

**PRODUCT MONOGRAPH**  
 INCLUDING PATIENT MEDICATION INFORMATION  
**ALLERGENIC EXTRACT – POLLENS, ALLERGENIC EXTRACT NON-POLLENS and**  
**NEGATIVE SKIN TEST CONTROL - GLYCERIN**  
 Allergenic Extracts for Scratch, Prick, Puncture (Percutaneous) Testing Diagnostic Agent  
 Schedule D-Biologic Drugs

360400-C09  
 Rev. November 26, 2024

Allergenic Extract – Pollens and Allergenic Extract – Non-Pollens, indicated for:  
 The diagnosis of allergic conditions have been issued market authorization without conditions.

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Date of Initial Authorization:  
 ALLERGENIC EXTRACT-NON-POLLENS:  
 December 01, 1997

ALLERGENIC EXTRACT-POLLENS:  
 December 05, 1997

NEGATIVE SKIN TEST CONTROL – GLYCERIN:  
 June 06, 2014

**ALLERGENIC EXTRACT – POLLENS**

Submission Control Number: 285785

Date of Revision: February 27, 2026

**ALLERGENIC EXTRACT NON-POLLENS**

Submission Control Number: 285782

**NEGATIVE SKIN TEST CONTROL - GLYCERIN**

Submission Control Number: 300045

**RECENT MAJOR LABEL CHANGES**

All Sections and Subsections updated to Plain Language Labeling Format	10/2024
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**TABLE OF CONTENTS**

Sections or subsections that are not applicable at the time of authorization are not listed.

<b>RECENT MAJOR LABEL CHANGES</b> .....	<b>2</b>
<b>TABLE OF CONTENTS</b> .....	<b>2</b>
<b>PART I: HEALTH PROFESSIONAL INFORMATION</b> .....	<b>4</b>
<b>1. INDICATIONS</b> .....	<b>4</b>
1.1. Pediatrics.....	4
1.2. Geriatrics.....	4
<b>2. CONTRAINDICATIONS</b> .....	<b>4</b>
<b>3. SERIOUS WARNINGS AND PRECAUTIONS BOX</b> .....	<b>4</b>
<b>4. DOSAGE AND ADMINISTRATION</b> .....	<b>5</b>
4.1. Dosing Considerations .....	5
4.2. Recommended Dose and Dosage Adjustment.....	5
4.3. Reconstitution.....	5
4.4. Administration .....	6
<b>5. OVERDOSAGE</b> .....	<b>7</b>
<b>6. DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING</b> .....	<b>7</b>
<b>7. WARNINGS AND PRECAUTIONS</b> .....	<b>10</b>
7.1. Special Populations .....	11
7.1.1. Pregnant Women .....	11
7.1.2. Breast Feeding .....	11
7.1.3. Pediatrics.....	11
7.1.4. Geriatrics.....	11
<b>8. ADVERSE REACTIONS</b> .....	<b>11</b>
8.1. Adverse Reaction Overview .....	11
8.5. Post-Market Adverse Reactions.....	12
<b>9. DRUG INTERACTIONS</b> .....	<b>12</b>
9.1. Serious Drug Interactions.....	12
9.2. Drug Interactions Overview .....	12
9.4. Drug-Drug Interactions .....	12
9.5. Drug-Food Interactions .....	14
9.6. Drug-Herb Interactions .....	14
9.7. Drug-Laboratory Test Interactions.....	14
<b>10. CLINICAL PHARMACOLOGY</b> .....	<b>14</b>
10.1. Mechanism of Action .....	14
<b>11. STORAGE, STABILITY AND DISPOSAL</b> .....	<b>14</b>
<b>12. SPECIAL HANDLING INSTRUCTIONS</b> .....	<b>15</b>
<b>PART II: SCIENTIFIC INFORMATION</b> .....	<b>15</b>

13. PHARMACEUTICAL INFORMATION ..... 15  
14. CLINICAL TRIALS ..... 15  
15. MICROBIOLOGY ..... 15  
16. NON-CLINICAL TOXICOLOGY ..... 15  
PATIENT MEDICATION INFORMATION ..... 16

**PART I: HEALTH PROFESSIONAL INFORMATION****1. INDICATIONS**

ALLERGENIC EXTRACT – POLLENS and ALLERGENIC EXTRACT – NON-POLLENS Scratch, Prick, Puncture (Percutaneous) Diagnostic Testing labeled in 50 % Glycerin are indicated for:

- Diagnosis of allergic conditions.

In addition to a carefully taken history, the use of glycerin-containing extracts in scratch, prick or puncture testing is an accepted method in the diagnosis of allergic conditions. Extracts of all allergens do not produce equivalent results in scratch, prick or puncture tests. The intensity of the skin reactions produced will be determined by two factors: the degree of sensitivity of the patient, and the nature of the allergenic extract applied.

Scratch, prick or puncture tests are not as sensitive as the intradermal test, but are safer and cause less discomfort. They may, therefore, be the method of choice when a large number of tests are needed, or when testing the pediatric patient. In some cases, where the relatively insensitive scratch, prick or puncture tests are negative or do not confirm the allergic history, follow-up intradermal tests may be positive. However, ANTIGENS PRODUCING LARGE 3 to 4+ SCRATCH, PRICK OR PUNCTURE TESTS SHOULD NOT BE TESTED INTRADERMALLY.

Certain diagnostics carry labelling which states Allergenic Extract for Diagnostic Use Only. Data to support the therapeutic use of products labelled with this statement have not been established.

**1.1. Pediatrics**

Allergenic extracts for diagnostic use have been given safely in infants and young children (see Section 7.1.3 Pediatrics).

