Two distinct strengths and a variety of vial sizes let you choose what best fits the needs of your practice...and your patients.

<table>
<thead>
<tr>
<th>ITEM NO.</th>
<th>DESCRIPTION</th>
<th>UNIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>6691</td>
<td>Standardized Mite Mix, D. pteronyssinus and D. farinae</td>
<td>Various, 10,000 AU/mL Concentration</td>
</tr>
<tr>
<td>6692</td>
<td>Standardized Mite, D. pteronyssinus</td>
<td>Various, 30,000 AU/mL Concentration</td>
</tr>
<tr>
<td>6720</td>
<td>Standardized Mite, D. farinae</td>
<td></td>
</tr>
</tbody>
</table>

HollisterStier grows mites in our own facilities according to our exacting standards, allowing us to control the product at every step of the process. Our manufacturing plant is regulated by both CBER and CDER.

**Two Strengths. Maximum Flexibility.**

- Effective diagnosis and treatment mean you reach and benefit more patients. Studies have shown that puncture skin testing with D. farinae at 30,000 AU/mL identified more than twice as many mite sensitive patients when compared to 10,000 AU/mL.¹ We offer both to give you more options.

- Available in 10,000 AU/mL and 30,000 AU/mL to help you meet immunotherapy guidelines.

- Also available in a variety of vial sizes, meaning you can match both strength and size to best meet your needs.

- Like all of our glycerinated antigens, our mite doesn’t contain phenol...which can denature the proteins in allergenic extracts.²

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**WARNING Important Safety Information**

(See full prescribing information for complete boxed warning.)

This product is intended for use only by licensed medical personnel experienced in administering allergenic extracts and trained to provide immediate emergency treatment in the event of a life-threatening reaction. Allergenic extracts may potentially elicit a severe life-threatening systemic reaction, rarely resulting in death. Therefore, emergency measures and personnel trained in their use should be available immediately in the event of such a reaction. Patients should be instructed to recognize adverse reaction symptoms and cautioned to contact the physician’s office if symptoms occur. Standardized glycerinated extracts may be more potent than regular extracts and therefore, are not directly interchangeable with non-standardized extracts, or other manufacturers’ products. This product should never be injected intravenously. Refer to the package insert for full prescribing information.

¹ See footnotes on reverse
Footnotes

1 Jones, J. and Wallen, N. (1991). Comparison of puncture skin test (PST) reactivity to standardized D. farina (DF) extracts at 30,000 AU/mL (30k) and 10,000 AU/mL (10k). AAAAI.


Adverse reactions on our products can be reported by calling 800-495-7437, or by emailing adversereactions@jhs.jubl.com. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 800-FDA-1088.
INSTRUCTIONS AND DOSAGE SCHEDULE

ALLERGIC EXTRACTS

STANDARDIZED MITES

342014 H06

Printed in U.S.A.
Rev. 02/18

Jubilant HollisterStier, LLC
Spokane, WA 99207

U.S. Lic. No. 1272

DESCRIPTION: (CBER) of the Food and Drug Administration.

3. Concentrate. Concentrate label terminology applies to allergenic extract mixtures where the individual allergens being combined vary in strength or the designation of strength.

4. Pregnancy

Long-term studies in animals have not been conducted with allergenic extracts to determine their potential for carcinogenicity, mutagenicity or impairment of fertility.

2. Systemic Reactions

Some reactions are likely to be severe, requiring emergency resuscitation, and may produce irreversible or fatal consequences. Therefore, emergency resuscitation measures and personnel trained in their use should be immediately available.

5. Adverse Events

Individuals allergic to spider venom may experience life-threatening reactions, including anaphylaxis, urticaria, angioedema, or respiratory distress, which can be rapidly fatal. In cases of severe systemic reactions, administration of epinephrine should be administered and personnel trained in the use of emergency resuscitation equipment should be immediately available. 

INJECTION: 0.5 to 1 mL of 0.1% epinephrine hydrochloride intramuscularly or subcutaneously opposite the arm. Lose the vial once at least 15 minutes. Do not connect arterial blood flow with the torrent. Adverse Reactions: 0.05-0.1 mL for 7 mg of epinephrine sulfate.

injection is recommended. Intramuscular or intravenous injections may produce large local reactions or be excessively painful. After INSERTING NEEDLE SUBCUTANEOUSLY, BUT BEFORE INJECTING, ALWAYS WITHDRAW THE PLUNGEBEFORE IF BLOOD APPEARS IN THE SYRINGE, CHANGE NEEDLE AND GIVE THE INJECTION IN ANOTHER SITE.

IF CHANGING TO A DIFFERENT LOT OF STANDARDIZED EXTRACT: Even though it is the same formula and concentration, the first dose of the new extract should not exceed 50% of the last administered dose prior to the previous extract.

IF THE STANDARDIZED EXTRACT PREVIOUSLY USED WAS FROM ANOTHER MANUFACTURER: Since manufacturing processes and sources of raw materials differ among manufacturers, the interchangeability of extracts from different manufacturers cannot be ensured. The starting dose of the standardized glycerinated extract therefore should greatly decrease in the latter case (see below). The maximum total dose for any skin test using serial dilutions of the extract. In highly sensitive subjects, the skin test method may be preferable. See DOSE ADMINISTRATION AND ADVERSE REACTIONS Sections.

