

ALDURAZYME®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ALDURAZYME?

ALDURAZYME contains the active ingredient laronidase. 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. For more information, see Section [1. Why am I using ALDURAZYME?](#) in the full CMI.

2. What should I know before I use ALDURAZYME?

Do not use if you have ever had an allergic reaction to laronidase or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions (particularly breathing problems), take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use ALDURAZYME?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ALDURAZYME and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use ALDURAZYME?

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

More instructions can be found in Section [4. How do I use ALDURAZYME?](#) in the full CMI.

5. What should I know while using ALDURAZYME?

| | |
|------------------------------------|---|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist, or pharmacist you visit that you are using ALDURAZYME• Have any tests when your treating physician says to |
| Driving or using machines | <ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how ALDURAZYME affects you |
| Drinking alcohol | <ul style="list-style-type: none">• Tell your doctor if you drink alcohol |
| Looking after your medicine | <ul style="list-style-type: none">• ALDURAZYME will be stored in the hospital or clinic pharmacy |

For more information, see Section [5. What should I know while using ALDURAZYME?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects include infusion-associated reactions such as flushing or redness, itchiness, tenderness, pain or discomfort, warmth, burning or stinging, swelling, the formation of hard lumps or scars, rash, build-up of fluid, pale colour of the skin and discoloured skin. Other less serious side effects include headaches, chest pain, chest infection, abnormally slower heart rate, stomachache, soreness, aching muscles, muscle tenderness or weakness (not caused by exercise), a blood protein (antibody) produced in response to the medicine and an antibody that neutralizes the effect of the medicine. You may need urgent medical attention if you experience any of the following: 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; respiratory failure (inability of the lungs to work properly).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ALDURAZYME[®] [al-dur-a-ZIME]

Active ingredient(s): laronidase-rch [lar-on-i-daze R.C.H.]

Consumer Medicine Information (CMI)

This leaflet provides important information about using ALDURAZYME. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ALDURAZYME.**

Where to find information in this leaflet:

- [1. Why am I using ALDURAZYME?](#)
- [2. What should I know before I use ALDURAZYME?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ALDURAZYME?](#)
- [5. What should I know while using ALDURAZYME?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ALDURAZYME?

ALDURAZYME contains the active ingredient laronidase. ALDURAZYME is an enzyme replacement therapy.

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.

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.

2. What should I know before I use ALDURAZYME?

Warnings

Do not use ALDURAZYME if:

- You have had severe allergic (hypersensitive) reactions to laronidase, or any of the ingredients listed at the end of this leaflet and these reactions occurred again after stopping and restarting the medicine.
- You are allergic to any other medicines or other substances, such as foods, preservatives or dyes
- 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
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- have difficulty breathing or suffer from acute breathing problems
- have a child under 5 years who has been prescribed ALDURAZYME

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and/or breastfeeding and fertility

Check with 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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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.

No information is available on the effects of ALDURAZYME on fertility.

3. What if I am taking other medicines?

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

Some medicines may interfere with ALDURAZYME and affect how it works.

Tell your treating physician or nurse if you 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 ALDURAZYME.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ALDURAZYME.

4. How do I use ALDURAZYME?

How much to take / use

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

When to take / use ALDURAZYME

- ALDURAZYME should be used once every week.

If you forget to use ALDURAZYME

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.

Keep appointments with your treating physician or clinic.

If you are given too much ALDURAZYME

Your treating physician is trained to work out the correct dose for you, however, if the dose of ALDURAZYME given is too high or the infusion is too fast, adverse drug reactions may occur.

Receiving an excessively fast infusion of ALDURAZYME may cause nausea, abdominal pain, headache, dizziness, and dyspnea. In such situations, the infusion must be stopped immediately. Your doctor will decide if further intervention is required.

If you think that you have been given too much ALDURAZYME, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 in Australia or 0800 764 766 in New Zealand), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using ALDURAZYME?

Things you should do

Have any tests when your treating physician says to.

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

Remind any doctor, dentist or pharmacist you visit that you are using ALDURAZYME.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- ALDURAZYME will be stored in the hospital or clinic pharmacy.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

| Less serious side effects | What to do |
|---|---|
| <p>Infusion-associated reaction:</p> <ul style="list-style-type: none">• Flushing or redness• Itchiness• Tenderness• Pain or discomfort• Warmth• Burning or stinging• Swelling• Formation of hard lumps or scars• Rash• Build-up of fluid• Pale colour of the skin• Discoloured skin <p>Head and chest:</p> <ul style="list-style-type: none">• Headaches• Chest pain• Chest infection• Abnormally slower heart rate <p>General Body:</p> <ul style="list-style-type: none">• Stomachache• Soreness, aching muscles, muscle tenderness or weakness (not caused by exercise) | <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> |

| Less serious side effects | What to do |
|--|------------|
| <ul style="list-style-type: none"> • A blood protein (antibody) produced in response to the medicine • An antibody that neutralizes the effect of the medicine | |

Serious side effects

| Serious side effects | What to do |
|--|--|
| <ul style="list-style-type: none"> • 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 • Respiratory failure (inability of the lungs to work properly) | <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> |

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems in Australia or in New Zealand at <https://pophealth.my.site.com/carmreportnz/s/>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ALDURAZYME contains

| | |
|---|--|
| Active ingredient (main ingredient) | laronidase |
| Other ingredients (inactive ingredients) | sodium chloride monobasic sodium phosphate monohydrate dibasic sodium phosphate heptahydrate polysorbate 80 water for injections |
| Potential allergens | not applicable |

Do not take this medicine if you are allergic to any of these ingredients.

What ALDURAZYME looks like

ALDURAZYME is a colourless to pale yellow, clear to slightly opalescent solution. (Aust R 100847).

Who distributes ALDURAZYME

Distributed in Australia by:

sanofi-aventis australia Pty Ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Freecall: 1800 818 806

Email: medinfo.australia@sanofi.com

Distributed in New Zealand by:

Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics

PO Box 62027

Sylvia Park Auckland 1644

Freecall: 0800 283 684

Email: medinfo.australia@sanofi.com

ALDURAZYME® is manufactured by BioMarin Pharmaceutical Inc, USA.

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