

PART III: CONSUMER INFORMATION

Allergenic Extracts

Standardized Grass Pollen Extracts

This leaflet is part III of a three-part "Product Monograph" published when Allergenic Extracts, Pollen was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Allergenic Extracts, Pollen. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

Allergenic Pollen Extracts are used for:

- skin-test diagnosis of allergy.
- treatment of patients with a history of allergy to a specific grass pollen.

What it does:

Reduces symptoms associated with exposure to specific grass allergens.

When it should not be used:

- Children with kidney disease.
- Extreme sensitivity to specific allergen.
- Patients with autoimmune disease which can worsen symptoms of the existing disease.

What the medicinal ingredient is:

Standardized grass pollen extracts can contain one or a combination of the following grass pollens as per recommended by your doctor:

June (*Poa pratensis*), Meadow Fescue (*Festuca elatior*), Orchard (*Dactylis glomerata*), Perennial Rye (*Lolium perenne*), Redtop (*Agrostis alba*), Sweet Vernal (*Anthoxanthum odoratum*), and Timothy (*Phleum pratense*).

What the important nonmedicinal ingredients are:

Phenol, Glycerin, Sodium Chloride and Sodium Bicarbonate

What dosage forms it comes in:

Injectable solution.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- **Not for intravenous use**
- **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.**
- **Not to be interchanged with grass pollen extracts labelled in allergy units (AU)/mL or with non-standardized grass pollen extracts.**
- **Risk of severe reaction (anaphylaxis) in patients receiving beta blockers; in those with uncontrolled asthma ; or in patients with heart disease.**
- **Allergenic extract injections should not be administered in the presence of diseases characterized by a bleeding diathesis.**
- **Children with nephrotic syndrome (immunization, can cause an exacerbation of their nephrotic disease).**

BEFORE you use Allergenic Extracts, Pollen talk to your doctor or pharmacist if:

- You have not been treated with pollen allergenic extracts before or you are receiving extracts from another manufacturer.
- You are switched from other types of extracts to standardized extracts.
- Emergency care of anaphylaxis is available at the treatment clinic.
- You are taking any medications that will interact with this product.
- You have any conditions mentioned above under **Serious Warnings and Precautions**.

INTERACTIONS WITH THIS MEDICATION

Skin test diagnosis with Allergenic Extracts may give false negative results when used within 3-10 days of antihistamines such as cetirizine (Reactine), loratadine (Claritin), astemizole (Hisminal), certain types of antidepressants and topical steroids.

PROPER USE OF THIS MEDICATION

Usual dose:

Consult your physician for the correct dose for your treatment.

Overdose:

Signs and symptoms of overdose are typically local and systemic reactions. For a description and management of overdose reactions, refer to "Adverse Reactions" section above.

Missed Dose:

Not applicable.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

If you experience any adverse reactions please report to Canada's Therapeutic Products Programme at the Adverse Drug Reaction Unit, Bureau of Drug Surveillance, Tel: 613-946-1138 or Fax: 613-957-0335.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	Skin erythema			✓
	Urticaria			✓
	Pruritus			✓
	Angioedema			✓
	Rhinitis			✓
	Wheezing			✓
	laryngeal edema			✓
	hypotension			✓
Uncommon	Nausea			✓
	Emesis			✓
	Abdominal cramps			✓
	Diarrhea			✓
	Uterine contractions			✓
	Shock			✓
	Loss of consciousness			✓
	fatalities			✓

This is not a complete list of side effects. For any unexpected effects while taking Allergenic Extracts, Pollen, contact your doctor or pharmacist.

HOW TO STORE IT

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.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

toll-free telephone: 866-234-2345

toll-free fax 866-678-6789

By email: cadtmp@hc-sc.gc.ca

By regular mail:

National AR Centre

Marketed Health Products Safety and Effectiveness

Information Division

Marketed Health Products Directorate

Tunney's Pasture, AL 0701C

Ottawa ON K1A 0K9

NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be obtained by contacting, ALK-Abelló Pharmaceutical, Inc., at: 1-800-663-0972

This leaflet was prepared by ALK-Abelló Inc.

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