ALDURAZYME®

[al-dur-a-ZIME]

laronidase-rch [lar-on-I-daze R.C.H.] 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 treating physician or a trained health care professional.

All medicines have risks and benefits. Your treating physician 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 treating physician 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 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 treating physician or nurse.

Before you or your child are given it

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

- life-threatening allergic reaction
- difficulty breathing

Tell your treating physician if you or your child have allergies to:

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

Tell your treating physician if you are pregnant or intend to become pregnant.
There is no information available regarding the use of ALDURAZYME in pregnant women. Your treating physician will discuss the possible risks and benefits of having ALDURAZYME during pregnancy.

Tell your treating physician if you are breast-feeding.
It is not known whether ALDURAZYME passes into breast milk. Your treating physician will discuss the possible risks and benefits of having ALDURAZYME during breast-feeding.

Tell your treating physician if you or your child have difficulty breathing or suffer from acute breathing problems.

Your treating physician will discuss the possible risks and benefits of treatment with ALDURAZYME.

Tell your treating physician if your child is under 5 years of age and has been prescribed ALDURAZYME.
If your child has been prescribed ALDURAZYME, you may wish to discuss this with your child's treating physician.

Patients with an acute illness at the time of ALDURAZYME infusion may be at greater risk for infusion-associated reactions. Your treating physician may recommend you receive pre-treatment to minimise your risk of an infusion-associated reaction.

Taking other medicines

Tell your treating physician or nurse if you or your child is 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 treating physician 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, or may affect how well it works (different amounts of these medicines may be needed or different medicines may need to be taken). Your treating physician or nurse will advise you and decide whether or not to give you or your child ALDURAZYME.

How ALDURAZYME is given

How much to use

The recommended dosage for ALDURAZYME is 100 U/kg (0.58 mg/kg) of body weight once every week. ALDURAZYME will be given to you or your child directly into the vein (intravenously) by a trained health care professional in a hospital or a clinic.

If you are given too much (overdose)

There have been no reported overdoses of ALDURAZYME.

Your treating physician is trained to work out the correct dose and to contact the Australian Poisons Information Centre (telephone 13 11 26), or the New Zealand National Poisons Centre (telephone 0800 POISON or 0800 764 766) in case of an overdose.

Things you or your child must do

Keep appointments with your treating physician 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 treating physician says to.

Your treating physician may recommend to perform blood tests to monitor your or your child's body's response to ALDURAZYME to make sure that it is working, and to check your or your child's immune reaction to ALDURAZYME's active ingredient.

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 treating physician or nurse as soon as possible if you or your child do not feel well after having ALDURAZYME.

ALDURAZYME may have unwanted side effects. Sometimes the side effects are serious, most of the time they are not. You or your child may need urgent medical treatment if you experience a serious reaction.

Pre-existing upper airway obstruction may contribute to the severity of some reactions.

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

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

- 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

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- sudden signs of allergy such as rash, itching or hives on the skin,
- swelling of the face, lips, tongue or other parts of the body,
- shortness of breath, wheezing or trouble breathing

The above list includes side effects which may be very serious. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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

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

In Australia this product is registered by:

Genzyme Australasia Pty Ltd.
12-24 Talavera Road
Macquarie Park, NSW 2113
Australia
Toll Free Number: 1800 818 806
Email:
medinfo.australia@sanofi.com

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