THREE QUESTIONS
Three Answers:

1. **Innovations & Differentiations**

HollisterStier has been an innovator since our founding in 1921. In fact, both our histamine and AP Dog products are listed in the Allergy practice parameters. Now approaching our 100th year, we have produced many breakthroughs.

- **Acetone Precipitated (AP) Extraction**
  Our exclusive process, often using as much as 50 times the source material, creates highly potent extract.

- **Phenol-Free Extraction**
  We do not use phenol in any of our glycerin extracts, which helps prevent denaturing of the proteins. This, in turn, helps preserve potency.

- **Subcutaneous Immunotherapy, Without Compromise**
  Our focus has always been on subcutaneous immunotherapy and bulk extracts. We create products specifically for allergists and allergy specialists.

As a result, we are able to offer many high-quality products, such as:

- **AP Dog**
  The highest concentration of dog hair extract available. Studies suggest it’s more effective for diagnosis and treatment.

- **Mite Extracts**
  We introduced mite extracts in 1985, and culture our source material to produce mite products—including a highly concentrated bulk extract.

- **Venom Extracts**
  Our venom products pass a minimum of 12 quality control checks. We are the only manufacturer that lets you order venom diagnostics by individual species.

- **Comforten® Multiple Skin Test System**
  The only ten-test, self-loading, surgical steel skin test device on the market.

- **Cat Hair and Cat Pelt**
  We offer both Cat Hair and Cat Pelt. Cat Pelt contains a higher concentration of albumin than conventional cat hair extracts.

2. **Quality Control & Manufacturing Standards**

HollisterStier’s facility is rigorously inspected by CBER, CDER and multiple foreign agencies. We also meet ISO-9001 standards certification, exhibiting strong GMP standards.

We strive to meet multiple agency guidelines as part of our commitment to high quality allergenic extracts for you and your patients. This requires careful control and exacting processes. For instance, a single batch of our yellow jacket venom requires 130,000 yellow jackets and 300 hours of careful handling by 40 people. Simply put: we don’t take the easy route. We take the best route.

3. **Commitment to Your Practice & Patients**

Our focus, subcutaneous immunotherapy, has been shown in studies to be effective for diagnosis and treatment. We continue to innovate our manufacturing methods. We’ve invested in equipment, technology and facilities. And we’ve responded to your needs and wants by creating a product portfolio that focuses on the antigens most important to you.

Finally, we are patient-focused in what we produce. We offer educational materials to help answer the questions your patients ask. For instance, we created and funded the BeeAware Program to inform the public about life-saving treatment, demonstrating our commitment to both patients and allergists.

**Call us today:**
1.800.992.1120  
hsallergy.com

Request a copy of our product catalog and schedule your complimentary consultation.

*see back for footnotes*
WARNING Important Safety Information
(See full prescribing information for complete boxed warning.)

Intended for use only by licensed health care provider experienced in administering allergenic extracts and trained to provide immediate emergency treatment in the event of a life-threatening reaction. Observe patients for at least 30 minutes following administration. Immunotherapy may not be suitable for patients with medical conditions that reduce their ability to withstand a systemic reaction. Allergenic extracts can cause serious systemic reactions, including anaphylactic shock and in rare cases death, especially in patients who have severe or steroid-dependent asthma, cardiovascular disease, or in patients who use beta blockers. Do not inject intravenously. This product is intended for subcutaneous injection for immunotherapy and percutaneous use for diagnosis. Refer to contraindications, warnings, precautions, adverse reaction and over dosage for more detailed information.
Footnotes


2 Anne M. Lent, MD, Ronald Harbeck, PhD, Matthew Strand, PhD, Michael Stils, BS, Kimberly Schmidt, RN, BSN, Benjamin Efaw, MS, Terri Lebo, BS, and Harold S. Nelson, MD. Immunologic response to administration of standardized dog allergen extract at differing doses. The Journal of Allergy and Clinical Immunology, Volume 118, No. 6 (2006).


4 Cox ET AL. Allergen Immunotherapy: A practice parameter third update. The Journal of Allergy and Clinical Immunology, January 2011.

INSTRUCTIONS AND DOSAGE SCHEDULE
ALLOGENIC EXTRACTS IN BULK VIALS

Jubilant HollisterStier, LLC
Spokane, WA 99207
hstlarry.com
U.S. LIC. No. 1272

WARNINGS

This product is intended for use only by licensed medical personnel in administering allogenic extracts and trained to provide immediate emergency treatment in the event of a life-threatening reaction. Allogenic extracts may potentially elicit a severe life-threatening systemic reaction, rarely resulting in death.

Therefore, emergency medical training in their use must be available immediately in the event of such a reaction. Patients should be instructed to recognize adverse recognition reactions, be observed in the office for at least 30 minutes after skin testing or treatment, and be cautioned to contact the physician's office by telephone or otherwise, if a reaction should occur with this package regarding adverse reporting.

Standardized glycercinated material may be more potent than regular extracts and therefore are not directly interchangeable with unstandardized extracts of any of the manufacturer's products. Patients with cardiovascular diseases and pulmonary diseases such as systemic urticaria, steroid-dependent asthma, and/or who are receiving cardiovascular drugs or bronchodilators for severe asthma reactions. These patients should be observed for a minimum of 30 minutes after the skin test or treatment.

Patients should be treated only if the benefit of treatment outweighs the risks. Patients on beta blockers may be more reactive to allergens for treating compared to non-beta blocker patients.

ICD-10-CM codes for the skin testing and treatment of allergic patients may be found in the Medicare Payment Advisory Commission report.

Ref to the WARNINGS, PRECAUTIONS, ADVERSE REACTIONS and OVERDOSAGE Sections for further discussion.

DESCRIPTION

The allogenic extract in this vial is referred to as a “bulk” or stock extract since it is designed for the primary physician to prepare to distillates and mixtures as required. The extract is sterile and intended for subcutaneous injection. For PROMAX™, 1 mg = 1 cc or 1 cc = 1 mg.

In order to prepare allergenic extracts, the patient’s own serum is removed and then mixed with appropriate antigens, usually prepared by animals or by using extracts of the allergens. To prepare the antigen, the allergens are processed or digested, usually by a process such as boiling, steaming, or boiling water, or by using enzymes. The antigen is then filtered and mixed with serum to prepare an extract.

The extract is then stored at temperatures of 2°C to 8°C for use in skin testing. The extract is discarded after a limited time. The extract is then reconstituted with the patient’s own serum to use in skin testing. The extract is then discarded after a limited time. The extract is then reconstituted with the patient’s own serum to use in skin testing. The extract is then discarded after a limited time.

Glycercinated extracts are also administered by intradermal injection. Injection of the extract is made into the skin at a site remote from the site of the previous injection.

The histamine release response of circulating basophils to a specific allergen is reduced in some patients by immunotherapy, but the mechanism of this change is not clear. CLINICAL IMMUNOTHERAPY: The mechanism by which hyporesponsiveness is achieved is not well known. It has been shown that repeated injections of appropriate allergenic extracts may ameliorate the symptoms associated with the medical condition.

The selection of allogenic extracts to be used should be based on a thorough and carefully taken history of allergy and on the results of skin testing. The selection of the allergenic extracts to be used should be based on a thorough and carefully taken history of allergy and on the results of skin testing. The selection of the allergenic extracts to be used should be based on a thorough and carefully taken history of allergy and on the results of skin testing. The selection of the allergenic extracts to be used should be based on a thorough and carefully taken history of allergy and on the results of skin testing. The selection of the allergenic extracts to be used should be based on a thorough and carefully taken history of allergy and on the results of skin testing.

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Adverse reactions to allergenic extracts can include local and systemic reactions. Local reactions are usually mild and include erythema, swelling, itching, pain, and tenderness at the injection site. These reactions are often temporary and resolve within a few hours of the injection. Systemic reactions, on the other hand, can be severe and include symptoms such as rash, hives, itching, difficulty breathing, palpitations, and collapse. In some cases, systemic reactions may progress to anaphylaxis, a life-threatening reaction that requires immediate medical attention.

Systemic reactions are less common than local reactions but can occur in patients who have a history of anaphylaxis. The most common systemic reactions are urticaria, followed by angioedema, and anaphylaxis. In the event of a systemic reaction, it is important to stop the injection and seek medical attention immediately. The patient should be treated with epinephrine, antihistamines, and corticosteroids as needed. In severe cases, treatment may also include intubation, mechanical ventilation, or vasopressors.

To prevent adverse reactions, healthcare providers should follow the guidelines for the preparation, administration, and monitoring of allergenic extracts. The patient should be observed for at least 20 minutes after each injection to ensure that no adverse reactions occur. Repeat injections should be given at intervals of 2 to 4 weeks, and the dose should be increased gradually to avoid overwhelming the immune system. Patients should be instructed to report any symptoms of an allergic reaction immediately to the healthcare provider.