**1.2. Geriatrics**

Geriatrics: Evidence from clinical studies and experience suggests that use in the geriatric population is associated with differences in safety or effectiveness (see Section 7.1.4 Geriatrics).

**2. CONTRAINDICATIONS**

- There are no known absolute contraindications to allergy skin testing. Patients with cardiovascular diseases or pulmonary may be at higher risk for severe adverse reactions (see Section 3 SERIOUS WARNINGS AND PRECAUTIONS BOX, Section 7 WARNINGS AND PRECAUTIONS, Section 9 DRUG INTERACTIONS).

**3. SERIOUS WARNINGS AND PRECAUTIONS BOX****Serious Warnings and Precautions**

- The product is intended for use only by physicians who are experienced in the use of allergenic extracts, or for use under the guidance of an allergist.
- Allergenic extracts may potentially elicit a severe life-threatening systemic reaction (anaphylaxis), which can result in death. Therefore, emergency measures and personnel trained in their use must 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.
- Patients on beta blockers may be more reactive to allergens given for testing or treatment and may be unresponsive to the usual doses of epinephrine used to treat allergic reactions (see Section 9 DRUG INTERACTIONS).
- This product should never be injected intravenously.

Refer also to the Section 2 CONTRAINDICATIONS, Section 4 DOSAGE AND ADMINISTRATION, Section 5 OVERDOSAGE, Section 7 WARNINGS AND PRECAUTIONS, and Section 8 ADVERSE REACTIONS for further

discussion.

#### 4. DOSAGE AND ADMINISTRATION

##### 4.1. Dosing Considerations

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 a sequence of serial 10-fold dilutions of undiluted allergenic extract spaced 15-20 minutes apart (see Section 4.2 RECOMMENDED DOSE AND DOSAGE ADMINISTRATION).

There is a potential for systemic reactions to occur, but it must be remembered that allergenic extracts are highly potent in sensitive individuals and OVERDOSE could result in anaphylactic symptoms. Therefore, it is imperative that physicians administering allergenic extracts understand and be prepared for the treatment of severe reactions.

##### 4.2. Recommended Dose and Dosage Adjustment

The dose is the same in patients of all age groups. Unless an individual is suspected to be at greater risk for anaphylaxis (see Section 4.1 DOSING CONSIDERATIONS), the initial starting dose is 1 drop (approximately 0.05 mL) of undiluted allergenic extract. The dose amount may be less when using self-loading skin test devices.

##### 4.3. Reconstitution

See Section 4.2 RECOMMENDED DOSE AND DOSAGE ADJUSTMENT and Section 6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING.

**Table – Reconstitution**

Product	Vial Size	Volume of Diluent to be Added to Vial	Approximate Available Volume	Concentration
AP Dog Hair-Dander	5 mL (Diagnostic)	N/A – Concentrate Used	5 mL	1:100 w/v
AP Cattle Hair and Dander / AP Horse Hair and Dander	5 mL (Diagnostic)	N/A – Concentrate Used	5 mL	1:50 w/v
Non-AP Epidermals/Inhalants	5 mL (Diagnostic)	N/A – Concentrate Used	5 mL	1:10 w/v
UF Dog Hair and Dander	5 mL (Diagnostic)	N/A – Concentrate Used	5 mL	1:650 w/v
Grass Pollen	5 mL (Diagnostic)	N/A – Concentrate Used	5 mL	1:20 w/v
Insects	5 mL (Diagnostic)	N/A – Concentrate Used	5 mL	1:10 w/v
Molds	5 mL (Diagnostic)	N/A – Concentrate Used	5 mL	1:10 w/v or 1:1,000 w/v
Tree Pollen	5 mL (Diagnostic)	N/A – Concentrate Used	5 mL	1:20 w/v or 1:50 w/v
Ragweed	5 mL (Diagnostic)	N/A – Concentrate Used	5 mL	100 Amb a 1 UA/mL or 200 Amb a 1 UA/mL
Weed Pollen	5 mL (Diagnostic)	N/A – Concentrate Used	5 mL	1:20 w/v

#### 4.4. Administration

All skin tests should be validated by appropriate positive control tests (e.g., histamine) and negative control tests [e.g., Glycerin, Sterile Albumin Saline with Phenol (0.4%), or Buffered Saline with Phenol (0.4%)]. The negative control test should be the same material used as a diluting fluid in the tested extracts. Diluting fluid is used in the same way as an active test extract.

Test sites should be examined at 15 and 20 minutes immediate reactions to allergens typically peak at 15 minutes. To prevent excessive absorption, wipe off antigens producing large reactions as soon as the wheal appears. Record the size of the reaction. Delayed reactions rarely occur from tests, so it may be helpful to examine the test sites in 24 hours.

Use of Self-Loading Devices. The criteria for interpretation of positive and negative results of percutaneous allergen tests (wheal diameter) are specific to the device used.

Use of Scarifiers and Spacing. Make scarifications at least 2.5 cm apart. Use more space between pollen tests to prevent smearing into adjacent sites. Hold the scarifier between the thumb and index finger, press the sharp edge of the instrument against the skin and twirl instrument rapidly. The scratch should disrupt only the outer layers of epidermis, but should not produce immediate oozing of blood. The amount of pressure needed to produce a satisfactory scratch will vary between patients according to the thickness or fragility of their skin. Experience will indicate the proper amount of pressure to exert in making the scratch. If the scarifier is kept sharp and the scratch made quickly, discomfort to the patient is minimized.

Use of Prick Test Needles. The skin is cleaned and single drops of each extract applied to the properly identified test sites. A small, sterile disposable needle, such as a 1/2-inch 26-gauge needle (with the bevel up), a bifurcated vaccinating needle, or a Prick Lancetter™ is inserted through the drop superficially into the skin, the skin lifted slightly and the needle withdrawn. No bleeding should be produced. After about 1 minute the extract may be wiped away.

