

ALDURAZYME[®]

Laronidase-rch 500 U, Concentrate for Solution for Infusion

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Aldurazyme[®].

It does not contain all the available information.

It does not take the place of talking to your doctor or a trained health care professional.

All medicines have risks and benefits. Your doctor has weighed the risks of you or your child having Aldurazyme[®] against the benefits they expect it will have.

If you have any concerns about this medicine, ask your doctor or nurse.

Keep this leaflet.

You may need to read it again.

What Aldurazyme[®] is used for

Aldurazyme[®] is used as enzyme replacement therapy in Mucopolysaccharidosis I (MPS I) storage disorder, a disease in which the level of α -L-iduronidase is absent or lower than normal.

How it works

Patients with MPS I disease do not produce enough of their own enzyme, α -L-iduronidase. The reduced or absent α -L-iduronidase activity in patients results in the accumulation of substances called glycosaminoglycans (GAGs) in most cell types and tissues. Aldurazyme[®] is an enzyme replacement therapy that is intended to restore a level of enzyme activity sufficient to remove

the accumulated GAGs and to prevent further accumulation.

Before you are given Aldurazyme[®]

When you or your child must not be given it

Do not take Aldurazyme[®] if you or your child have a known, severe, life-threatening allergic reaction to:

- Aldurazyme[®]
- any of the ingredients listed at the end of this leaflet

Symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- skin rash, itching or hives

If you are not sure whether you or your child should have Aldurazyme[®], talk to your doctor or nurse.

Before you or your child are given it

Tell your doctor if you or your child have reacted to previous treatments with any of the following:

- life-threatening allergic reaction
- difficulty breathing

Tell your doctor if you or your child have allergies to:

- any other medicines

- any other substances, such as foods, preservatives or dyes

Tell your doctor if you are pregnant or intend to become pregnant.

There is no information available regarding the use of Aldurazyme[®] in pregnant women. Your doctor will discuss the possible risks and benefits of having Aldurazyme[®] during pregnancy.

Tell your doctor if you are breast-feeding.

It is not known whether Aldurazyme[®] passes into breast milk. Your doctor will discuss the possible risks and benefits of having Aldurazyme[®] during breast-feeding.

Tell your doctor if your child is under 5 years of age and has been prescribed Aldurazyme[®].

Safety in children below the age of 5 years has not been studied. If your child has been prescribed Aldurazyme, you may wish to discuss this with your child's doctor.

Taking other medicines

Tell your doctor or nurse if you or your child are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Aldurazyme[®] may interfere with each other. No studies have been carried out on drug interactions.

Tell your doctor or nurse if you or your child are using medicines with chloroquine (a medicine that is used as an antimalarial) or procaine (a medicine used as local anaesthetic) as these medicines may be affected by Aldurazyme[®], SUPERCEDES: ALD ANZ CMI D0404-02

or may affect how well it works (different amounts of these medicines may be needed or different medicines may need to be taken). Your doctor or nurse will advise you and decide whether or not to give you or your child Aldurazyme®.

How Aldurazyme® is given

Aldurazyme® will be given to you or your child once a week directly into the vein (intravenously) by a trained health care professional in a hospital or a clinic.

Your doctor will decide on the dose that is most suitable.

If are given too much (overdose)

There have been no reported overdoses of Aldurazyme®.

Things you or your child must do

Keep appointments with your doctor or clinic.

It is important to have the infusion with Aldurazyme® at the appropriate times to make sure the medicine has the best chance of providing treatment for the condition.

After having Aldurazyme®

Have any tests when your doctor says to.

Your doctor may wish to test your or your child's body's response to Aldurazyme® to make sure that it is working.

Things to be careful of

Be careful driving or operating machinery until you know how Aldurazyme® affects you.

The effect of Aldurazyme® on your ability to drive a car or operate machinery has not been studied. Make sure that you know how you react to Aldurazyme® before you drive a car or operate machinery or

do anything else that may be dangerous if you are dizzy, light-headed, tired or drowsy.

Side effects

Tell your doctor or nurse as soon as possible if you or your child do not feel well after having Aldurazyme®.

Aldurazyme® may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You or your child may need urgent medical treatment if you notice some side effects.

Ask your doctor or nurse to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- local reaction around the injection site such as redness, itchiness, tenderness, pain or discomfort, warmth, burning or stinging, swelling or the formation of hard lumps or scars
- flushing or redness of the skin
- headaches
- chest pain
- soreness, aching muscles, muscle tenderness or weakness (not caused by exercise)
- chest infection
- stomach ache

Storing Aldurazyme®

Aldurazyme® will be stored in the hospital or clinic pharmacy

Product Description

What it looks like

Aldurazyme® is a colourless to pale yellow, clear to slightly opalescent solution.

Ingredients

Active ingredient: laronidase-rch

Other ingredients: sodium chloride, monobasic sodium phosphate monohydrate, dibasic sodium phosphate, polysorbate 80 and water for injection.

Supplied by

In Australia this product is registered by:

Genzyme Australasia Pty Ltd
Suite 2.02, 21 Solent Crt
Baulkham Hills NSW 2153

Phone: +61 2 8852 3900

AUST R 100847

In New Zealand this product is registered by:

Medra Services Limited
PO Box 115
Fielding
New Zealand

Aldurazyme[®] is manufactured by BioMarin Pharmaceutical Inc, USA.

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