of Wheal and Flare

Use a paper or plastic millimeter skin reaction guide as shown below.



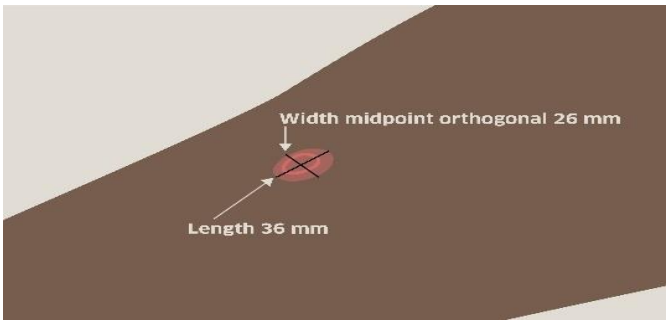
Fifteen minutes after application of the skin test, measure the length and midpoint orthogonal width of each flare and wheal from the inner edge of the reaction.



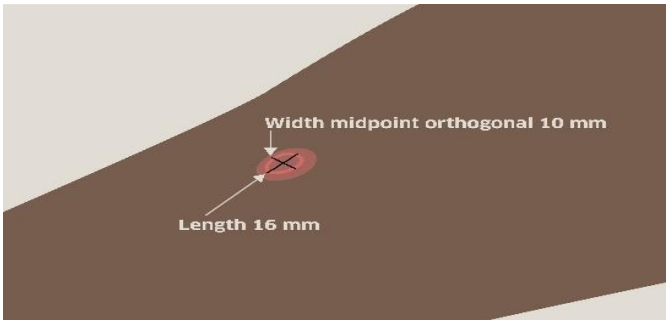
The wheal is a smooth, slightly elevated area which is redder or paler than the surrounding skin. The flare is the red outermost zone of the skin test reaction.

The length of the skin test is defined as the largest diameter and the width of the skin test is defined as the diameter perpendicular to the length at its midpoint. Consider the wheal and flare as separate entities. First, measure the flare and then independently measure the wheal.

Measuring the Flare



Measuring the Wheal



The average diameter measurement in the example above of the flare is (26 mm + 36 mm)/2 = 31 mm and the average diameter of the wheal is (10 mm + 16 mm)/2 = 13 mm.

Intradermal *(Intracutaneous)* Skin Testing

Always perform percutaneous tests prior to intradermal skin tests.[22]

Dose
For patients with negative or equivocal percutaneous testing for whom there is a high index of suspicion of dust mite allergy, intradermal testing may be performed with 0.02 to 0.05 mL of a 30 AU/mL extract solution. [see *Preparation for Administration (2.1* Preparation for Administration)]. If this test is negative, a second intradermal test may be performed with 0.02 to 0.05 mL of a 300 AU/mL extract solution.

Administration
Intradermally inject the dose of the diluted allergenic extract using a 1 mL syringe.

Include a positive histamine control at intradermal strength to identify patients whose recent use of drugs with antihistamine activity may result in a false negative skin test. [see *Drug Interactions (7.1)*].

Include an aqueous buffer negative control (Sterile Albumin Saline with Phenol, Sterile Buffered Saline with Phenol) to detect false positive responses, which can occur when the patient has a non-specific reaction to the diluent or due to dermographism.

Interpreting Results
Measure wheal responses for the histamine positive control test and allergen tests at 15-20 minutes after injection. Refer to Figure 1 for the measurement of wheal and flare.

- Response to the positive control should be at least 3 millimeters larger than the response to the negative control.
- The negative control (sterile aqueous diluent) response should measure < 3 mm wheal and ≤ 10 mm flare (erythema).
- If either the response to the histamine positive control or to the negative control do not meet the criteria above for acceptable wheal size, the results for the allergenic extracts tested at the same time should be considered invalid and be repeated.

2.3 Immunotherapy

For subcutaneous use only.

Subcutaneous injections for immunotherapy should be prepared by dilution of stock concentrate. See Table 1 for dilution preparation.

Administration
Administer immunotherapy by subcutaneous injection in the lateral aspect of the arm or thigh. Do not inject directly into any blood vessels.

Most adverse reactions occur within 30 minutes after injection. Therefore, observe patients for at least 30 minutes.[23]

Dose Build-up
Dosing of standardized mite extracts for allergen immunotherapy is highly individualized. The initial dose should be based on the patient's percutaneous skin test reactivity and clinical history. The initial dose is typically 0.05 mL of a 0.01 to 0.03 AU/mL dilution. In patients who appear to be exquisitely sensitive by skin test and history, consider a lower initial dose such as 0.05 mL of a 0.001 to 0.003 AU/mL dilution. The dose 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. Dosing is increased in increments until 0.5 mL is reached, following which 0.05 mL is administered from the next most concentrated allergen extract or allergen mixture vial in the dilution series. Injections are typically given one or two times per week until the maintenance dose is reached.

