

PART III: CONSUMER INFORMATION

PrELAPRASE™
idursulfase

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

ABOUT THIS MEDICATION

What the medication is used for:

ELAPRASE is an enzyme replacement therapy for patients with Hunter syndrome and has been shown to improve walking capacity in these patients. Treatment with ELAPRASE should be supervised by a physician or other experienced health care provider.

What it does:

Patients with Hunter syndrome do not produce enough of their own enzyme, iduronate-2-sulfatase. The reduced iduronate-2-sulfatase levels in patients result in the accumulation of substances called glycosaminoglycans (GAG) in a number of cell types and tissues. ELAPRASE is an enzyme replacement therapy that is intended to restore sufficient levels of enzyme to assist in the removal of these accumulated substances and to reduce further accumulation.

When it should not be used:

Do not use ELAPRASE if you are allergic (hypersensitive) to idursulfase or any of the other nonmedicinal ingredients.

What the medicinal ingredient is:

The active substance in ELAPRASE is idursulfase (2 mg/mL). Idursulfase is a form of the human enzyme iduronate-2-sulfatase. It is produced by recombinant DNA technology.

What the important nonmedicinal ingredients are:

The other ingredients are sodium chloride, sodium phosphate monobasic monohydrate, sodium phosphate dibasic heptahydrate, polysorbate 20, and water for injection.

What dosage forms it comes in:

2 mg/mL concentrate for solution for infusion in a clear, glass vial (bottle).

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

RISK OF HYPERSENSITIVITY REACTIONS

Allergic reactions, which have the potential to be life threatening, have been observed in some patients treated with ELAPRASE.

Patients with compromised respiratory function or acute respiratory disease may be at risk of serious exacerbation of their respiratory dysfunction due to infusion related reactions. These patients require additional monitoring. Late-emergent allergic reactions have been observed after ELAPRASE administration. Patients who have experienced severe and refractory allergic reactions may require prolonged observation times.

Due to the potential for severe infusion reactions appropriate medical support measure should be readily available when ELAPRASE is administered.

If you are treated with ELAPRASE you may experience reactions during or following an infusion. Most infusion reactions are mild or moderate but some may be serious. The most common symptoms are itching, rash, hives, fever, headache, increased blood pressure, and flushing (redness). Most of the time, you can still be given ELAPRASE even if these symptoms occur. If you experience an allergic side effect following administration of ELAPRASE, you should contact your doctor immediately. You may be given additional medicines such as antihistamines and corticosteroids to treat or help prevent allergic-type reactions.

If severe, allergic-type (hypersensitivity) reactions occur, your doctor may consider stopping the infusion immediately, and should start giving you suitable treatment.

INTERACTIONS WITH THIS MEDICATION

There is no known interaction of ELAPRASE with other medicines.

PROPER USE OF THIS MEDICATION

Usual dose:

ELAPRASE has to be diluted in 9 mg/mL (0.9%) sodium chloride solution before use. The usual dose is an infusion of 0.5 mg (half a milligram) for every kg you weigh. This would be about 18 mg or 3 vials (bottles) of ELAPRASE for a 36 kg individual. After dilution ELAPRASE is given through a vein (drip feed). The infusion will normally last for 1 to 3 hours and will be given every week.

Overdose:

There is no experience of overdose with ELAPRASE.

for infusion-related reactions.

If you notice any side effects not mentioned in this leaflet, please inform your doctor. A registry (the Hunter Outcome Survey) has been established in order to better understand the variability and progression of the disease and monitoring and evaluation of treatments. All patients are encouraged to participate and advised that their participation may involve long-term follow-up. Information on this registry program is available by calling 1-888-550-6060.

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

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, ELAPRASE can cause side effects, although not everybody gets them. Most side effects are mild to moderate and generally are associated with the infusion; however some side effects may be serious and may need treatment. Over time the number of these infusion-associated reactions generally decreases.

Very common side effects (more than 1 per 10) are:

- Headache
- Increased blood pressure
- Chest pain
- Hives, rash, itching
- Fever, and infusion site swelling

Common side effects (more than 1 per 100) are:

- Dizziness, tremor
- Teary eyes
- Changes in the way your heart beats, bluish skin
- Decreased blood pressure, flushing (redness)
- Difficulty breathing, wheezing, blood clot in the lung artery, cough, quickened breathing
- Abdominal pain, nausea, diarrhoea, swollen tongue
- Facial swelling, skin lesions (redness, eczema)
- Pain in the joints
- Swelling of the extremities

HOW TO STORE IT

Store at 2°C to 8°C (in a refrigerator).

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: cadmp@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.

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

Symptom/Effect		Talk with your doctor or pharmacist
Common (occurring in ≥ 5% of patients)	Drop in blood oxygen level from difficulty in breathing	Yes
Uncommon (occurring in < 5% of patients)	Seizure, blood clot in the lungs, missed or extra heartbeats	Yes

In clinical trials with ELAPRASE, 11 of 108 patients (10%) experienced allergic reactions during 19 of 8274 infusions (0.2%). Reactions have included temporary breathing difficulty, decreased blood pressure, or swelling. In a more severe reaction, in a single patient, a seizure occurred because of a drop in blood oxygen level from difficulty in breathing. Inform your doctor immediately if you have any of these side effects. Patients with compromised respiratory function or acute respiratory disease are at greater risk

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals, can be obtained by contacting Paladin Labs Inc., at: 1-888-550-6060.

This leaflet was prepared by Shire Human Genetic Therapies, Inc.

Last revised: 28 January 2008.