PART III: CONSUMER INFORMATION

Pr Aldurazyme® *[al-dur-a-ZIME]*
Laronidase for injection

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

ABOUT THIS MEDICATION

What the medication is used for:
Aldurazyme® (laronidase for injection) is used to treat the non-central nervous system manifestations of Mucopolysaccharidosis I (MPS I; α-L-iduronidase deficiency) in patients with a confirmed diagnosis of this disease.

What it does:
Patients with MPS I are deficient in the enzyme α -L-iduronidase. Laronidase is a form of α-L-iduronidase produced by recombinant DNA technology. Laronidase can help to treat some of the symptoms of MPS I by replacing the deficient enzyme.

When it should not be used:
Do not use Aldurazyme® if you are allergic to laronidase or to any ingredient of Aldurazyme® or component of the container.

What the medicinal ingredient is:
Laronidase

What the important nonmedicinal ingredients are:
Polysorbate 80, Sodium chloride, Sodium phosphate monobasic monohydrate, Sodium phosphate dibasic heptahydrate, Water for Injection
For a full listing of nonmedicinal ingredients see Part 1 of the product monograph.

What dosage forms it comes in:
Aldurazyme® is supplied as a sterile concentrate for solution to be used as intravenous infusion.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions
Do not use Aldurazyme® if you are severely allergic to any ingredients of Aldurazyme® or if you have experienced a severe allergic or anaphylactic reaction to laronidase.

If you are treated with Aldurazyme® you may experience an infusion related reaction. Infusion related reaction is defined as any related side effect occurring during the infusion or during the 3 hours following infusion. Life-threatening infusion related reactions including anaphylactic reactions have been observed in some patients during Aldurazyme® infusions. Reactions have included: inability to breath independently, difficulty breathing, noisy breathing, fast breathing, temporary narrowing of the airway, partial or complete blockage of the airway, low levels of oxygen in the blood, low blood pressure, slow heartrate, and hives. Interventions have included: life saving emergency medical treatment, the use of a machine to help with breathing,, emergency access to the patient's windpipe, and hospitalization. Other treatment may include inhaled beta-adrenergic agonists to help with breathing, epinephrine as part of emergency care and intravenous corticosteroids to help fight inflammation. In clinical trials and post-marketing experience with Aldurazyme®, approximately 1% of patients experienced severe or serious allergic reactions. In patients with MPS I, pre-existing upper airway obstruction may have contributed to the severity of some reactions. Because of the potential for severe infusion reactions, appropriate medical support should be readily available when Aldurazyme® is administered. Because of the potential for recurrent severe reactions, some patients may require additional observation.

Patients with an acute underlying illness (e.g. cold or flu, severe infections, bronchitis, wheezing/difficulty in breathing) at the time of Aldurazyme® infusion may be at risk for infusion-related reactions. Careful consideration should be given to your clinical status prior to administration of Aldurazyme®.

BEFORE you use Aldurazyme®, talk to your doctor or pharmacist if:

- If you have an acute underlying illness such as cold or flu
- If you have had a severe allergic or anaphylactic reaction to administration of Aldurazyme®
- Any allergies to this drug or its ingredients or components of the container
- If you are pregnant or plan to become pregnant or are breast-feeding

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with Aldurazyme® include:
No formal drug/drug interaction studies have been conducted. Please inform your doctor if you use medicinal products containing chloroquine or procaine due to the possible risk they may decrease the action of Aldurazyme®.

PROPER USE OF THIS MEDICATION

Usual dose:
The recommended dosage regimen of Aldurazyme® is 0.58 mg/kg body weight administered once weekly as an intravenous infusion.

Aldurazyme® treatment should be supervised by a physician experienced in the management of patients with MPS I or other inherited metabolic diseases.

Administration of Aldurazyme® should be carried out in an appropriate clinical setting where resuscitation equipment to manage medical emergencies would be readily available.

Overdose:
There is no experience with overdoses of Aldurazyme®.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:
If you have missed an Aldurazyme® infusion, please contact your doctor.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, Aldurazyme® can have side effects.