- Any evidence of a systemic reaction to immunotherapy is an indication for a significant reduction (at least 75%) in the subsequent dose or the cessation of immunotherapy. Proceed cautiously in subsequent dosing if immunotherapy is continued.
- Repeated systemic reactions, even of a mild nature, are sufficient reason for the cessation of further attempts to increase the reaction-causing dose.
- The volume of solution for immunotherapy may produce increased discomfort in pediatric individuals. In order to achieve the total dose required, the volume of the dose may be divided into more than one injection per visit.

Maintenance Dose Selection and Intervals

Select a maintenance dose based on the patient's clinical response and tolerance.

- Typical maintenance dose is 500-2,000 AU.[23] Occasionally, higher doses are necessary to relieve symptoms.
- The two mite species are highly cross-reactive. Therefore, consider the total Allergy Units when determining the target maintenance dose.
- Maintenance doses larger than 0.2 mL of undiluted allergen extract are rarely administered because an extract in 50% glycerin may cause patient discomfort upon injection.
- After the maintenance dose is achieved, increase the injection interval to 2 weeks, then 3 weeks, and finally 4 weeks as tolerated. The optimal interval between maintenance doses of allergenic extract varies among individuals. Administer the maintenance dose at a given interval three or four times before further increasing the interval to ensure that no reactions occur. Protection may be lost rapidly if the interval between doses is more than 4 weeks.

Dosage Modification for Immunotherapy

Withhold immunotherapy and/or reduce dosage, if any of the following conditions exist:

- Severe symptoms of rhinitis and/or asthma.
- Infection accompanied by fever.

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

In situations prompting dose reduction, a cautious increase in dose can be attempted once the reduced dose is tolerated. The dose 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.

Prolonged period has elapsed since the last injection: Patients may lose tolerance for allergen injections during prolonged intervals (> 4 weeks) between doses. The duration of tolerance is an individual characteristic and varies from patient to patient. In general, the longer the lapse in the injection schedule, the greater dose reduction required.

Changing to a different lot of standardized extract: All extracts can lose allergenic activity over time and extracts vary in allergenic activity. Two different lots of extract could differ substantially in allergenic activity, even if they are the same formula and concentration. The volume of the first dose from the new vial should not exceed 50% of the previous dose. Do not use extracts beyond their expiry date.

Changing to an extract from a 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 new extract when the extract is the same formula and dilution as the one previously used. In general, a volume dose reduction to 50% of the previous product dose is adequate, but each situation must be evaluated separately considering the patient's history of sensitivity, tolerance of previous injections, and other factors. If the patient tolerates the 50% decrease, then raise the next dose to the previous tolerated dose amount. To re-establish the maintenance dose the starting interval between doses should not be greater than one week.

Changes made in the extract concentrate formula: Changes other than those listed above such as a difference in extracting fluid (e.g., change from non-glycerin extracts to 50% glycerin extracts), combining two or more stock concentrates, or any other change can affect a patient’s tolerance of the treatment. Extra dilutions are recommended whenever starting a revised formula. The greater the change, the greater the number of dilutions required.[23]

Duration of Treatment

The duration of treatment for immunotherapy has not been established. A period of three to five years of injection therapy constitutes an average minimum course of treatment. Evaluate patients for treatment response at least every 6 to 12 months while they receive immunotherapy. The decision to continue or stop immunotherapy must be individualized.[23]

3 DOSAGE FORMS AND STRENGTHS

Injection. Standardized mite extracts are labeled in Allergenic Units per milliliter (AU/mL) [see *Description* (11)]. Refer to the vial label for the product concentration [see *How Supplied/Storage and Handling* (11)].

- For percutaneous testing, standardized mite extract stock concentrates containing 30,000 AU/mL of *D. farinae* or *D. pteronyssinus* are supplied in 5 mL dropper vials [see *Description* (11)].
- For intradermal testing, standardized mite extract stock concentrates containing 30,000 AU/mL of *D. farinae* or *D. pteronyssinus* are supplied in 10 mL and 30 mL multi-dose vials [see *Description* (11)].
- For immunotherapy, standardized mite extract stock concentrates containing a total of 10,000 or 30,000 AU/mL of *D. farinae* or *D. pteronyssinus* or 5,000 or 15,000 AU/mL of an equal mixture of *D. farinae* and *D. pteronyssinus* are supplied in 10, 30, and 50 mL multiple-dose vials [see *Description* (11)].

4 CONTRAINDICATIONS

Standardized mite extracts are contraindicated in individuals with the following conditions:

- Severe, unstable or uncontrolled asthma.
- History of any severe systemic reaction to the allergen extract when administered for diagnosis or treatment.
- Medical conditions that reduce the ability to survive anaphylaxis.