References:
INSTRUCTIONS AND DOSAGE SCHEDULE

Allergenic Extracts

Standardized Mites

Jubilant HollisterStier, LLC

Spokane, WA 99207

U.S. Lic. No. 1227

16, 17, 18, 26

The selection of allergenic extracts to be used should be based on a thorough and carefully taken history of hypersensitivity, and confirmed by skin testing.

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may occur to the highly reactive allergen.

less sensitivity, but should be administered separately. This allows individualized and better control of dosage increases, including adjustments in dosage becoming necessary after severe reactions which

3.

Concentrate. Concentrate labeling terminology applies to allergenic extract mixtures where the final allergens being recognized are shown in vertical or design感 of the strength.

1.

Concentrate and dilution: The mechanism by which hyporesponsiveness is achieved is not completely understood. It has been shown that repeated injections of appropriate allergenic extracts will ameliorate the intensity of allergic reactions of varying degrees of severity may occur, including urticaria, rhinitis, conjunctivitis, wheezing, coughing, angioedema, hypotension, bradycardia, pallor, erythema, fever, or even anaphylactic shock. Therefore, the information is provided if and the prescribing of this drug to children or adolescents is contraindicated. A strong systemic reaction should be avoided.

When switching from non-stabilized to stabilized diluent, consider weaker initial dilutions for both intradermal testing and immunotherapy. Sterile solutions, vials, syringes, etc., should be used and the drug should be given to the patient. If such reactions (erythema or swelling) which exceed 4-5 cm in diameter are not only uncomfortable, but also indicate the possibility of a systemic reaction if dosage is increased. In such cases the dosage should

3.

Local 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 epinephrine on the cardiovascular system. The practitioner should be prepared to treat the reactions from immunotherapy.

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Drug Interactions

Patients on non-selective beta blockers may be more reactive to allergens given for diagnosis or treatment, and may be unresponsive to the usual doses of epinephrine used to treat allergic reactions. Certain medications like tricyclic antidepressants, oral contraceptives, and sympathomimetic agents should be discontinued at least 7 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.

2.

Systemic Reactions

The treatment and management of reactions to the allergenic extracts is similar to that for other forms of immunotherapy. Dosage adjustments should be made initially based on the patient's reaction to the injection and then continued on the basis of the patient's total response.

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Pregnancy

Category C. Allergic Extracts. Animal reproduction studies have not been conducted with allergic extracts. It is also not known whether allergic extracts can cause fetal harm when administered to pregnant women or can affect reproductive capacity. Therefore, allergy extracts should not be given to a pregnant woman only if it is clearly needed. For women who have been getting maintenance doses of allergen without side effect, the occurrence of pregnancy is not an indication to stop immunotherapy.

1.

Pregnancy

Nursing Mothers

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

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Patients should be advised to return to the office promptly if symptoms occur after leaving.

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INFORMATION FOR PATIENTS

If a systemic or anaphylactic reaction does occur, apply a tourniquet above the site of injection and inject 1:1000 epinephrine-hydrochloride solution intra-muscularly just proximal to the site (See Dose and dilution under DOSAGE AND ADMINISTRATION Section). If the patient is unconscious or the site of injection is not visible, the injection is recommended. Intranasal or intramuscular injections may produce local reactions or be excessively painful. After INSERTING NEEDLE SUBCUTANEOUSLY, BEFORE INJECTING, ALWAYS WITHDRAW THE PLUNGER SLIGHTLY. IF BLOOD APPEARS IN THE SYRINGE, CHANGE NEEDLE AND GIVE THE INJECTION IN ANOTHER SITE.

1.

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 from the previous extract.

1.

If the STANDARDIZED EXTRACT WAS FROM ANOTHER MANUFACTURER: Since manufacturing processes and sources of raw materials differ among manufacturers, the interchangeability of extracts from different manufacturers cannot be assumed. The starting dose of the standardized glycerinated extract therefore should greatly decrease for the new formula, on the same formula and dilution. Initiate therapy only after patient has not been receiving immunotherapy, or determine initial dose by skin test using serial dilutions of the extract. In highly sensitive patients, the skin test method may be preferable. See DOSAGE AND ADMINISTRATION AND ADVERSE REACTIONS Sections.

1.

If PROLONGED PERIOD OF TIME HAS ELAPSED SINCE THE LAST INJECTION: Patients may be susceptible for allergic reactions during prolonged periods between doses. The duration of treatment for allergic extracts should not exceed 6 months. If the interval between injections is less than four weeks, perform skin tests in order to detect delayed-type reactions.