#### Most Satisfactory Sites for Testing

Prior to testing, clean the skin area to be tested with ether or alcohol and allow to dry. Use a sterile instrument for each patient. The back or the volar surface of the arms are the most satisfactory sites for testing. Skin of the posterior thighs or abdomen may be used if necessary. Avoid very hairy areas where possible, since the reactions will be smaller and more difficult to interpret. The most satisfactory areas of the back are from the posterior axillary fold to 2.5 cm from the spinal column, and from the top of the scapula to the lower rib margins. The best areas of the arms are the volar surfaces from the axilla to 2.5 or 5 cm above the wrist skipping the antecubital space.

#### Use of Antigen Mixes

The use of mixed or unrelated antigens for skin testing is not recommended since in the case of a positive reaction it does not indicate which antigens are responsible, and in the case of a negative reaction it fails to indicate whether the individual antigens at full concentration would give a positive reaction.

The extracts for scratch, prick or puncture testing are supplied in dropper vials and should be kept in a rack or box in rows of 10 vials corresponding to the rows of tests to be applied to the skin.

#### Reading Skin Test Reactions

Testing is performed to identify patients that exhibit an allergic response at the site of administration. False positive/negative reactions may occur. A positive reaction consists of an urticarial wheal with surrounding erythema (resembling somewhat a mosquito bite reaction) larger than the control site. The smallest reaction considered positive is erythema with a central papule at least 3-5 mm in diameter. In some instances when there

is no reaction at the control site, erythema may be considered an indication of sensitivity. In general, the size of wheal and erythema response correlates directly with the patient's sensitivity to that allergen. If using self-loading devices, refer to the manufacturer's directions for use.

Interpretation of test results is variable depending on the test method and device employed. Manufacturers of commercially available skin test devices often recommend a specific grading system. When available, follow the manufacturer's recommended grading system.

The sum of a skin response is the sum of the longest diameter and the mid-point orthogonal diameter.

Ragweed Pollen: (Short Ragweed or Giant and Short Ragweed Mixture) Amb a 1: Short Ragweed extract in 50 % glycerin containing 200 Units of Amb a 1/mL or Giant and Short Ragweed Mix in 50 % glycerin containing 100 Units of Amb a 1/mL, are usually used for scratch, prick or puncture testing.

Refer to the following table to determine the skin test sensitivity grade. The corresponding  $\Sigma E$  (sum of the longest diameter and the mid-point orthogonal diameters of erythema) is also presented.

Grade	Erythema mm	Papule or Wheal mm	Corresponding mm $\Sigma$
0	<5	<5	<10
±	5-10	5-10	10-20
1+	11-20	5-10	20-40
2+	21-30	5-10	40-60
3+	31-40	10-15 <sup>a</sup>	60-80
4+	>40	>15 <sup>b</sup>	>80
a. or with pseudopods.			
b. or with many pseudopods.			

A positive skin reaction to any allergen must be interpreted in light of the patient's history of symptoms, time of the year, known exposures, and eating habits.

THE SKIN TESTS ARE IN NO WAY A SUBSTITUTE FOR A CAREFUL ALLERGIC HISTORY. RATHER THEY SERVE AS ADDITIONAL INFORMATION TO AID IN IDENTIFYING CAUSATIVE ALLERGENS IN PATIENTS WITH ALLERGIC DISORDERS.

## 5. OVERDOSAGE

See Section 4 DOSAGE AND ADMINISTRATION and Section 8 ADVERSE REACTIONS.

For management of a suspected drug overdose, contact your regional poison control center.

## 6. DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

In 5 mL dropper bottles of extract at 1:10 w/v, except pollens at 1:20 w/v; Short Ragweed at 200 Amb a 1 Units/mL; Giant and Short Ragweed Mixture at 100 Amb a 1 Units/mL; and AP™ Cattle Hair and Dander plus Horse Hair and Dander extracts at 1:50 w/v; AP™ Dog Hair and Dander at 1:100 w/v; and UF Dog 1:650 w/v; Negative Skin Test Control at 50% Glycerin v/v.

Weight per volume (w/v). For regular extracts this describes the extraction ratio, i.e., the amount of crude allergen added to the extracting fluid. A 1:10 extract, therefore indicates that the solution contains the extracted material from one gram of raw material added to each 10 mL of extracting fluid. The amount and composition of extracted materials will vary with the type of antigen, the extracting fluid, duration of extraction, pH, temperature, and other variables.

AP™ (acetone precipitated) extracts, if present, are prepared by reconstituting dry, allergenically active concentrates produced by precipitation process from extracts of raw materials. For those AP™ extracts labelled on a weight per volume (w/v) basis, the strength designation indicates the dry weight of finished (acetone) precipitate per volume of reconstituting fluid. For example, 1:50 (w/v) means that each gram of dry precipitate obtained from the original extract is reconstituted in 50 mL of solution.

Amb a 1 (UA/mL). Amb a 1 is considered the most important allergen in Ragweed Pollen and is measured by agar gel immune-diffusion against a reference standard established by the CBER. The concentration of Amb a 1 is expressed as units of Amb a 1 per mL of extract.