IF PROLONGED TIME OF THE NEW EXTRACT ELAPSED SINCE THE LAST INJECTION: Patients may be less tolerant for antigen injections during prolonged periods between doses. The duration of tolerance is critical and it is possible that the therapeutic effect of the injectate may be lost. Should the interval be longer than 12 weeks, the therapeutic dose should be reinstated. If the interval is less than 12 weeks, the dose may be increased by 50% at each injection. DILUTE IF THE PREVIOUS EXTRACT WAS NOT-STANDARDIZED: Standardized extracts may be more potent than non-standardized extracts. Initiate therapy as though the patient had not received immunotherapy previously, and be prepared to reduce dosage during the initial stages of treatment. Immunotherapists should be informed of this, and the patient should be discussed prior to immunotherapy. (See PRECAUTIONS below). Severe systemic reactions should be treated as indicated in the ADVERSE REACTIONS Section.

PHYSICIAN

Some erythema, swelling or pruritus at the site of injection are common, the extent varying with the patient. Such reactions should not be considered significant unless they persist for at least 24 hours. Local reactions should be evaluated for possible atopy, and not misinterpreted as an allergic reaction.

2. Systemic Reactions

There are no current studies on sensitization of the allergenic extract components in human milk, or of effect on the nursing infant. Because many drugs are excreted in human milk, caution should be exercised when allergenic extracts are administered to a nursing woman.

6. Pediatric Use

Among the reasons for which a patient might request treatment are: (1) the presence of atopy, (2) severe symptoms of rhinitis and/or asthma; (3) infection or flu accompa-

Allergenic extract should be temporarily withheld from patients or the dose adjusted downward if any of the following conditions exist: (1) severe symptoms of rhinitis and/or asthma; (2) infection or flu accompa-

sary antigens and, in the latter case, in the omission of a needed allergen. Allergens to which a patient is extremely sensitive should not be included in treatment mixes with allergens to which there is much

proposed schedule would be the pattern required by the patient. VIDA testing is the most sensitive measurement of bronchial hyperactivity. It is not a substitute test for skin testing.

2. Systemic Reactions

The reactions from immunotherapy can be expected to be the same in elderly patients as in younger ones. Elderly patients may be more likely to be on medication that could block the effect of ephinephrine on the autonomic nervous system or on the cardiovascular system, or they could be more sensitive to the cardiovascular effect of ephinephrine because of pre-existing cardiovascular disease.

1. General

Easily-exchanged antigenic material may produce a patient's immunologic response, which may be less than the original antigenic material. In general, the patient's response to the final product will be less than the response to the total original antigens. Immunotherapists should be informed of this, and the patient should be discussed prior to immunotherapy. (See PRECAUTIONS below). Severe systemic reactions should be treated as indicated in the ADVERSE REACTIONS Section.

2. Systemic Reactions

1. General

Allergenic extract mixtures may be more potent than individual allergens and therefore, are not directly interchangeable with non-standardized extracts, or other manufacturers' extracts. Allergen extracts with the same specified strength may differ in potency from one lot to another. Some are more potent because of a more concentrated antigenic content, while others may have antigenic material of a different potency. These patients may also be more refractory to the normal allergy treatment regimen.

stead, the occurrence of epinephrine is not an indication to stop immunotherapy.

5. Adverse Events

In the OFFICE FOR 30 MINUTES AFTER EACH TREATMENT INJECTION. Most severe reactions will occur within this time period, and rapid treatment measures should be instituted. See ADVERSE

IN THE OFFICE FOR 30 MINUTES AFTER EACH TREATMENT INJECTION. Most severe reactions will occur within this time period, and rapid treatment measures should be instituted. See ADVERSE REACTIONS Section for treatment measures.

Wet dressings and/or the use of oral antihistamines. They should be considered a warning of possible severe systemic reactions and an indication of the need for temporarily reduced dosages. A mild burning

Following the injection, a large local reaction may appear, which may persist for several weeks. This is not an indication of an allergic reaction. Such reactions are usually self-limiting and resolve quickly. Continued administration should be discontinued at least 3 days before skin testing. Local anesthetics should be discontinued for at least 3 weeks prior to skin testing. Topical steroids should be discontinued at the skin test site for at least 2-3 weeks before skin testing.


3. Adverse Event Reporting

Report adverse events to Hoffmann-La Roche, Inc., Technical Services Department at 1 (800) 660-1120. A voluntary adverse event reporting system for health professionals is available through the FDA MEDWATCH program. Preprinted forms (FDA Form 3500) are available from the FDA by calling 1 (800) FDA-1088. Completed forms should be mailed to MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9767 or Fax to 1 (800) FDA-0179.

4. Pediatric Use

The data on the pediatric population are the same as for adults. (See PRECAUTIONS.)

5. Geriatric Use

The data on the elderly population are the same as for adult patients under 65.

HOW SUPPLIED:

Standardized allergenic extracts are supplied for diagnostic and therapeutic use:

Diagnoses:

Extracts: O. pleurisyasis and D. farinae

Scrap, print or punch test, or punch tests, 30 mL Au/mL (30,000 Au/mL) in 5 mL dropper vial. Intradermal Testing (Table II.): Available for use in 10 mL Au/mL, 30 mLAu/mL or 100 mL Au/mL. 30 mL Au/mL, 60 mL Au/mL or 100 mL Au/mL.

A mixture of the two species, in equal parts, resulting in O. pleurisyasis at 15,000 Au/mL, and D. farinae at 15,000 Au/mL, is available for therapeutic use in 10 mL Au/mL and 30 mL Au/mL. A mixture of the two species is also available at 5,000, 15,000, and 30 mL Au/mL.

LIMITED WARRANTY:

The expiration date of the mixture is labeled on the container. The extract should be stored at 2°-8°C and kept in this temperature range during office use. Dilutions containing less than 50% glycerin are less stable, and if loss of potency is suspected, should be checked by skin testing with equal units of freshly prepared dilute known mite allergic individuals. The expiration date of the intradermal tests is labeled on container labels. Store at 2°-8°C.

REFERENCES:


