Product Monograph

Including Patient Medication Information

ALLERGENIC EXTRACT POLLENS

ALLERGENIC EXTRACT NON POLLENS

Non-Standardized Allergenic Extracts for Therapeutic Use

For subcutaneous injection

Allergy Immunotherapy

ALK- Abelló, Inc.

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Recent Major Label Changes

None at time of the most recent authorization	

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Certain sections or subsections that are not applicable at the time of the preparation of the most recent authorized product monograph are not listed.

Part 1: Healthcare Professional Information

1. Indications

ALLERGENIC EXTRACTS (Non-standardized Allergenic Extracts) is indicated as an allergy immunotherapy for treatment of patients experiencing allergic reactions to related seasonal pollens, molds, animal danders or various other inhalants in situations where the offending allergen cannot be avoided.

Prior to initiation of therapy, the clinical sensitivity should be established by careful evaluation of the patient's history confirmed by diagnostic skin testing.

1.1. Pediatrics

Children can receive the same dose as adults, however, to minimize the discomfort associated with dose volume it may be advisable to reduce the volume of the dose by one-half and administer the injection at two different sites.

1.2. Geriatrics

Geriatrics: No data are available to Health Canada; therefore, Health Canada has not authorized an indication for geriatric use.

2. Contraindications

- A patient should not be treated with an allergen extract to which the patient has not demonstrated symptoms, IgE antibodies, positive skin tests, or properly controlled challenge testing. In most cases, allergy immunotherapy is not indicated for those allergens that can be eliminated or minimized by environmental control.
- Patients previously have had a severe systemic allergic reaction to the related allergenic extract immunotherapy.
- Patients on beta-blockers are not candidates for allergy immunotherapy, as they 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).
- Also, there is some evidence, although inconclusive, that routine immunizations may exacerbate autoimmune diseases. Hyposensitization should be given cautiously to patients with this predisposition. Patients with severe cardiorespiratory symptoms are at an additional risk during a systemic reaction. The physician must weigh risk to benefit in these cases.
- .Patients with unstable, severe, uncontrolled chronic or seasonal asthma (FEV1 <70% of predicted value after adequate pharmacologic treatment) or steroid dependent asthmatics.
- Patients with severe cardiovascular diseases. See also 7 Warnings and Precautions and 8 Adverse Reactions.

3. Serious Warnings and Precautions Box

- 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. Patients should be observed for 20 to 30 minutes following each treatment. 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.
- 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 7 Warnings and Precautions, and 8 Adverse Reactions.
- This product should not be injected intravenously.

4. Dosage and Administration

4.1. Dosing Considerations

- If the protective action of allergenic extract injections is considered essential for the patient's welfare, appropriate symptomatic therapy with antihistaminic, adrenergic or other drugs might be needed either prior to or in conjunction with the allergenic extract injections.
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

4.2. Recommended Dose and Dosage Adjustment

- Starting dose for immunotherapy is related directly to a patient's sensitivity as determined by carefully executed skin testing. Degree of sensitivity can be established by determination of D_{50}. A general rule is to begin at 1/10 of the dose that produces sum of erythema of 50 mm (approximately a 2+ positive skin test reaction).
- For example, if a patient exhibits a 2+ intradermal reaction to 1 AU/mL, the first dose should be no higher than 0.05 mL of 0.1 AU/mL. Dosage may be increased by 0.05 mL each time until 0.5 mL is reached, at which time the next 10-fold more concentrated dilution can be used, beginning with 0.05 mL, if no untoward reaction is observed.
- Interval between doses in the early stages of immunotherapy is no more than once to twice a week, and may gradually be increased to once every two weeks. Generally, maintenance injections may be given as infrequently as once every two weeks to once a month.

Pre-Seasonal Method of Treatment

- Treatment of hay fever by the pre-seasonal method should be started 6-10 weeks prior to the usual onset of symptoms. Therapy should be started early enough to permit a graduated series of doses at 2-7 day intervals. It is recommended that the larger doses be spaced 5-7 days apart.
- Some physicians continue therapy into or through the season by repeating a reduced or MAINTENANCE dose at weekly or biweekly intervals. If during the season, hay fever symptoms develop, relief may be provided by giving supplemental treatment. If the last dose was well-

tolerated and not more than 2 weeks has elapsed since it was given, this dose may be given again and repeated every 4 to 7 days.