**Table #1 – ALLERGENIC EXTRACT – NON-POLLENS Dosage Forms, Strengths, Composition and Packaging**

Route of Administration	Dosage Form / Strength / Composition	Non-medicinal Ingredients
Percutaneous (scratch, prick/puncture)	Solution/ Refer to Product List Table	50 % Glycerin (v/v) 0.5 % Sodium chloride (w/v) 0.275 % Sodium bicarbonate (w/v)

**Table #2 – ALLERGENIC EXTRACT – POLLENS Dosage Forms, Strengths, Composition and Packaging**

Route of Administration	Dosage Form / Strength / Composition	Non-medicinal Ingredients
Percutaneous (scratch, prick/puncture)	Solution/ Refer to Product List Table	Variable % Glycerin or Phenol 0.5 % Sodium chloride (w/v) 0.275 % Sodium bicarbonate (w/v)

**Table #3 – NEGATIVE SKIN TEST CONTROL – GLYCERIN Dosage Forms, Strengths, Composition and Packaging**

Route of Administration	Dosage Form / Strength / Composition	Non-medicinal Ingredients
Percutaneous (scratch, prick/puncture)	Liquid/No Active Pharmaceutical Ingredient	50 % Glycerin (v/v) 0.5 % Sodium chloride (w/v) 0.275 % Sodium bicarbonate (w/v) In Water for Injection

Table – Product List

ALLERGENIC EXTRACT - POLLENS ANTIGEN		CONC.
TREE	ACACIA, GOLDEN	1:20 w/v
	ALDER, RED	
	ASH, WHITE	
	BEECH, AMERICAN	
	BIRCH MIX (PRW)	
	BOTTLEBRUSH TREE	
	BOXELDER/MAPLE MIX (BHR)	
	CEDAR, MOUNTAIN	
	CEDAR, RED	
	COTTONWOOD, COMMON	
	CYPRESS, ARIZONA	
	ELM, AMERICAN	
	ELM, CHINESE	
	GUM, SWEET	
	HACKBERRY	
	HICKORY, SHAGBARK	
	MAPLE, HARD/SUGAR	
	MELALEUCA	
	MESQUITE TREE	
	MULBERRY MIX (RW)	
	OAK MIX (RVW)	
	OAK, RED	
	OLIVE TREE	
	PALM, QUEEN	
	PECAN TREE	
	PINE MIX (LY)	
PRIVET, COMMON		
SYCAMORE, AMERICAN		
TREE MIX #5		
TREE MIX #11		
WALNUT, BLACK		
WILLOW, BLACK		
CYPRESS, BALD	1:50 w/v	
GRASS	BAHIA GRASS	1:20 w/v
	BROME, SMOOTH	
	CORN, COMMON CULTIVATED	
	JOHNSON GRASS	
	OATS, COMMON CULTIVATED	

ALLERGENIC EXTRACT - POLLENS ANTIGEN (CONT.)		CONC.
WEED	CARELESS WEED	1:20 w/v
	CARELESS/PIGWEEED (CR)	
	COCKLEBUR, COMMON	
	DOCK/SORREL MIX (DS)	
	DOG FENNEL, EASTERN	
	GOLDENROD	
	KOCHIA	
	LAMBS QUARTERS	
	MARSHOLDER/POVERTY MIX (BPT)	
	NETTLE	
	PIGWEEED, ROUGH REDOOT	
	PLANTAIN, ENGLISH	
	RAGWEEED, GIANT	
	RAGWEEED, WESTERN	
	RUSSIAN THISTLE	
	SAGEBRUSH, MUGWORT	
SCALE, WING		
SHEEP SORREL		
WEED MIX 2630		
RAGWEEED, MIX (GS)	100 Amb a 1 UA/mL	
RAGWEEED, SHORT	200 Amb a 1 UA/mL	
ALLERGENIC EXTRACT NON-POLLENS ANTIGEN		CONC.
EPIDERMAL	DOG HAIR & DANDER	1:10 w/v
	FEATHER MIX	
	GUINEA PIG HAIR & DANDER	1:50 w/v
	A.P. CATTLE HAIR & DANDER	
	A.P. HORSE HAIR & DANDER	
A.P. DOG HAIR & DANDER	1:100 w/v	
U.F. DOG HAIR & DANDER	1:650 w/v	
INSECT	COCKROACH, AMERICAN	1:10 w/v
	COCKROACH, GERMAN	
	COCKROACH MIX	
	FIRE ANT, RED	
MOLD	ALTERNARIA TENUIS	1:10 w/v
	ASPERGILLUS FUMIGATUS	
	CEPHALOSPORIUM	
	ACREMORIUM	
	EPICACCUM NIGRUM	
	FUSARIUM VASINFECTUM	
	HELMINTHOSPORIUM	
	INTERSEMINATUM	
	MUCOR RACEMOSUS	
	PENICILLIUM NOTATUM	
	PHOMA HERBARUM	
	PULLULARIA PULLULANS	
CANDIDA ALBICANS		
CANDIDA ALBICANS	1:1,000 w/v	

## 7. WARNINGS AND PRECAUTIONS

### General

Please see Section 3 SERIOUS WARNINGS AND PRECAUTIONS BOX.

Always have injectable epinephrine and a tourniquet available when tests are being made. Emergency resuscitation measures and personnel trained in their use should be available immediately in the event of a serious systemic or anaphylactic reaction not responsive to the above measures. See Section 8 ADVERSE REACTIONS.

Generally, 50-60 scratch, prick or puncture tests can be applied safely at one sitting. Patients whose history suggests severe sensitivity should have only 5-10 tests applied at a time and these tests applied to the volar surface of one arm. These tests should not all be of the same type of antigen; that is, all grass pollens, all weed pollens, all danders, etc. One or two tests from several classes of antigens should be applied at a time.

As soon as a large wheal begins to develop, wipe the antigen from it with a damp cotton sponge. After 30 minutes wipe off all the antigens with a damp cotton sponge, followed by a dry cotton sponge. Be careful not to wipe antigen from a positive reaction into an adjacent scratch site.

### Carcinogenesis and Mutagenesis

Long-term studies in animals have not been conducted with allergenic extracts to determine their potential for carcinogenicity or mutagenicity. See Section 16 NON-CLINICAL TOXICOLOGY.