1.

If the PREVIOUS EXTRACT WAS NON-STANDARDIZED: Standardized extracts may be more potent than non-standardized extracts. Initiate therapy as though the patient had not been receiving immunotherapy or allergic extracts and determine initial dose by skin test using serial dilutions of the extract. See PRECAUTIONS AND DOSAGE AND ADMINISTRATION Sections.

1.

If ANY OTHER CHANGES HAVE BEEN MADE IN THE EXTRACT CONCENTRATE FORMULA: Changes other than those listed above may include situations such as a redistribution of components or percentages, a difference in extracting fluid (i.e., change from non-glycerin extracts to glycerin extracts), combining two or more stock concentrates, or any other change. Changes in the formula may affect the way in which a patient can react to a particular allergen, but do not affect the original concentration of the allergen. The cautionary advice given in the appearance of other extracts in the concentrate. It is imperative that physicians administering allergic extracts be prepared for the treatment of severe reactions. Other possible systemic reactions which may occur in varying degrees of severity include: (1) severe symptoms of rhinitis and/or asthma; (2) infection or flu accompanied by new or increased cough or sputum; (3) profuse sweating; (4) palpitations or tachycardia; (5) fainting; or even anaphylactic shock. Therefore, the information is provided if and the prescribing of this drug to children or adolescents is contraindicated. A strong systemic reaction should be avoided.

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2.

Systemic Reactions

The treatment and management of reactions to the allergenic extracts is similar to that for other forms of immunotherapy. Dosage adjustments should be made initially based on the patient's reaction to the injection and then continued on the basis of the patient's total response.

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Menses

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Pediatrics

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Patients on non-selective beta blockers may be more reactive to allergens given for diagnosis or treatment, and may be unresponsive to the usual doses of epinephrine used to treat allergic reactions. Certain medications like tricyclic antidepressants, oral contraceptives, and sympathomimetic agents should be discontinued at least 7 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.

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2.

Adverse Reactions

If the previous extract was non-standardized, the dating and the potency of extracts labeled in Allergy Units/mL are determined by in vitro comparison to a reference standard established by the Center for Biologics Evaluation and Research (CBER) of the Food and Drug Administration.

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2.

Standardized mite extracts are indicated for use in diagnosis and immunotherapy of patients presenting symptoms of allergy (hay fever, rhinitis, etc.) to specific environmental allergens. The allergenic extracts to be used should be based on a thorough and carefully taken history of hypersensitivity, and confirmed by skin tests 19. The use of skin or oral antihistamines for the skin testing is not recommended since, in the case of a positive reaction, it does not indicate whether the component of the mix is the reactive one against which the patient is allergic, and to which he will be more reactive than his environmental allergens.

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3. Adverse Event Reporting

Report adverse events to HOS Prescriber Support Services, Inc. at 1-800-660-1320. 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 Fish Lake Road, Rossville, IN 46970-9975 or Fax (1-800) FDA-0179.

OVERDOSAGE: See ADVERSE REACTIONS Section.

DOSAGE AND ADMINISTRATION:

1. General

Skin products should be dispensed with caution and not ingested. Parenteral drug products should be inspected visually for particulate matter and viscosity prior to administration whenever solution and container permit.

2. Diagnosis

To identify highly sensitive individuals and as a safety precaution, it is recommended that a scratch, prick or puncture test using a drop of the extract concentrate be performed prior to initiating intradermal testing. Prick tests are performed by placing a drop of extract on the skin and pricking through the drop into the skin with a slight lifting motion. Pricking tests are performed by placing a drop of extract concentrate on the skin and pricking through the drop with a small needle such as a Prick Lancet. Fifteen minutes after puncture is made the diameter of wheal and erythema reactions are measured, and the sensitivity class of the patient determined by the table presented at end of Diagnosis Section. Less sensitive extracts with smaller dilutions can be used when high sensitivity is expected.

3. Intradermal Tests

Skin tests are graded in terms of the wheal and erythema diameters. Extracts of P. o. o physicians report that this product is often poorly taken up by 1 mL of 50% glycerin in 5 mL vials. Results of skin testing in selected highly sensitive subjects are presented for reference purposes:

<table>
<thead>
<tr>
<th>Patient</th>
<th>Test Number</th>
<th>Diameter</th>
<th>Concentration</th>
<th>Allergen</th>
<th>Test Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>6</td>
<td>&lt;5 mm</td>
<td>0.0003</td>
<td>D. farinae</td>
<td>1 mL dilution</td>
</tr>
<tr>
<td>2</td>
<td>3</td>
<td>=5 mm</td>
<td>0.005</td>
<td>D. farinae</td>
<td>1 mL dilution</td>
</tr>
<tr>
<td>3</td>
<td>8</td>
<td>&gt;5 mm</td>
<td>0.003</td>
<td>D. farinae</td>
<td>1 mL dilution</td>
</tr>
</tbody>
</table>

The dose for elderly patients is the same as for adult patients under 65.

