

PRODUCT MONOGRAPH
INCLUDING PATIENT MEDICATION INFORMATION

ALLERGENIC EXTRACT POLLENS
ALLERGENIC EXTRACT NON POLLENS
Allergenic Extracts for Diagnostic Use Only
Liquid, Intradermal, Percutaneous

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

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PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

ALLERGENIC EXTRACTS are indicated for:

- use in skin testing to establish the clinical relevance of specific allergens to which the patient has been exposed.

These products are for diagnostic use only. By measuring skin test response, the physician may assess the degree of sensitivity that patients have to the allergens.

1.1 Pediatrics

Allergenic extracts for diagnostic use have been given safely in infants and young children. Infants have lower skin test reactivity to histamine, as well as common allergens. Skin test reactivity gradually increases to age 6 and plateaus to age 60. Therefore, small skin test reactions should be anticipated in children under age 6. The pediatric population includes those patients from birth to younger than 17 years (i.e., birth through 16 years of age), and includes the following subpopulation age groups of neonates, infants, children, and adolescents, Consistent with International Council for Harmonisation (ICH) guidelines:

- Neonates: birth through 27 days (corrected gestational age)
- Infants: 28 days to 23 months
- Children: 2 years to 11 years
- Adolescents: 12 years to younger than 17 years

1.2 Geriatrics

Skin test reactivity gradually decreases after age 60. Therefore, smaller skin test reactions should be anticipated in adults over age 60.

2 CONTRAINDICATIONS

- Patients on beta blockers can be non-responsive to beta agonists that may be required to reverse a systemic reaction (also, see [3 SERIOUS WARNINGS AND PRECAUTIONS BOX](#) and [8 ADVERSE REACTIONS](#)). The physician should carefully weigh the benefit derived from skin testing vs. the risk to the patient should a systemic reaction arise.
- Patients with unstable asthma or steroid dependent asthmatics and patients with underlying cardiovascular disease are at greater risk to a fatal outcome from a systemic allergic reaction^{2,3}. See also [7 WARNINGS AND PRECAUTIONS](#) and [8 ADVERSE REACTIONS](#).

3 SERIOUS WARNINGS AND PRECAUTIONS BOX

Serious Warnings and Precautions

- This product is intended for use by physicians who are experienced in the administration of allergenic extracts and the emergency care of anaphylaxis, or for use under the guidance of an allergy specialist.
- As with all allergenic extracts, severe systemic reactions may occur. In certain individuals these

life-threatening reactions may result in death. Fatalities associated with skin testing have been reported. Patients should be observed for at least 20 - 30 minutes following testing. Emergency measures and adequately trained personnel should be immediately available in the event of a life-threatening reaction.

- Patients with unstable asthma or steroid dependent asthmatics and patients with underlying cardiovascular disease are at greater risk to a fatal outcome from a systemic allergic reaction.
- Sensitive patients may experience severe anaphylactic reactions resulting in respiratory obstruction, shock, coma and/or death. Adverse events are to be reported 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>) or calling toll-free at 1-866-234-2345. This product should not be injected intravenously. Patients receiving beta blockers may not be responsive to epinephrine or inhaled bronchodilators. Respiratory obstruction not responding to parenteral or inhaled bronchodilators may require theophylline, oxygen, intubation and the use of life support systems. Parenteral fluid and/or plasma expanders may be utilized for the treatment of shock. Adrenocorticosteroids may be administered parenterally or intravenously. Refer to **3 SERIOUS WARNINGS AND PRECAUTIONS BOX**, **7 WARNINGS AND PRECAUTIONS**, and **8 ADVERSE REACTIONS**.
- This product should not be injected intravenously.

4 DOSAGE AND ADMINISTRATION

4.1 Dosing Considerations

- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.
- Skin test techniques for immediate (Type I) hypersensitivity testing fall into two major categories: percutaneous, and intracutaneous.

4.2 Recommended Dose and Dosage Adjustment

- **Percutaneous techniques:** For percutaneous testing, in general, skin is scratched, punctured or pricked just before the allergen is applied or through a drop of test allergen. There are several devices available for this technique. Refer to the manufacturer or distributor's circular for specific directions for their use.
- **Intradermal testing:** General: Intradermal testing is more sensitive than percutaneous testing and its specificity is dependent on dose. Intradermal testing is not intended as an initial screen unless used in highly dilute solutions. Intradermal testing is usually reserved for allergens that have demonstrated either negative or equivocal percutaneous skin test response in the face of positive or unclear history.
- Intradermal testing of one allergen in several serial dilutions (beginning with the weakest to the more concentrated dilutions) may also be useful in assessing degree of patient sensitivity for the establishment of a safe starting dose for immunotherapy.
- Selection of the proper strength for intradermal testing: A general rule for the prevention of untoward reactions, particularly in extremely sensitive patients, is to screen by percutaneous methods initially, and begin intradermal testing at a strength not more than 1/100 of a negative or

equivocal percutaneous reaction.

4.3 Dilution

Intradermal testing:

- Bulk extracts must be diluted for intradermal testing. Use of Sterile Diluent for Allergenic Extracts or Sterile Diluent for Allergenic Extracts Normal Saline with HSA (albumin saline) is recommended. Dilutions should be made with sterile disposable syringes using aseptic technique. Commonly 10 fold dilutions are used to achieve a desired concentration for intradermal testing and continuation of immunotherapy. For example, transferring 0.5 mL of a 10,000 PNU/mL extract into 4.5 mL of diluent will yield 5 mL of extract at 1,000 PNU/mL. For weight volume products, a 1:100 w/v dilution may be prepared from a 1:10 w/v by transferring 0.5 mL of the 1:10 w/v to 4.5 mL of diluent. Prepare as many additional serial dilutions as necessary to reach the appropriate concentration. As a general rule intradermal strength should begin at no higher than 1/100 to 1/1000 of the percutaneous strength that resulted in a negative skin test reaction.

4.4 Administration

Percutaneous techniques: In General:

1. It is recommended that the test areas should be placed no closer than 4 - 5 cm apart to avoid interference of reactions when several tests are applied.
2. Skin test areas should be cleansed with alcohol and air dried.
3. Preferably, testing should be performed on the volar surface of the forearm, upper arm, or the patient's back. The patient should be placed in a comfortable position prior to testing.
4. For scratch testing, a sharp, clean, sterile instrument is used to abrade the skin, but not to draw blood. Each scratch should be about 2 - 4 mm in length. A small drop of extract is placed on the area of skin that was scratched.
5. Prick testing: For prick testing, a sharp, sterile instrument is used to puncture the skin slightly, applying it at a 15 - 20° angle to the skin. The instrument is gently raised, "tenting" the skin until it pops out, generally pricking through the drop of allergen. Do not draw blood.
6. For puncture testing, a drop of allergen is applied to the skin, then a sharp, clean, sterile instrument must be used to puncture the skin. Puncture the skin, through the drop of allergen, perpendicular to the skin. Do not draw blood.
7. Care must be taken to avoid drawing blood. If blood is observed, immediately wipe the allergen from the site.

For all of the above techniques, a separate instrument must be used for each patient; if the instrument is to be used to pass through the allergen, to avoid cross-contamination, a separate instrument is to be used for each allergen. The test should be read in 15 minutes, measuring both wheal size and erythema.

Intradermal testing:

1. It is recommended that the test areas should be spaced no less than 5 cm apart to avoid interference with adjacent allergen or control.
2. Skin should be cleansed with alcohol and air dried.
3. A sterile 1 mL or 1/2 mL syringe should be used to draw 0.01 - 0.02 mL of extract from the vial. Intradermal injection should be performed with a 26 - 30 gauge needle. A separate sterile syringe should be used for each extract and each patient.

4. Care should be taken to eliminate air bubbles from the syringe prior to injecting the test dose. It is suggested that not more than 6 - 10 allergens of each different type be used at any one time. Very sensitive patients may show rapid response.
5. The skin is held tensely, and the needle is inserted almost parallel to the skin, beveled side up far enough to cover the beveled portion. Pull gently on the syringe plunger and note if any blood enters the syringe. If blood is obtained, reposition the needle and repeat before injecting. Slowly inject sufficient extract to make a small bleb of approximately 5 mm in diameter (0.01 - 0.02 mL).
6. Read the test results in 15 minutes.