### Cardiovascular

Patients with cardiovascular diseases or pulmonary diseases such as symptomatic asthma, and/or who are receiving cardiovascular drugs such as beta blockers, may be at higher risk for severe adverse reactions (see Section 3 SERIOUS WARNINGS AND PRECAUTIONS BOX, Section 9 DRUG INTERACTIONS). These patients may also be more refractory to the normal anaphylaxis treatment regimen.

### Reproductive Health: Female-and Male Potential

- **Fertility**

Long-term studies in animals have not been conducted with allergenic extracts to determine their potential for impairment of fertility. See Section 7.1.1 Pregnant Women.

### Respiratory

The presence of asthmatic signs and symptoms appear to be an indicator for severe reactions following allergy testing or injections. An assessment of airway obstruction either by measurement of peak flow or an alternate procedure may provide a useful indicator as to the advisability of administering diagnostic testing or an allergy injection.

### Sensitivity/Resistance

Excessively large local reactions or systemic reactions are more likely to occur if the patient is skin tested shortly after exposure to large amounts of antigen to which they are sensitive. Use caution when skin testing patients during a season when pollen is present or after exposure to inhalant allergens that produce symptoms. See Section 8 ADVERSE REACTIONS.

### Skin

Allergenic extracts for percutaneous testing, used according to Section 4 DOSAGE AND ADMINISTRATION, produce erythema or erythema and wheal reactions in patients with significant IgE-mediated sensitivity to the relevant

allergen. This allergic inflammatory response, although not completely understood, is thought to begin with reaction of antigen with IgE on the surface of basophils or mast cells, which initiates a series of biochemical events resulting in the production of histamine and other mediators. These, in turn, produce the immediate-type “wheal and flare” skin reaction. See Section 8.1 Adverse Reaction Overview.

If a severe local reaction occurs during scratch, prick or puncture testing, WIPE OFF test antigen. Large, persistent local reactions or minor exacerbations of the patient’s allergic symptoms may be treated by local cold applications and/or the use of oral antihistamines, but they should be considered a warning of possible severe systemic reactions.

## **7.1. Special Populations**

### **7.1.1. Pregnant Women**

#### **Use in Pregnancy**

Animal reproduction studies have not been conducted with allergenic extracts. It is also not known whether allergenic extracts can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Allergenic extracts should be given to a pregnant woman only if clearly needed.

On the basis of histamine’s known ability to contract the uterine muscle, allergenic extracts should be used cautiously in pregnant women.

### **7.1.2. Breast Feeding**

There are no current studies on the secretion of the allergenic extract components in human milk, or 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.

### **7.1.3. Pediatrics**

The dose is the same in patients of all age groups.

Wheal sizes in response to allergen skin testing can be smaller in infants than in adults. The skin response to histamine parallels that for allergens; therefore, appropriate positive control skin tests should always be performed.

### **7.1.4. Geriatrics**

The dose is the same in patients of all age groups. Skin test wheal size decreases with age, therefore, appropriate positive skin test controls should always be performed.

## **8. ADVERSE REACTIONS**

### **8.1. Adverse Reaction Overview**

#### **Information to be Provided to the Patient**

Patients should be instructed in the recognition of adverse reactions to diagnostic testing. Patients should be made to understand the importance of a 30-minute observation period, and be warned to return to the office promptly if symptoms occur after leaving.

#### **Systemic Reactions**

See Section 3 SERIOUS WARNINGS AND PRECAUTIONS BOX.

Frequency data for adverse reactions resulting from allergenic extract administration for testing and treatment show that risk is low.

It cannot be overemphasized that, under certain unpredictable combinations of circumstances, anaphylactic shock is a possibility. Other possible systemic reaction symptoms include fainting, pallor, bradycardia, hypotension, angioedema, cough, wheezing, conjunctivitis, rhinitis and urticaria.

**If a systemic or anaphylactic reaction does occur, WIPE OFF test antigen, and apply epinephrine.**

Emergency resuscitation measures and personnel trained in their use should be available immediately in the event of a serious systemic or anaphylactic reaction not responsive to the above measures. Patients should have an emergency anaphylaxis kit containing epinephrine available and be instructed in its use for emergency treatment of possible systemic reactions occurring at times after the patient has departed from treatment premises.

### 8.5. Post-Market Adverse Reactions

The most frequently reported serious and expected reactions is anaphylaxis.

## 9. DRUG INTERACTIONS

### 9.1. Serious Drug Interactions

#### Serious Drug Interactions

- Patients on beta blockers. See Section 9.4 Drug-Drug Interactions.

### 9.2. Drug Interactions Overview

Patients on beta blockers may be more reactive to allergens given for testing or treatment and may be unresponsive to the usual doses of epinephrine used to treat allergic reactions.

Certain medications may lessen the skin test wheal and erythema responses elicited by allergens and histamine for varying time periods. Conventional antihistamines should be discontinued at least 5 days before skin testing. Long acting antihistamines 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.

Tricyclic antidepressants such as doxepin should be withheld for at least 7 days before skin testing. Topical local anesthetics may suppress the flare responses and should be avoided in skin test sites.

### 9.4. Drug-Drug Interactions

The drugs listed in this table are based on either drug interaction case reports or studies, or potential interactions due to the expected magnitude and seriousness of the interaction (i.e., those identified as contraindicated).