Side effects were mainly seen while patients were being given the medicine or shortly after (infusion-related reactions).
The number of these reactions decreased the longer the patients were on Aldurazyme®. Most side effects seen in the clinical studies were thought to be not related to Aldurazyme. The majority of these reactions were of mild to moderate intensity.

In clinical trials, the most common infusion associated reactions in patients 6 years and older were flushing, headache, rash, fever, stomach pain, and problems where the catheter was placed to give the drug. One life threatening allergic reaction occurred resulting in swelling and blockage of the trachea (breathing airway) which required treatment with a breathing tube placed through the neck. One event of an abnormal heart rhythm thought to be unrelated to Aldurazyme resulted in a patient death.
The most common infusion associated reactions in patients less than 5 years of age were fever and chills. In an early clinical study, three patients had episodes of swelling of their mouth and breathing passage (see table below).

In post-marketing experience with Aldurazyme®, severe and serious infusion-related reactions have been reported, some of which were life threatening. The most frequently reported side effects included chills, vomiting, nausea, joint pain, diarrhea, fast heart rate, abdominal pain, blood pressure increased, and oxygen saturation decreased. Additional adverse reactions identified in the post marketing setting also include difficulty breathing, bluish color of the skin (due to lower levels of oxygen in blood), feeling cold, redness of skin, swelling of larynx (voice box), and feeling tingling. There have been a small number of reports of leakage of IV drug from the injection site into the surrounding area under the skin. However, there have been no reports that this leakage has caused severe damage to this area under the skin near the injection site.

If you exhibit such a reaction following the administration of Aldurazyme®, you should immediately contact your doctor. You may be given additional medication such as antihistamines and paracetamol to help prevent allergic-type reactions.

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

Symptom / effect		Talk with your doctor or pharmacist
45 Patients 6 years and older treated for up to 12 months		
Very common (occurred in ≥ 10% of patients)	Flushing, joint disease, infusion reactions	Yes
Common (occurred in <10% of patients)	Back pain, headache, joint pain, rash, feeling hot or feeling cold, abdominal pain, severe allergic reaction with airway obstruction, swelling of the mouth and breathing passage	Yes
45 patients 6 years and older treated up to 208 weeks (48 months)		
Very Common (occurred in > = to 10%)	Fever, flushing, rash, infusion reactions	Yes
Common (occurred in <10% of patients)	Diarrhea, difficulty breathing, feeling a change in temperature, headache, hernia, low blood pressure, nausea, problems where the catheter was placed to give the drug, problems with lungs, problems with a vein, severe allergic reaction, stomach pain, vomiting, back pain, sleep apnea, problems accessing a vein	Yes
Uncommon	Anaphylaxis (life-threatening allergic reaction). abnormal heart rhythm resulting in death	Yes
20 Patients younger than 5 years treated for up to 12 months		
Very Common (occurred in ≥ 10% of patients)	Fever, chills, fast heart rate, increased blood pressure, decreased oxygen in the blood, infusion reactions	Yes
Common (occurred in <10% of patients)	Heart rate increased, respiratory distress, wheezing, itching, rash	Yes

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

HOW TO STORE IT

Keep out of reach and sight of children.
Store under refrigeration at 2°C to 8°C (36°F to 46°F). Do not use after the expiration date on the vial. This product contains no preservatives.

MPS I Registry:

A registry for MPS I patients has been established in order to better understand the variability and progression of MPS I disease, and to continue to monitor and evaluate treatments. You are encouraged to participate. Your participation, or your child's participation, may involve long-term follow-up. Information regarding the registry program may be found at www.MPSIregistry.com or by calling (800) 745-4447. If you are interested in participating, please contact your doctor. You can only participate in the Registry through your doctor.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at www.healthcanada.gc.ca/medeffect**
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  - **Fax toll-free to 1-866-678-6789, or**
  - **Mail to: Canada Vigilance Program**
    Health Canada
    Postal Locator 0701D
    Ottawa, Ontario
    K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:
www.sanofi.ca or by contacting the sponsor, sanofi-aventis Canada Inc.,
at: 1-877-220-8918.

This leaflet was prepared by sanofi-aventis Canada Inc.

Date of Revision: April 26, 2024

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