Controls: In both percutaneous and intracutaneous tests, a negative control test with diluent alone should be performed because some patients exhibit dermatographia, and/or other non-specific irritant responses.

As a positive control in the evaluation of allergenic skin testing, histamine 1 mg/mL (histamine base) should be used for percutaneous testing, and histamine 0.1 mg/mL (histamine base) should be used for intradermal testing.

Interpretation of results: Patient's response is graded on the basis of the size of erythema or wheal.⁶ General guidelines follow for percutaneous testing, different devices and/or techniques influence the size of the reaction, therefore it is important to refer to the device manufacturer's or distributor's instructions when grading reactions

Percutaneous (prick or scratch) test:

- 0 No reaction or less than control.
- + Erythema greater than control, smaller than a nickel (21 mm diameter).
- ++ Erythema greater than a nickel in diameter, no wheal.
- +++ Wheal and erythema without pseudopods.
- ++++ Wheal and erythema with pseudopods.

Intradermal test:

- 0 No reaction or less than negative control.
- + 3-4 mm wheal with erythema, or erythema alone larger than a nickel (21 mm diameter).
- ++ 4-8 mm wheal and erythema, without pseudopods.
- +++ Over 8 mm wheal and erythema without pseudopods.
- ++++ Wheal and erythema with pseudopods.

5 OVERDOSAGE

Systemic reactions are uncommon after injection, but if the patient receives more extract than can be tolerated at that particular time and begins to experience immediate hypersensitivity anaphylaxis, the procedures listed under 8 [ADVERSE REACTIONS](#) should be instituted.

Overdosage may occur because of an error in the volume of extract injected, or an

incorrect dilution injected, or because the patient may be exposed to airborne or environmental antigens simultaneously with injection of the same antigens. In the event of a systemic reaction occurring, the dosage schedule should be carefully adjusted as outlined above under 7 [WARNINGS AND PRECAUTIONS](#).

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

Table – Dosage Forms, Strengths, Composition and Packaging

Route of Administration	Dosage Form / Strength/Composition	Non-medicinal Ingredients
Intradermal, Percutaneous	Liquid, W/V or PNU/mL	Phenol, glycerin, sodium bicarbonate as a buffer, sodium chloride for isotonicity

For scratch and prick testing/percutaneous: 5 mL dropper applicator vials in 50% v/v glycerin or 10 mL stoppered vial in 50% v/v glycerin. Available individually and in a complete set of the most common allergens. Available in weight to volume (w/v).

For intradermal testing: 5 mL sterile vials, aqueous based, individually and in a complete set of the most common allergens. Available in either Protein Nitrogen Units (PNU/mL) or weight to volume (w/v).

Histatrol® Positive Skin Test Control - Histamine (1 mg/mL and 0.1 mg/mL histamine base).

See Product Catalog for specific diagnostic concentrations available.

7 WARNINGS AND PRECAUTIONS

General

- In the presence of active symptoms such as rhinitis, wheezing, dyspnea, etc., the indications for skin testing must be weighed carefully against the risk of temporarily aggravating the symptoms by the testing itself. Objective assessment of pulmonary function such as Peak Expiratory Flow Rate (PEFR) before allergen administration and prior to discharge may be useful in unstable asthmatics to reduce the chances of exacerbation of the patient's asthma. Patients should be instructed to describe any active allergic symptoms as described above prior to skin testing and encouraged to report any late reactions from this testing. Also, see [3 SERIOUS WARNINGS AND PRECAUTIONS BOX](#) and [8 ADVERSE REACTIONS](#).
- Store allergenic extracts between 2°-8°C at all times, even during use.
- Care must be taken to avoid drawing blood.
 - For percutaneous testing, if blood is observed, immediately wipe the allergen from the site.
 - For intradermal skin testing, pull gently on the syringe plunger and note if any blood enters the syringe. If blood is obtained, reposition the needle and repeat before injecting (see [4 DOSAGE AND ADMINISTRATION](#)).
- Allergenic extracts become less potent with age. Allergenic extracts containing glycerin 50% v/v are relatively stable. Non-glycerinated aqueous extracts, particularly dilute forms as used for intradermal skin testing, have been shown to be extremely unstable. Until such time as stability studies are complete with dilute allergens, new intradermal strength materials should be prepared every few weeks.
- Use standard aseptic precautions if making dilutions from stock concentrates to intradermal

strength.

6. For intradermal testing: Extracts in glycerin 50% v/v must be diluted with a non-glycerinated diluent and must be diluted at least 25-fold to less than 2% glycerin by volume, as glycerin above this level can cause false positive intradermal skin test results.

Severe Allergic Reactions:

Patients should always be observed for at least 20 - 30 minutes after skin testing. In the event of a marked systemic reaction such as urticaria, angioedema, wheezing, dyspnea, respiratory obstruction, hypotension, coma and death (see 8 **ADVERSE REACTIONS**), applications of a tourniquet above the injection site and administration of 0.2 mL to 1 mL (0.01 mg/kg) of epinephrine injection (1:1,000) are recommended. Maximal recommended dose for children between 2 and 12 years of age is 0.5 mL. The tourniquet is then gradually released at 15-minute intervals. Patients under treatment with beta blockers may be refractory to the usual dose of epinephrine.

Volume expanders and vasopressor agents may be required to reverse hypotension, inhalation bronchodilators and parenteral aminophylline may be required to reverse bronchospasm. In case of respiratory obstruction, oxygen and intubation may be necessary. Life-threatening reactions unresponsive to the above may require cardiopulmonary resuscitation.

Anaphylaxis Following False Negative Food Allergen Skin Test Results:

There have been post-market reports of false negative skin test results, associated with anaphylaxis from subsequent exposure to the allergen. Based on the patient's clinical history, and if there is a high index of suspicion, healthcare providers should confirm negative skin testing with serologic testing by measuring specific serum IgE or with a medically-supervised oral food challenge.

Carcinogenesis and Mutagenesis

Studies in animals have not been performed.

Monitoring and Laboratory Tests

Patients should always be observed 20 to 30 minutes after skin testing.

7.1 Special Populations

7.1.1 Pregnant Women

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.

Controlled studies of hyposensitization with moderate to high doses of allergenic extracts during conception and all trimesters of pregnancy have failed to demonstrate any risk to the fetus or to the mother⁴. However, on the basis of histamine's known ability to contract the uterine muscle, the release of significant amounts of histamine from allergen exposure to skin test overdose should be avoided on theoretical grounds. Therefore, allergenic extracts should be used cautiously in a pregnant woman and only if clearly needed.

7.1.2 Breast-feeding

It is not known if allergens administered subcutaneously appear in human milk. 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

Allergenic extracts for diagnostic use have been given safely in infants and young children. Infants have lower skin test reactivity to histamine, as well as common allergens. Skin test reactivity gradually increases to age 6 and plateaus to age 60. Therefore, small skin test reactions should be anticipated in children under age 6. The pediatric population includes those patients from birth to younger than 17 years (i.e., birth through 16 years of age), and includes the following subpopulation age groups of neonates, infants, children, and adolescents, Consistent with International Council for Harmonisation (ICH) guidelines:

- Neonates: birth through 27 days (corrected gestational age)
- Infants: 28 days to 23 months
- Children: 2 years to 11 years
- Adolescents: 12 years to younger than 17 years

7.1.4 Geriatrics

Skin test reactivity gradually decreases after age 60. Therefore, smaller skin test reactions should be anticipated in adults over age 60.

8 ADVERSE REACTIONS

8.1 Adverse Reaction Overview

Fatalities from skin testing in the United States have been extensively reviewed by Lockey.² Six fatalities were associated with intradermal testing without previous percutaneous testing, and one was associated with a combination of percutaneous (scratch) and intradermal skin testing. With careful attention to dosage and administration, fatal reactions occur infrequently, but it must be remembered that allergenic extracts are highly potent to sensitive individuals and overdosage could result in anaphylactic symptoms. Therefore, it is imperative that physicians administering allergenic extracts for skin testing understand and be prepared for the treatment of severe reactions.

Local: Immediate wheal and erythema reactions are to be expected; but if very large, may be the first manifestation of a systemic reaction. In such cases, immediately wipe the test site(s) with sterile gauze or cotton to remove excess allergen.

Systemic Reactions: Systemic reactions are characterized by one or more of the following symptoms: sneezing, mild to severe generalized urticaria, itching (other than at the skin test site), extensive or generalized edema, wheezing, asthma, dyspnea, cyanosis, hypotension, syncope, and upper airway obstruction. Symptoms may progress to shock and death. Patients should always be observed for at least 20 - 30 minutes after testing.

Volume expanders and vasopressor agents may be required to reverse hypotension. Inhalational bronchodilators and parenteral aminophylline may be required to reverse bronchospasm. Severe

airway obstruction unresponsive to bronchodilator may require tracheal intubation and use of oxygen. In the event of a marked systemic reaction, application of a tourniquet above the injection site and the administration of 0.2 mL to 1.0 mL of epinephrine injection (1:1,000) is recommended. Maximum recommended dose for children between 2 and 12 years of age is 0.3 mL. The tourniquet should not be left in place without loosening for 90 seconds every 15 minutes.

Adverse events should be reported 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>) or calling toll-free at 1-866-234-2345.

9 DRUG INTERACTIONS

9.2 Drug Interactions Overview

Drugs can interfere with the performance of skin tests⁵.

9.4 Drug-Drug Interactions

Antihistamines: Response to mediator (histamine) released by allergens is suppressed by antihistamines. The length of suppression varies and is dependent on individual patient, type of antihistamine and length of time the patient has been on antihistamines. The duration of this suppression may be as little as 24 hours (chlorpheniramine) and can be as long as 40 days (astemizole).

Tricyclic Antidepressants: These exert a potent and sustained decrease of skin reactivity to histamine which may last for a few weeks.

Beta₂ Agonists: Oral terbutaline and parenteral ephedrine, in general, have been shown to decrease allergen induced wheal.

Dopamine: Intravenous infusion of dopamine may inhibit skin test responses.

Beta Blocking Agents: Propranolol can significantly increase skin test reactivity.

Other Drugs: Short acting steroids, inhaled beta₂ agonists, theophylline and cromolyn do not seem to affect skin test response.

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

Diagnostically (for skin testing) the allergen combines with IgE antibodies fixed to mast cells in the skin. This complexing causes an increase in cellular permeability and degranulation of the mast cells releasing chemical mediators. These mediators (such as histamine) are responsible for a local inflammatory response of wheal and erythema typical of a positive skin test reaction and also, the symptoms commonly associated with allergic disease.¹ The more mediator release, the larger the reaction (wheal and erythema).

11 STORAGE, STABILITY AND DISPOSAL

To maintain stability of allergenic extracts, proper storage conditions are essential. Bulk concentrates and diluted extracts are to be stored at 2 to 8°C even during use. Bulk or diluted extracts are not to be frozen. Do not use after the expiration date shown on the vial label.

PART II: SCIENTIFIC INFORMATION

13 PHARMACEUTICAL INFORMATION

Drug Substance

Proper name: Allergenic Extract Pollens

Allergenic Extract Non Pollens

Product Characteristics:

Sterile diagnostic extracts are supplied in either phenol-saline diluent for Intradermal Testing or in diluent containing glycerin 50% (v/v) for Percutaneous Testing and phenol 0.4% (preservative). Inactive ingredients may include: sodium chloride for isotonicity, glycerin, and sodium bicarbonate as a buffer.

Pollens are individually extracted from pure pollen extracted in a phenol-preserved sodium bicarbonate solution. Short Ragweed and Mixed (Tall and Short) Ragweed extracts are standardized by Antigen E content and so labeled. The Antigen E content of extracts containing Short Ragweed at a concentration more dilute than a weight/volume ratio of 1:10 are obtained by calculating the Antigen E content based on the assay value of more concentrated extract. Pollen extracts are filtered aseptically and after final packaging, they are tested for sterility and safety. Molds are individually extracted from pure powdered inactivated mold source material extracted in phenol preserved saline. Mold extracts are filtered aseptically and after final packaging are tested for sterility and safety. Molds (fungi) are present in all inhabited places at all seasons of the year; they are so ubiquitous that they are prevalent at times when common allergic pollens and other inhalants are not. In the home and surroundings, molds are found in upholstered furniture, mattresses, drapes, cellar and storage room dust, woolens, leather goods, fruits, meats, cheeses, garden soil and on plants. Spores, mycelial fragments and mold residues are thus inhaled, contacted and ingested continuously.