**Table #4 - Established or Potential Drug-Drug Interactions**

[Proper/Common name]	*Source of Evidence	Effect	Clinical comment
<b>Beta Blocking Agents</b> (ex. Acebutolol, Atenolol, Bisoprolol, Carvedilol, Labetalol, Metoprolol, Nadolol, Nebivolol, Oxprenolol, Pindolol, Sotalol, Propranolol, Timolol)	C	Increased reactivity on skin test	Beta-blockers may attenuate the response to epinephrine in the treatment of anaphylactic reactions. Noncardioselective beta-blockers, in particular, can antagonize the bronchodilating effects of epinephrine by blocking beta-2 adrenergic receptors in smooth muscles of the bronchial tree. Consider alternative medication or withholding medication for 24 hours prior to skin test or an immunotherapy injection; consult prescribing physician on risks of switching or withholding medication.
	C	Blocks cardio-stimulatory effects of epinephrine	

[Proper/Common name]	*Source of Evidence	Effect	Clinical comment
<b>Beta2 Agonists</b> (ex. Oral terbutaline and parenteral ephedrine)	T	Possible suppression of skin test response to allergen	Do not withhold if prescribed for asthma or other respiratory conditions.
<b>First/Second Generation Antihistamines</b> (ex. Chlorpheniramine, Dexchlorpheniramine, Diphenhydramine, Promethazine, Azelastine nasal, Fexofenadine, Levocabastine)	C	Suppression of wheal & flare response to skin test	First- and second-generation antihistamines should be discontinued 2 to 3 days before skin tests with notable exceptions being cetirizine, hydroxyzine, clemastine, loratadine, and cyproheptadine which may suppress skin test responses for up to 11 days.
<b>Long acting antihistamines</b> (ex. Cetirizine, Fexofenadine, Desloratadine, Hydroxyzine, Astemizole)	C	Suppression of wheal & flare response to skin test	Discontinue for at least 2 weeks prior to skin testing.
<b>Histamine<sub>2</sub> Antagonists</b> (ex. Ranitidine)	C	Mild suppression of skin test responses	Discontinue for 24 hours prior to skin testing.
<b>Prostaglandin D<sub>2</sub> Inhibitors</b> (ex. Indomethacin)	C	Increases wheal response on skin test	Withhold on day of skin testing.
<b>Tricyclic antidepressants</b> (ex. Amitriptyline, Amoxapine, Desipramine, Doxepin, Imipramine, Maprotiline, Nortriptyline, Protriptyline, Trimipramine)	C	Suppression of wheal & flare response to skin test	Withhold for at least 7 days before skin testing. Consult with prescribing physician to determine whether the risk of severe depression in patients who discontinue their medication outweighs the benefits that could be obtained from skin testing.
<b>Benzodiazepines</b> (ex. Clonazepam, Diazepam, Lorazepam, Midazolam, Alprazolam)	C, T	Suppression of wheal & flare response to skin test	Withhold for at least 7 days before skin testing. Consult with prescribing physician to determine whether the risk discontinuing medication outweighs the benefits that could be obtained from skin testing.
<b>Dopamine</b> (ex. Pramipexole, Ropinirole, Rotigotine, Apomorphine, Bromocriptine, Amantadine, Fenoldopam, Piribedil, Aripiprazole, Brexpiprazole, Cabergoline, Cariprazine) (ex. Pramipexole, Ropinirole, Rotigotine, Apomorphine, Bromocriptine, Amantadine, Fenoldopam, Piribedil, Aripiprazole, Brexpiprazole, Cabergoline, Cariprazine)	C	Suppression of skin test response	Withhold on day of skin testing.
<b>Topical local anesthetics</b> (ex. Lidocaine, Mepivacaine, Ropivacaine, Bupivacaine, Chloroprocaine, Etidocaine, Tetracaine, Benzocaine, Prilocaine, Procaine, Proparacaine, Cocaine, Dibucaine, Lidoderm, Tetracaine)	C	May suppress the flare (i.e. erythema) response to skin test	Avoid skin testing at sites of topical administration; or withhold on day of test.

[Proper/Common name]	*Source of Evidence	Effect	Clinical comment
<b>Oral corticosteroids</b> (ex. Dexamethasone, Prednisolone, Betamethasone, Decadron, Beclomethasone Methylprednisolone, Medrol, Kenalog)	C	Suppression of skin test response	Avoid skin testing at sites where medication was applied for greater than 3 weeks.
	T	Reduced efficacy of allergy immunotherapy	There is a theoretical risk of reduced immune response to allergy immunotherapy in patients requiring systemic corticosteroid treatment
<b>Topical steroids</b> (ex. Hydrocortisone, Betamethasone, Mometasone, Clobetasol, Fluocinonide, Diflorasone)	C	Suppression of skin test response	Avoid skin testing at sites where medication was applied for greater than 3 weeks.
<b>Omalizumab</b> (Xolair)	C, T	Suppression of wheal & flare response to skin test	Discontinue for 5 half-lives (~100 days) prior to skin testing
<b>In Vitro Immunoglobulin</b> (IVIG)	T	Possible suppression of skin test response	Discontinue for 5 half-lives (4-6 months) prior to skin testing
<b>Immunomodulating Biologics</b> (ex. Tecfidera, Abetacept, Enbrel, Humira)	T	Reduced efficacy of allergy immunotherapy	There is a theoretical risk of reduced immune response to allergy immunotherapy in patients treated with biologics for other immune disorders.

\* Legend: C = Case Study; CT = Clinical Trial; T = Theoretical

### 9.5. Drug-Food Interactions

Interactions with food have not been established.

### 9.6. Drug-Herb Interactions

Interactions with herbal products have not been established.

### 9.7. Drug-Laboratory Test Interactions

Interactions with laboratory tests have not been established.