LIMITED WARRANTY:

No warranty is made of the drug concentrate. The manufacturer assumes no liability in the event of a serious systemic or anaphylactic reaction not responsive to the above measures [Ref. J. Allergy and Clinical Immunology, 77(2): p. 271-273, 1986]. Rarely are all of the above reactions reported.

REFERENCES

INSTRUCTIONS AND DOSAGE SCHEDULE FOR ALLERGIC EXTRACTS HYMENOPTERA VENOM PRODucts

(Honey Bee, Yellow Jacket, Yellow Hornet, White-Faced Hornet, Wasp, and Mixed Vespid)

VENOM®

Jubilant Hollister-Stier, LLC
SPOKANE, WASHINGTON 99207

U.S. L.I.C. No. 1272

532561-H03

Printed in U.S.A.

INFORMATION

The products listed are for use under the supervision of licensed medical personnel experienced in the administration of allergic extracts and to provide immediate emergency treatment of anaphylactic shock. These products are intended for use in the United States.

HYMENOPTERA VENOM EXTRACTS

Insect stings may induce a wide range of allergic symptoms in sensitive patients. A normal sting response is initial burning or stinging pain that may be intense and last for seconds to minutes. The area may swell, and a red rash may appear. If the sting is from a bee or yellow jacket, a new, and possibly more potent extract. In general, the longer the material has been outdated, the greater the dose reduction required when starting the fresh extract.

For a prolonged period of time elapsed since the last injection, the patient may lose tolerance for allergen injections during prolonged periods of non-use (1-3 months). If such a situation is expected, the dose reduction recommended for a prolonged period of time should be used when the fresh extract is utilized. However, if the doses do not change, the next dose could be raised to the previous dose amount. This is greater than 50%. The next dose would need to be determined by the allergist, however, the starting dose of the venom extract should be decreased, and the dose reduced in increments of 50%. If the interval since the last injection is over four weeks, perform skin tests to determine starting dose. See DOSAGE AND ADMINISTRATION.

The CONCENTRATE MUST NOT BE INJECTED AT ANY TIME UNLESS TOLERANCE HAS BEEN ESTABLISHED. DILUTE CONCENTRATED EXTRACTS WITH STEERILE ALBUMIN SALINE WITH PHENOL (3.0%) FOR SKIN TESTING AND IMMUNOTHERAPY.

CONCENTRATIONS

In general, the dose of venom extract should be selected so as to achieve 100 µg per venom per injection of the concentrated venom extract at each dose level. This is based on the assumes that patients with serological evidence of clinical or immediate hypersensitivity to venom have been identified and are not allergic to the venom extract used in the clinical study. The clinical study with Jubilant Hollister-Stier venom products, injections (using the Suggested Dose Schedule under DOSAGE AND ADMINISTRATION) were given once per week at a starting concentration and two or more per week at an escalation rate. For further discussion, see below. For patients who have lost tolerance for allergen injections during prolonged periods of non-use (1-3 months), the dose should be reduced from the last dose given to the patient.

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Diagnosis
The diagnosis of an insect sting allergy is based on a history of a previous allergic reaction to an insect sting and a positive skin test (intracutaneous reaction) or a positive basophil activating test (BAT).

Treatment
The treatment of insect sting allergy involves the following strategies:

1. Avoidance: Identifying and avoiding the source of the sting is the most effective way to prevent allergic reactions.
2. Desensitization: This involves gradually increasing the dose of the allergen to build up tolerance. It is typically done with insect venom extract, which contains the allergens responsible for the allergic reaction.
3. Antihistamines: These are used to manage symptoms of an allergic reaction, such as rash, swelling, and itchiness.
4. Corticosteroids: These are used to reduce inflammation and swelling in severe cases.
5. Epinephrine: This is used for emergency treatment of severe allergic reactions, such as anaphylaxis.
6. Immunotherapy: This involves the administration of small, gradually increasing doses of the allergen to build up tolerance and prevent future reactions.

References