5 WARNINGS AND PRECAUTIONS

5.1 Anaphylaxis

Anaphylaxis, which may lead to death, can occur in individuals following the administration of standardized mite extracts, particularly in the following situations [see *Adverse Reactions (*6 ADVERSE REACTIONS*)*]: [18, 19, 20, 21]

- Extreme sensitivity to the standardized mite extracts.
- Receipt of an accelerated build-up schedule.
- Change from one lot of a particular standardized mite extract to another lot of the same standardized mite extract.
- Receipt of high doses of the standardized mite extracts.
- Exposure to excessive amounts of dust mite.

Standardized mite extracts may not be suitable for individuals who may be unresponsive to epinephrine or inhaled bronchodilators, such as those taking beta-blockers.

Medications to treat systemic reactions, as well as emergency equipment should be available for immediate use. Administer standardized mite extracts in a healthcare setting under the supervision of a healthcare provider prepared to manage anaphylaxis. Individuals should remain in the provider's office for a minimum of 30 minutes after receiving an injection of standardized mite extracts, so that any adverse reaction can be observed and appropriately managed.

6 ADVERSE REACTIONS

Common adverse reactions reported for standardized mite extracts are:

- Local reactions occurred in 26 to 82 % of all patients who received subcutaneous allergen immunotherapy, at the injection site (e.g., erythema, swelling, pruritus, tenderness and pain).[23]
- Systemic adverse reactions, occurred in ≤ 7 % of patients who received subcutaneous allergen immunotherapy (e.g., generalized skin erythema, urticaria, pruritus, angioedema, rhinitis, wheezing, laryngeal edema, hypotension, and shock).[24] Systemic reactions may be fatal.[1, 23]

No clinical trials of standardized mite extracts have been conducted.

Published studies of allergenic extracts report systemic reactions occurring in fewer than 1 % in patients receiving conventional immunotherapy and greater than 36 % in patients receiving rush immunotherapy.[1, 14, 26, 27] Most systemic reactions occurred within 30 minutes of injection. However, systemic reactions have been reported to occur up to 2 hours after the final injection with rush schedules. Some reactions have occurred up to 6 hours after skin tests or immunotherapy.[23, 24, 28]

7 DRUG INTERACTIONS

7.1 Antihistamines

Do not perform skin testing with standardized mite extracts within 3 to 10 days of first-generation H1-histamine receptor blockers (e.g., clemastine, diphenhydramine) and second-generation antihistamines (e.g., loratadine, fexofenadine) being used. These products suppress histamine skin test reactions and could mask a positive response.[2, 22, 23]

7.2 Topical Corticosteroids and Topical Anesthetics

Topical corticosteroids may suppress skin reactivity; therefore, discontinue use at the skin test site for at least 2 to 3 weeks before skin testing.[2, 3] Avoid use of topical local anesthetics at skin test sites because they can suppress flare responses.[4, 22, 23]

7.3 Tricyclic Antidepressants

Tricyclic antidepressants, such as doxepin, can have potent antihistamine effects and may alter skin test results. Allow 7 to 14 days after discontinuation of tricyclic medication prior to skin testing.[17, 22, 23]

8 USES IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4 % and 15 to 20 %, respectively. There are no human or animal data to establish the presence or absence of standardized mite extracts associated risks during pregnancy.[16]

8.2 Lactation

Risk Summary

It is not known whether standardized mite extracts are present in human milk. Data are not available to assess the effects of these extracts on the breastfed child or on milk production/excretion. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for standardized mite extracts and any potential adverse effects on the breastfed child from the extracts or from the underlying maternal condition.

8.4 Pediatric Use

For use of these products in children younger than 5 years of age, consideration should be given to the patient's ability to comply and cooperate with receipt of the product and the potential for difficulty in communicating with the child regarding systemic reactions.[13, 23]

The volume of a dose for immunotherapy may need to be divided for pediatric patients [see *Immunotherapy (2.3* Immunotherapy*)*].

8.5 Geriatric Use

Data are not available to determine if subjects 65 years of age and older respond differently to allergen immunotherapy than younger subjects.[15]

11 DESCRIPTION

Standardized mite extracts are injections for percutaneous, intradermal, or subcutaneous use labeled in Allergy Units per milliliter (AU/mL).[5] Standardized Mite Extract (*Dermatophagoides farinae*), Standardized Mite Extract (*Dermatophagoides pteronyssinus*), and Standardized Mite Mixture Extract (*Dermatophagoides farinae* and *Dermatophagoides pteronyssinus*) are sterile solutions containing the extractables of *D. farinae* and/or *D. pteronyssinus*, 0.5 % sodium chloride, 0.275 % sodium bicarbonate, and 50 % glycerin by volume as a preservative. Source material for the extracts is the whole bodies of the mites. The mites are each grown on a medium of brine shrimp eggs and wheat germ, and are handled and cleaned in a manner such that the maximum carryover of the medium components is less than 1%. The medium contains no material of human origin.