## 10. CLINICAL PHARMACOLOGY

### 10.1. Mechanism of Action

Allergenic extracts for scratch, prick or puncture testing, used according to the DOSAGE AND ADMINISTRATION section, produce erythema or erythema and wheal reactions in patients with significant IgE-mediated sensitivity to the relevant allergen. This allergic inflammatory response, although not completely understood, is thought to begin with reaction of antigen with IgE on the surface of basophils or mast cells, which initiates a series of biochemical events resulting in the production of histamine and other mediators. These, in turn, produce the immediate-type “wheal and flare” skin reaction.

### 11. STORAGE, STABILITY AND DISPOSAL

The expiration date of the diagnostic extracts is listed on the container label. The extract should be stored at 2-8 °C and kept at this temperature range during office use.

## 12. SPECIAL HANDLING INSTRUCTIONS

A number of factors beyond our control could reduce the efficacy of this product or even result in an ill effect following its use. These include storage and handling of the product after it leaves our hands, diagnosis, dosage, method of administration, and biological differences in individual patients. Because of these factors, it is important that this product be stored properly, and that the directions be followed carefully during use.

For disposal of allergenic extracts, consider the use of a licensed disposal company or dispose of product in accordance with local, provincial, and federal regulations.

## PART II: SCIENTIFIC INFORMATION

### 13. PHARMACEUTICAL INFORMATION

#### Drug Substance

Proper name: ALLERGENIC EXTRACT- POLLENS and ALLERGENIC EXTRACT- NON-POLLENS.

Various Proteins extracted from biological source materials:

- Chicken, Duck and Goose: Feathers
- Variable Bovine Type: Hair/Dander
- Mixed Breed Canine Type: Hair/Dander
- Variable Equine: Hair/Dander
- Guinea Pig: Hair/Dander
- Whole Body Insects: Fire Ant and Cockroach
- Various Grasses
- Various Molds
- Various Trees
- Various Weeds

Pharmaceutical standard: Sterile extracts for scratch, prick or puncture (percutaneous) testing are supplied in dropper vials containing, in addition to the extract allergens and antigens, 50 % (v/v) glycerin as preservative, 0.5 % sodium chloride and 0.275 % sodium bicarbonate. The extracts may be labelled in terms of:

1. Weight to Volume (w/v)
2. Amb a 1 Units/mL

**Product Characteristics:** Appearance is clear to slightly opalescent. Parenteral Drug Products should be inspected visually for particulate matter and discoloration, prior to administration, whenever solution and container permit.

### 14. CLINICAL TRIALS

No clinical trials were sponsored by Jubilant HollisterStier LLC for the ALLERGENIC EXTRACT – POLLENS or ALLERGENIC EXTRACT – NON-POLLENS when the products were approved in 1997.

### 15. MICROBIOLOGY

No microbiological information is required for this drug product.

### 16. NON-CLINICAL TOXICOLOGY

**General Toxicology:** No long-term animal studies have been performed to evaluate carcinogenic or mutagenic potential or whether ALLERGENIC EXTRACT – POLLENS and ALLERGENIC EXTRACT – NON-POLLENS affects fertility in males or females.

**Carcinogenicity:** No long-term animal studies have been performed to evaluate carcinogenic potential on ALLERGENIC EXTRACT – POLLENS and ALLERGENIC EXTRACT – NON-POLLENS.

**PATIENT MEDICATION INFORMATION****READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE****ALLERGENIC EXTRACT – POLLENS,  
ALLERGENIC EXTRACT – NON-POLLENS and  
NEGATIVE SKIN TEST CONTROL – GLYCERIN**

Allergenic Extracts for Scratch, Prick, Puncture (Percutaneous) Testing Diagnostic Agent

Read this carefully before you are provided ALLERGENIC EXTRACT – POLLENS, ALLERGENIC EXTRACT – NON-POLLENS or NEGATIVE SKIN TEST CONTROL – GLYCERIN. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about ALLERGENIC EXTRACT – POLLENS, ALLERGENIC EXTRACT – NON-POLLENS or NEGATIVE SKIN TEST CONTROL – GLYCERIN prior to each doctor visit where an injection is provided.

**Serious Warnings and Precautions**

- The product should only be provided by physicians who are experienced in the use of allergenic extracts, or for use under the guidance of an allergist.
- Allergenic extracts may potentially cause a severe life-threatening systemic reaction (anaphylaxis), which can result in death. Therefore, emergency measures and personnel trained in their use must be available immediately in the event of such a reaction. You should also be instructed to recognize serious symptoms and contact the physician's office if symptoms occur.
- If you are on beta blockers, you may be more reactive to allergens given for testing or treatment and may be unresponsive to the usual doses of epinephrine used to treat allergic reactions.
- The diagnosis process with this product should not cause bleeding.

**What are ALLERGENIC EXTRACT – POLLENS, ALLERGENIC EXTRACT – NON-POLLENS or NEGATIVE SKIN TEST CONTROL – GLYCERIN used for?**

“ALLERGENIC EXTRACT – POLLENS, ALLERGENIC EXTRACT – NON-POLLENS and NEGATIVE SKIN TEST CONTROL – GLYCERIN have been approved for the following indication(s) by Health Canada. This means they have passed Health Canada's review and can be purchased and administered in Canada. For more information, talk to your healthcare professional.”

- These products are used for the diagnosis of patients with specific allergic conditions.

**How do ALLERGENIC EXTRACT – POLLENS, ALLERGENIC EXTRACT – NON-POLLENS and NEGATIVE SKIN TEST CONTROL – GLYCERIN work?**

You will have allergenic extracts placed on your skin. A prick will be made through the extract into your skin. If you are allergic to a specific extract, a bump in the skin will form. Your physician will measure the bump. Based on the size of the bump, the physician will determine if treatment (immunotherapy) is an option to relieve or lessen your responses to that allergen.