Foods, miscellaneous inhalants and epidermals are individually extracted in phenol preserved saline or glycerin, filtered aseptically and after final packaging are tested for sterility and safety.

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

ALLERGENIC EXTRACT POLLENS

ALLERGENIC EXTRACT NON POLLENS

Allergenic Extracts for Diagnostic Use Only

Read this carefully before you start taking **Allergenic Extracts** and each time you get a refill. 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 Extracts**.

Serious Warnings and Precautions

- This product is intended for use only by physicians who are experienced in the administration of allergenic extracts and the emergency care of severe reactions (such as anaphylaxis), or for use under the guidance of an allergy specialist.
- As with all allergenic extracts, severe reactions may occur. In certain individuals these life-threatening reactions may result in death. Fatalities associated with skin testing have been reported. Patients should be observed for at least 20 - 30 minutes following testing. Emergency measures and adequately trained personnel should be immediately available in the event of a life-threatening reaction.
- Patients with unstable asthma and patients with heart disease are at greater risk to a fatal outcome from a severe allergic reaction.
- Sensitive patients may experience severe reactions resulting in difficulty breathing, shock, coma and/or death.
- This product should not be injected intravenously.

Anaphylaxis Following False Negative Food Allergen Skin Test Results:

There have been post-market reports of false negative skin test results that are linked to anaphylaxis, after being exposed again to the allergen. Healthcare providers are instructed to confirm negative skin test results with additional testing, in case of doubt.

What are Allergenic Extracts used for?

- Skin-test diagnosis of allergy.

How do Allergenic Extracts work?

By measuring skin test response, the physician may assess the degree of sensitivity that patients have to the allergens.

What are the ingredients in Allergenic Extracts?

Medicinal ingredients: pollens, molds, foods, miscellaneous inhalants, epidermals

Non-medicinal ingredients: glycerin, sodium bicarbonate, sodium chloride and phenol

Allergenic Extracts come in the following dosage forms:

Liquid solution

Do not use Allergenic Extracts if:

- Patients on beta blockers
- Patients with unstable asthma and patients with heart disease

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Allergenic Extracts. Talk about any health conditions or problems you may have, including if you:

- are pregnant
- are breast-feeding

Other warnings you should know about:

- Patients should be instructed to describe any active allergic symptoms prior to testing.
- Patients should always be observed 20 to 30 minutes after testing.

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 Extracts:

- Antihistamines (chlorpheniramine, astemizole)
- Tricyclic Antidepressants
- Beta₂ Agonists (oral terbutaline and parenteral ephedrine)
- Dopamine
- Beta Blocking Agents (propranolol)

How to take Allergenic Extracts:

- Allergenic Extracts will be given to you by a healthcare professional in a healthcare setting.

Overdose:

Signs and symptoms of overdose are typically large local and systemic reactions. For management of overdose reactions, refer to 8 [ADVERSE REACTIONS](#).

If you think you, or a person you are caring for, has received too much Allergenic Extracts, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using Allergenic Extracts?

These are not all the possible side effects you may have when taking Allergenic Extracts. 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	
COMMON			
Skin erythema			√
Sneezing			√
Urticaria			√
Itching			√
Edema			√
Wheezing			√
Asthma			√
Dyspnea			√
Cyanosis			√
Hypotension			√
Syncope			√
Airway obstruction			√
RARE			
Shock			√
Death			√

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:

To maintain stability of allergenic extracts, proper storage conditions are essential. Bulk concentrates and diluted extracts are to be stored at 2 to 8°C even during use. Bulk or diluted extracts are not to be frozen. Do not use after the expiration date shown on the vial label.

Keep out of reach and sight of children.

If you want more information about Allergenic Extracts:

- 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/drug-product-database.html>); the manufacturer's website [www.alk.net/us], or by calling [1-800-325-7354].

This leaflet was prepared by ALK-Abelló, Inc.

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