Standardized Mite Extract (*Dermatophagoides farinae*) and Standardized Mite Extract (*Dermatophagoides pteronyssinus)* concentrates (stock concentrates) containing 30,000 AU/mL are supplied in dropper vials for percutaneous testing. Stock concentrates are also available in multiple-dose vials containing 10,000 AU/mL and 30,000 AU/mL to be diluted for intradermal testing and immunotherapy.

Standardized Mite Mixture Extract (*Dermatophagoides farinae* and *Dermatophagoides pteronyssinus*), is a mixture of the two mite species, in equal parts, resulting in *D. pteronyssinus* at 15,000 AU/mL and *D. farinae* at 15,000 AU/mL is available for therapeutic use. A mixture of the two species is also available at 5,000 AU/mL each species.

The potency of each lot of standardized mite extract is determined by comparison to the US reference preparation (10,000 AU/mL) provided by the Center for Biologics Evaluation and Research of the FDA. The relative potency of each extract is determined by ELISA inhibition and labeled in AU/mL.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The mechanisms of action of allergen immunotherapy have not been fully established.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

No studies in animals have been performed to evaluate carcinogenicity, mutagenicity or impairment of fertility.

14 CLINICAL STUDIES

Clinical studies that address the efficacy of immunotherapy are available.[6,7] Specific immunotherapy with allergenic extracts is helpful in reducing symptoms associated with exposure to the offending allergens. A summary of effectiveness by the Panel on Review of Allergenic Extracts, an advisory committee to the U.S. Food and Drug Administration, has been published.[25]

15 REFERENCES

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16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

Standardized mite extracts are supplied as 50 % glycerin stock concentrates labeled in Allergenic Units per Milliliter (AU/mL) and provided in 10 milliliter, 30 milliliter and 50 milliliter vials for use in percutaneous and intradermal skin testing and subcutaneous immunotherapy. These extracts may also be supplied in 5 milliliter dropper vials for percutaneous testing only. These products are supplied as listed in Table 2.

Table 2: Available Products

Available Products Name Allergenic Extracts	NDC	Vial Size
Standardized Mite, *Dermatophagoides farinae* 10,000 AU/mL	65044-6723-2	10 mL
Standardized Mite, *Dermatophagoides farinae* 10,000 AU/mL	65044-6723-4	50 mL
Standardized Mite, *Dermatophagoides farinae* 30,000 AU/mL	65044-6720-1	5 mL
Standardized Mite, *Dermatophagoides farinae* 30,000 AU/mL	65044-6720-2	10 mL
Standardized Mite, *Dermatophagoides farinae* 30,000 AU/mL	65044-6720-3	30 mL
Standardized Mite, *Dermatophagoides pteronyssinus* 10,000 AU/mL	65044-6695-2	10 mL
Standardized Mite, *Dermatophagoides pteronyssinus* 10,000 AU/mL	65044-6695-4	50 mL
Standardized Mite, *Dermatophagoides pteronyssinus* 30,000 AU/mL	65044-6692-1	5 mL
Standardized Mite, *Dermatophagoides pteronyssinus* 30,000 AU/mL	65044-6692-2	10 mL
Standardized Mite, *Dermatophagoides pteronyssinus* 30,000 AU/mL	65044-6692-3	30 mL
Standardized Mite Mix, *Dermatophagoides farinae and Dermatophagoides pteronyssinus* 5,000 AU/mL (each species)	65044-6691-2	10 mL
Standardized Mite Mix, *Dermatophagoides farinae and Dermatophagoides pteronyssinus* 5,000 AU/mL (each species)	65044-6691-4	50 mL
Standardized Mite Mix, *Dermatophagoides farinae and Dermatophagoides pteronyssinus* 15,000 AU/mL (each species)	65044-6690-2	10 mL
Standardized Mite Mix, *Dermatophagoides farinae and Dermatophagoides pteronyssinus* 15,000 AU/mL (each species)	65044-6690-3	30 mL

16.2 Storage and Handling

Store extracts at 2 °C to 8 °C (36 °F to 46 °F).

17 PATIENT COUNSELING INFORMATION

Instruct patients to remain in the office under observation for a minimum of 30 minutes after an injection or longer, if deemed necessary for the individual.

Inform patients that reactions may occur more than 30 minutes after skin testing or an injection.

Instruct patients to recognize the following symptoms as systemic adverse reactions and seek emergency medical care right away if any of these occur:

- 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:
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U.S. Lic. No. 1272
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