**What are the ingredients in ALLERGENIC EXTRACT – POLLENS, ALLERGENIC EXTRACT – NON-POLLENS and NEGATIVE SKIN TEST CONTROL – GLYCERIN?**

- **ALLERGENIC EXTRACT – POLLENS:**  
Medicinal ingredients: Various Pollen Extracts

Non-medicinal ingredients: Glycerin, Sodium chloride and Sodium bicarbonate

- **ALLERGENIC EXTRACT – NON-POLLENS:**

Medicinal ingredients: Various Epidermal, Insect and Mold Extracts

Non-medicinal ingredients: Glycerin, Sodium chloride and Sodium bicarbonate

- **NEGATIVE SKIN TEST CONTROL – GLYCERIN:**

Non-medicinal ingredients: Glycerin, Sodium chloride and Sodium bicarbonate

**ALLERGENIC EXTRACT – POLLENS, ALLERGENIC EXTRACT – NON-POLLENS and NEGATIVE SKIN TEST CONTROL – GLYCERIN come in the following dosage forms:**

- **ALLERGENIC EXTRACT – POLLENS:**

Dosage Form: Solution

Strength (*Product Dependent*): 1:20 w/v, 1:50 w/v, 100 Amb a 1 UA/mL and 200 Amb a 1 UA/mL)

- **ALLERGENIC EXTRACT – NON-POLLENS:**

Dosage Form – Solution

Strength (*Product Dependent*): 1:10 w/v, 1:50 w/v, 1:100 w/v, 1:650 w/v and 1:1,000 w/v)

- **NEGATIVE SKIN TEST CONTROL – GLYCERIN:**

Dosage Form – Liquid

Strength: 50 % v/v

**Do not use ALLERGENIC EXTRACT – POLLENS, ALLERGENIC EXTRACT – NON-POLLENS or NEGATIVE SKIN TEST CONTROL – GLYCERIN if:**

Your healthcare professional has not prescribed it and administered it within their medical office.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ALLERGENIC EXTRACTS – POLLENS, ALLERGENIC EXTRACTS – NON-POLLENS or NEGATIVE SKIN TEST CONTROL – GLYCERIN. Talk about any health conditions/circumstances you may have, including:**

- Cancer
- Heart Disease
- Female/Male Fertility concerns
- Respiratory Issues
- Allergen Sensitivity/Resistance
- Skin irritations
- Pregnancy
- Nursing Mother

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines. The following may interact with ALLERGENIC EXTRACT – POLLENS, ALLERGENIC EXTRACT – NON-POLLENS or NEGATIVE SKIN TEST CONTROL – GLYCERIN:**

When discussing with your healthcare professional, make specific reference to the following type of medications:

Medication Type	Treatment of:
Beta Blockers	High blood pressure
Dopamine	Low blood pressure, Parkinson's disease, Cardiac or Kidney function
Beta2 Agonists Omalizumab/Xolair Oral corticosteroids/Inhalers	Asthma/COPD
Prostaglandin D2 Inhibitors	Asthma, allergic rhinitis, and atopic dermatitis
Antihistamines	Motion Sickness, nausea or insomnia
Histamine2 Antagonists	Gastric ulcers, acid reflux or heart burn

Antidepressants	Depression, chronic pain, addiction or mental health conditions
Benzodiazepines	Anxiety, insomnia and seizures
Topical local anesthetics	Creams or lotions that numb the skin to reduce pain or itching
Topical steroids	Inflammatory skin conditions
In Vitro Immunoglobulin	In vitro fertilization (IVF) and recurrent pregnancy loss
Immunomodulating Biologics	Autoimmune diseases, rheumatoid arthritis, psoriasis, Crohn's disease; oncologic, allergic, rheumatologic, and neurologic conditions

**How to take ALLERGENIC EXTRACT – POLLENS, ALLERGENIC EXTRACT – NON-POLLENS or NEGATIVE SKIN TEST CONTROL – GLYCERIN:**

- Skin testing is performed by a healthcare professional by placing a drop of specific extract(s), positive skin test control and a negative skin test control on your skin. The healthcare provider will then superficially prick your skin with a sterile needle.
- This process should not make you bleed.

Usual dose:

- A single drop of a specific extract. The amount of extracts tested are based on the history you provide your healthcare professional and their expert recommendation.

Overdose:

- An overdose could occur based on your sensitivity to the extract(s) and in rare instances could result in anaphylactic symptoms. It is imperative that the physician administering your allergenic extracts understand and be prepared for the treatment of severe reactions.

**What are possible side effects from using ALLERGENIC EXTRACT – POLLENS, ALLERGENIC EXTRACT – NON-POLLENS or NEGATIVE SKIN TEST CONTROL – GLYCERIN?**

These are not all the possible side effects you may have when taking ALLERGENIC EXTRACT – POLLENS, ALLERGENIC EXTRACT – NON-POLLENS or NEGATIVE SKIN TEST CONTROL – GLYCERIN. If you experience any side effects not listed here, tell your healthcare professional.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>VERY COMMON</b>			
			N/A
<b>COMMON</b>			
			N/A
<b>RARE</b>			
Anaphylaxis		X	Seek emergency medical help immediately.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

**Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

**Storage:**

This product will be stored at 2-8 °C by your healthcare professional.

Keep out of reach and sight of children.

**If you want more information about ALLERGENIC EXTRACT – POLLENS, ALLERGENIC EXTRACT – NON-POLLENS and NEGATIVE SKIN TEST CONTROL – GLYCERIN:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the:
  - Health Canada website  
<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drugproduct-database.html>;
  - Manufacturer's website  
<https://www.hsallergy.com/>,
  - Manufacturer's phone  
1-800-992-1120

This leaflet was prepared by Jubilant HollisterStier LLC.

Last Revised February 2026