Perennial Treatment

- The patient's tolerance to the offending pollen or pollens is first established by the injection of a series of graduated doses as outlined in the PRE-SEASONAL METHOD, not necessarily given pre-seasonally, since perennial therapy may be begun at any time. After completion of the ascending series of injections, from 1/4 to 1/2 of the highest well-tolerated dose is continued at 2 to 3 week intervals throughout the year. Shortly before the usual onset of symptoms (4 to 5 weeks prior to the season) the interval between injections is shortened and the dosage is gradually increased, according to the Pre-Seasonal schedule, until maximum well-tolerated dose is again attained. This top dose should be reached just before the usual onset of symptoms at which time the treatment is discontinued. If patient's symptoms persist, therapy may be continued at a reduced dosage level, usually 1/4 to 1/2 of the top dose.

Dosage Adjustments

For Products Containing Short Ragweed.

- In transferring patients from non-standardized to standardized product, the physician should establish the potency relationships, perhaps by comparative skin testing, prior to injecting the first standardized dose.
- AgE is important in adjusting dosage of Short Ragweed extracts to accurately transfer a patient from older extracts to fresher material. In such cases, the dosage of AgE should be considered in addition to the W/V dilution or protein nitrogen units. Antigen E concentration continuously declines in Short Ragweed Pollen extracts at a rate that varies with the formulation of the product. Aqueous extracts retain Antigen E potency less effectively than glycerin 50% (v/v) extracts. These differences are reflected in the expiration date declared on the vial. The continuous decline should be considered. Also, where ragweed is a component of an allergen mixture, clinical response to the other components must be considered in adjustment of dosage based on AgE content alone. The usual course of immunotherapy is three to five years.
- **Caution:** A small percent of individuals allergic to Short Ragweed are more sensitive to minor antigens such as Ra3 Ra5 than AgE. There is no correlation between the amount of these antigens and either AgE or PNU content.
- **NOTE:** For extracts of Short Ragweed or equal part mixture of Short and Tall Ragweed refer to AgE dosage schedule. The AgE content for those products is indicated on the vial label. The physician may use the formula below to determine the AgE dosage for each injection.

  AgE dosage can be monitored by using the following formula:

  W/V compounded products:

  Labeled AgE X Dose (mL) = dose in AgE

  PNU compounded products:

  $\frac{\text{Labeled AgE/mL}}{\text{Labeled PNU/mL}}$ X dose in PNU = dose in AgE

4.3. Dilution

Bulk concentrated extracts must be diluted for therapy.

- When diluting bulk extracts, 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 initiation 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.
- Formal stability studies for diluted and undiluted forms of non-standardized extracts have not been performed; therefore, it is recommended that minimal amounts of the concentrate be diluted so that the diluted product is used up within a relatively short period of time; i.e., preferably not more than four weeks.

4.4. Administration

Injections are given subcutaneously, preferably in the arm. After inserting the needle, but before injecting the dose, pull plunger of the syringe slightly. If blood returns in the syringe, discard the syringe and contents and repeat injection at another site.

It is advantageous to give injections in alternate arms and routinely in the same area. In some patients, a local tolerance to the allergen may develop thus preventing a possible severe local reaction.

5. Overdose

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 under 7 Warnings and Precautions.

For the most recent information in the management of a suspected drug overdose, contact your regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669).

6. Dosage Forms, Strengths, Composition, and Packaging

Table 1 – Dosage Forms, Strengths, and Composition

Route of Administration	Dosage Form/ Strength/Composition	Non-Medicinal Ingredients
Subcutaneous	Liquid, W/V or PNU/mL	Phenol, glycerin, sodium bicarbonate as a

		buffer, sodium chloride for isotonicity

1. Concentrate in multiple dose vials:

   10 mL and 50 mL, single antigens or specified mixtures, potency expressed in PNU/mL (up to and including 40,000 PNU/mL) or W/V (up to and including 1:10 W/V) aqueous or in 50% glycerin (up to and including 1:10 W/V), to be diluted prior to use. 1:10 W/V Short Ragweed extracts contain ≥ 300 units/mL of AgE.

2. Sterile Diluent for Allergenic Extracts (Normal Saline with Phenol, Glycerinated Phenol Saline and Albumin Saline with Phenol) is supplied in vials of 5 mL, 10 mL, 50 mL and 100 mL.

See Tables below for specific therapeutic concentrations available.

Table 2 – Therapeutic Pollen Extracts

Description of Therapeutic Pollen Extracts	Strength	Type of extraction and preservation, such as pyridine extracted alum-complexed or aqueous extracted and glycerinated
4 WEED MIX	1:20 W/V, P40K	P40K AQUEOUS 1:20 w/v GLYCERINATED
9 TREE MIX	1:20 W/V	1:20 w/v GLYCERINATED
ACACIA	1:20 W/V	1:20 w/v GLYCERINATED
ALDER, WHITE	1:10 W/V, 1:20 W/V	1:10 w/v AQUEOUS 1:20 w/v GLYCERINATED
ALFALFA	1:20 W/V	1:20 w/v GLYCERINATED
ASH, WHITE	1:10 W/V, 1:20 W/V, P40K	P40K AQUEOUS 1:10 w/v AQUEOUS 1:20 w/v GLYCERINATED
ARIZONA CYPRESS	1:20 W/V	1:20 w/v GLYCERINATED
BAHIA	1:20 W/V	1:20 w/v GLYCERINATED
BEECH, AMERICAN	1:20 W/V	1:20 w/v GLYCERINATED
BIRCH MIX	1:20 W/V	1:20 w/v GLYCERINATED
BIRCH, WHITE	1:10 W/V, 1:20 W/V	1:10 w/v AQUEOUS 1:20 w/v GLYCERINATED
BOX ELDER	1:10 W/V, 1:20 W/V	1:10 w/v AQUEOUS 1:20 w/v GLYCERINATED
BROME	1:20 W/V	1:20 w/v GLYCERINATED
CEDAR, RED	1:10 W/V, 1:20 W/V	1:10 w/v AQUEOUS 1:20 w/v GLYCERINATED
COCKLEBUR	1:10 W/V, 1:20 W/V, P40K	P40K AQUEOUS 1:10 w/v AQUEOUS 1:20 w/v GLYCERINATED
CORN POLLEN	1:20 W/V	1:20 w/v GLYCERINATED
COTTONWOOD, EASTERN	1:10 W/V, 1:20 W/V	1:10 w/v AQUEOUS 1:20 w/v GLYCERINATED

Description of Therapeutic Pollen Extracts	Strength	Type of extraction and preservation, such as pyridine extracted alum-complexed or aqueous extracted and glycerinated
COTTONWOOD, WESTERN	1:10 W/V, 1:20 W/V	1:10 w/v AQUEOUS 1:20 w/v GLYCERINATED
DANDELION	1:20 W/V	1:20 w/v GLYCERINATED
DOCK, YELLOW	1:10 W/V, 1:20 W/V	1:10 w/v AQUEOUS 1:20 w/v GLYCERINATED
ELM, AMERICAN	1:10 W/V, 1:20 W/V, P40K	P40K AQUEOUS 1:10 w/v AQUEOUS 1:20 w/v GLYCERINATED
ELM, CHINESE	1:20 W/V	1:20 w/v GLYCERINATED
GOLDENROD	1:20 W/V	1:20 w/v GLYCERINATED
HICKORY, SHAGBARK	1:10 W/V, 1:20 W/V	1:10 w/v AQUEOUS 1:20 w/v GLYCERINATED
JOHNSON GRASS	1:10 W/V, 1:20 W/V	1:10 w/v AQUEOUS 1:20 w/v GLYCERINATED
JUNIPER, WESTERN	1:10 W/V, 1:20 W/V	1:10 w/v AQUEOUS 1:20 w/v GLYCERINATED
KOCHIA	1:10 W/V, 1:20 W/V	1:10 w/v AQUEOUS 1:20 w/v GLYCERINATED
LAMB'S QUARTERS	1:20 W/V	1:20 w/v GLYCERINATED
MAPLE MIX	1:20 W/V	1:20 w/v GLYCERINATED
MAPLE, SUGAR	1:10 W/V, 1:20 W/V, P40k	P40K AQUEOUS 1:10 w/v AQUEOUS 1:20 w/v GLYCERINATED
MARSHELDER, BURWEED	1:20 W/V	1:20 w/v GLYCERINATED
MARSHELDER, ROUGH	1:10 W/V, 1:20 W/V, P40k	P40K AQUEOUS 1:10 w/v AQUEOUS 1:20 w/v GLYCERINATED
MESQUITE	1:20 W/V	1:20 w/v GLYCERINATED
MUGWORT	1:20 W/V	1:20 w/v GLYCERINATED
MULBERRY, RED	1:10 W/V, 1:20 W/V	1:10 w/v AQUEOUS 1:20 w/v GLYCERINATED
OAK MIX	1:20 W/V	1:20 w/v GLYCERINATED
OAK, WHITE	1:10 W/V, 1:20 W/V, P40k	P40K AQUEOUS 1:10 w/v AQUEOUS 1:20 w/v GLYCERINATED
PIGWEED, ROUGH	1:10 W/V, 1:20 W/V	1:10 w/v AQUEOUS 1:20 w/v GLYCERINATED
PINE, AUSTRALIAN	1:20 W/V	1:20 W/V GLYCERINATED
PINE, WHITE	1:10 W/V, 1:20 W/V	1:10 w/v AQUEOUS 1:20 w/v GLYCERINATED
PLANTAIN, ENGLISH	1:10 W/V, 1:20 W/V, P40k	P40K AQUEOUS

Description of Therapeutic Pollen Extracts	Strength	Type of extraction and preservation, such as pyridine extracted alum-complexed or aqueous extracted and glycerinated
		1:10 w/v AQUEOUS 1:20 w/v GLYCERINATED
POPLAR, WHITE	1:10 W/V, 1:20 W/V	1:10 w/v AQUEOUS 1:20 w/v GLYCERINATED
QUACK GRASS	1:10 W/V	1:10 w/v AQUEOUS
RAGWEED, FALSE	1:20 W/V	1:20 w/v GLYCERINATED
RAGWEED, MIXED	1:20 W/V, P40k	P40K AQUEOUS 1:20 w/v GLYCERINATED
RAGWEED, SHORT	1:20 W/V	1:20 w/v GLYCERINATED
RAGWEED, TALL	1:20 W/V	1:20 w/v GLYCERINATED
RAGWEED, WESTERN	1:20 W/V	1:20 w/v GLYCERINATED
RUSSIAN THISTLE	1:20 W/V	1:20 w/v GLYCERINATED
SAGEBRUSH	1:10 W/V, 1:20 W/V	1:10 w/v AQUEOUS 1:20 w/v GLYCERINATED
SHEEP SORREL	1:10 W/V, 1:20 W/V	1:10 w/v AQUEOUS 1:20 w/v GLYCERINATED
SORREL/DOCK MIX	1:20 W/V	1:20 w/v GLYCERINATED
SYCAMORE, AMERICAN	1:10 W/V, 1:20 W/V	1:10 w/v AQUEOUS 1:20 w/v GLYCERINATED
WALNUT, BLACK (POLLEN)	1:10 W/V, 1:20 W/V	1:10 w/v AQUEOUS 1:20 w/v GLYCERINATED
WILLOW, BLACK	1:20 W/V	1:20 w/v GLYCERINATED

Table 3 – Therapeutic Non-Pollen Extracts

Description of Therapeutic Non-Pollen Extracts	Strength	Type of extraction and preservation, such as pyridine extracted alum-complexed or aqueous extracted and glycerinated
ALTERNARIA ALTERNATA	1:20 W/V	1:20 w/v GLYCERINATED
ASPERGILLUS FUMIGATUS	1:20 W/V	1:20 w/v GLYCERINATED
AUREOBASIDIUM PULLULANS	1:20 W/V	1:20 w/v GLYCERINATED
BIPOLARIS SOROKINIANA	1:20 W/V	1:20 w/v GLYCERINATED
BOTRYTIS CINEREA	1:20 W/V	1:20 w/v GLYCERINATED
CANDIDA ALBICANS	1:20 W/V	1:20 w/v GLYCERINATED
CATTLE EPITHELIUM	1:20 W/V	1:20 w/v GLYCERINATED

Description of Therapeutic Non-Pollen Extracts	Strength	Type of extraction and preservation, such as pyridine extracted alum-complexed or aqueous extracted and glycerinated
CLADOSPORIUM CLADOSPORIODES	1:20 W/V	1:20 w/v GLYCERINATED
COCKROACH, AMERICAN	1:20 W/V	1:20 w/v GLYCERINATED
COCKROACH, MIXED	1:20 W/V	1:20 w/v GLYCERINATED
DOG EPITHELIUM	1:10 W/V, 1:20 W/V, P20k	P20K AQUEOUS 1:10 w/v AQUEOUS 1:10 w/v GLYCERINATED 1:20 w/v GLYCERINATED
EPICOCCUM NIGRUM	1:20 W/V	1:20 w/v GLYCERINATED
FEATHERS, MIXED	1:10 W/V, 1:20 W/V	1:10 w/v GLYCERINATED 1:20 w/v GLYCERINATED
FIRE ANT	1:20 W/V	1:20 w/v GLYCERINATED
GIBBERELLA PULICARIS	1:20 W/V	1:20 w/v GLYCERINATED
GUINEA PIG EPITHELIUM	1:20 W/V	1:20 w/v GLYCERINATED
HORSE EPITHELIUM	1:10 W/V, 1:20 W/V	1:10 w/v GLYCERINATED 1:20 w/v GLYCERINATED
MOLD MIX A	1:20 W/V	1:20 w/v GLYCERINATED
MOLD MIX B	1:20 W/V	1:20 w/v GLYCERINATED
MOSQUITO	1:100 W/V	1:100 w/v GLYERINATED
MOUSE EPITHELIUM	1:20 W/V	1:20 w/v GLYCERINATED
MUCOR PLUMBEUS	1:20 W/V	1:20 w/v GLYCERINATED
PENICILLIUM NOTATUM	1:20 W/V	1:20 w/v GLYCERINATED
RABBIT EPITHELIUM	1:10 W/V, 1:20 W/V	1:10 w/v GLYCERINATED 1:20 w/v GLYCERINATED
SAROCLADIUM STRICTUM	1:20 W/V	1:20 w/v GLYCERINATED
SACCHAROMYCES CEREVISIAE	1:20 W/V	1:20 w/v GLYCERINATED
TRICHOPHYTON MENTAGROPHYTES	1:20 W/V	1:20 w/v GLYCERINATED

7. Warnings and Precautions

General

In the presence of active symptoms such as rhinitis, wheezing, dyspnea, etc., the indication of immunotherapy must be weighed carefully against the risk of temporarily aggravating the symptoms by the injection itself. Objective assessment of pulmonary function such as Peak Expiratory Flow Rate (PEFR) before allergen administration 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 such as rhinitis, wheezing, dyspnea, etc. prior to injection including any late reactions from previous administration. Also, see 3 Serious

Warnings and Precautions Box and 8 Adverse Reactions.

Severe Allergic Reactions:

Patients should always be observed for at least 20-30 minutes after any injection. In the event of a marked systemic reaction such as urticaria, angioedema, wheezing, dyspnea, respiratory obstruction, hypotension, coma and death (see 8 Adverse Reactions), application 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) is recommended. Maximal recommended dose for children between 2 and 12 years 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 cases of respiratory obstruction, oxygen and intubation may be necessary. Life-threatening reaction unresponsive to the above may require cardiopulmonary resuscitation.

Withhold allergenic extracts temporarily or reduce the dose in patients with any one of the following conditions:

- Severe rhinitis or asthma symptoms;
- Infection or flu accompanied by fever;
- Exposure to excessive amounts of clinically relevant allergen prior to therapy.

Switch between products with different formulations of an allergic extract in the same patient: From pyridine extracted alum-complexed allergenic extracts to aqueous extracted and glycerinated allergenic extracts : In order to avoid untoward reaction, it is recommended that therapy be initiated as though patients were previously untreated. The first dose should be related to the patient's sensitivity, determined by history and confirmed by skin testing.

From non-standardized aqueous extracts to standardized aqueous extracted and glycerinated allergenic extracts: The physician should establish the potency relationship, perhaps by comparative skin testing at equal concentration, prior to injecting the first standardized dose.

From aqueous alum precipitated or modified extracts to aqueous extracted and glycerinated allergenic extracts*:* Since this subject has not been studied, it is recommended that therapy be initiated as if the patient were not previously treated.

Carcinogenesis and Genotoxicity

Studies in animals have not been performed.

Monitoring and Laboratory Tests

Patients should always be observed for at least 20-30 minutes after any injection.

7.1. Special Populations

7.1.1. 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.

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 mother. However, on the basis of histamine's known ability to contract uterine muscle, the release of significant amounts of histamine from allergen exposure or hyposensitization 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. Breastfeeding

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

Children can receive the same dose as adults, however, to minimize the discomfort associated with dose volume it may be advisable to reduce the volume of the dose by one-half and administer the injection at two different sites.

8. Adverse Reactions

8.1. Adverse Reaction Overview

Anaphylaxis and deaths following the injection of =allergenic extracts have been reported.

With careful attention to dosage and administration, such reactions occur infrequently, but it must be remembered that allergenic extracts are highly potent to 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.

Local: Reactions at the site of injection may be immediate or delayed. Immediate wheal and erythema reactions are ordinarily of little consequence; but if very large, may be the first manifestation of a systemic reaction. If large local reactions occur, the patient should be observed for systemic symptoms for which treatment is outlined below.

Delayed reactions start several hours after injection with local edema, erythema, itching or pain. They are usually at their peak at 24 hours and usually require no treatment. Antihistamine drugs may be administered orally.

The next therapeutic dose should be reduced to the dose which did not elicit a reaction, and subsequent doses should be increased more slowly, i.e., use of intermediate dilutions.

Systemic: Systemic reactions are characterized by one or more of the following symptoms: Sneezing, mild to severe generalized urticaria, itching other than at the injection site, extensive or generalized

edema, wheezing, asthma, dyspnea, cyanosis, tachycardia, lacrimation, marked perspiration, cough, hypotension, syncope and upper airway obstruction. Symptoms may progress to shock and death. Patients should always be observed for at least 20 to 30 minutes after any injection.

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 mL of Epinephrine Injection (1:1,000) are recommended. Maximal recommended dose for children under 2 years of age is 0.3 mL. Maximal recommended dose for children between 2 and 12 years of age is 0.5 mL. The tourniquet should not be left in place without loosening for 90 seconds every 15 minutes.

The next therapeutic injection of extract should be reduced to the dose which did not elicit a reaction, and subsequent doses increased more slowly; i.e., use of intermediate dilutions.

9. Drug Interactions

9.2. Drug Interactions Overview

Drugs can interfere with the performance of skin tests.

9.3. Drug-Behaviour Interactions

The interaction of ALLERGENIC EXTRACTS with individual behavioural risks (*e.g.* cigarette smoking, cannabis use, and/or alcohol consumption) has not been studied.

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.

$Beta_2$ 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

The treatment consists of the subcutaneous injection of gradually increasing doses of the allergens to which the patient is allergic. It has been demonstrated that this method of treatment induces an increased tolerance to the allergens responsible for the symptoms on subsequent exposure. The exact relationships between allergen, skin-sensitizing antibody (IgE) and the blocking antibody (IgG) have not been precisely established. Clinically confirmed immunological studies have adduced evidence of the efficacy of hyposensitization therapy.

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 2: Scientific Information

13. Pharmaceutical Information

Drug Substance

Proper name: Allergenic Extract Pollens

Allergenic Extract Non Pollens

Product Characteristics:

Sterile therapeutic allergenic extracts are supplied in either phenol-saline diluent or in diluent containing glycerin 50% (v/v) for subcutaneous injection. 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. 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. 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, woolens, leather goods, fruits, meats, cheeses, garden soil and on plants. Spores, mycelial fragments and mold residues are thus inhaled, contacted and ingested continuously.

Miscellaneous inhalants and epidermals are individually extracted in phenol preserved saline, filtered aseptically and after final packaging are tested for sterility.

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

ALLERGENIC EXTRACT POLLENS

ALLERGENIC EXTRACT NON POLLENS

Therapeutic Allergenic Extracts

This Patient Medication Information is written for the person who will be taking **Allergenic Extracts**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **Allergenic Extracts**, talk to a healthcare professional.

Serious warnings and precautions box

- This product is intended for use 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 reactions may rarely result in death. Patients should be observed for 20 to 30 minutes following treatment, and emergency measures, as well as personnel trained in their use, 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.

What Allergenic Extracts are used for:

Treatment of allergic reactions to seasonal pollens, molds, animal danders, various other inhalants, and in situations where the offending allergen cannot be avoided.

How Allergenic Extracts work:

Reduces symptoms associated with exposure to the allergens.

The ingredients in Allergenic Extracts are:

Medicinal ingredient(s): Short Ragweed and Mixed (Tall and Short) Ragweed extracts, Pollen extracts, Molds, Miscellaneous Inhalants and Epidermals.

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

Allergenic Extracts come in the following dosage form(s):

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 injection.
- Patients should always be observed 20 to 30 minutes after injection.

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
- $Beta_2$ 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, have taken too much Allergenic Extracts, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

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

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Common			
Injection site reactions			√
Edema			√
Skin erythema			√
Itching			√
Pain			√
Sneezing			√
Urticaria			√
Wheezing			√
Asthma			√
Dyspnea			√
Cyanosis			√
Tachycardia			√
Lacrimation			√
Perspiration			√
Cough			√
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 (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare 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 the Patient Medication Information by visiting the Health Canada Drug Product Database website (Drug Product Database: Access the database); 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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