

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 Vimizim?

Vimizim contains the active ingredient elosulfase alfa (rch). Vimizim is used to treat patients with Mucopolysaccharidosis Type IVA (MPS IVA). For more information, see Section [1. Why am I using Vimizim?](#) in the full CMI.

2. What should I know before I use Vimizim?

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

Talk to your doctor if you have any other medical conditions, 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 Vimizim?](#) in the full CMI.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines that you buy without a prescription from your pharmacy, supermarket or health food. For more information, see Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Vimizim?

- The dose you receive is based on your body weight. The recommended dose regimen is 2 mg/kg body weight administered once every week through a drip into a vein (by intravenous infusion).
- Your doctor or nurse will administer Vimizim to you.
- Each infusion will take approximately 4 hours, and your doctor will decide how long you will receive Vimizim for.

More instructions can be found in Section [4. How am I given Vimizim?](#) in the full CMI.

5. What should I know while using Vimizim?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Vimizim.• Call your doctor immediately if you experience back pain, numbness or loss of feeling in parts of your body, any bowel or bladder problems.
Things you should not do	<ul style="list-style-type: none">• Do not stop going to your visits for treatment with Vimizim without checking with your doctor. Your condition may worsen if you stop receiving Vimizim.
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 Vimizim affects you.• Vimizim may cause dizziness in some people. If you feel dizzy, do not drive or operate machinery.
Looking after your medicine	<ul style="list-style-type: none">• Vimizim must be kept in a refrigerator at 2°C to 8°C, but it must not be frozen. The vial should be kept in the carton to protect it from light.• Each vial is intended for single use only.

For more information, see Section [5. What should I know while being treated with Vimizim?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If they do occur, they are usually minor and temporary. Do not be alarmed by this list. You may not experience any of them.

The most common side effects include ear pain, feeling nervous or jittery, headache, dizziness, flushing, tingling or prickling of the skin, drowsiness, mouth and throat pain, shortness of breath, vomiting, nausea, diarrhoea, abdominal pain, hives, neck or muscle pain, fever, chills, infusion site pain, chest discomfort and cloudiness in the eye. The most serious side effect is life-threatening allergic reaction.

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.

Vimizim[®]

Active ingredient: elosulfase alfa (rch)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Vimizim. **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 Vimizim.**

Where to find information in this leaflet:

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

1. Why am I using Vimizim?

Vimizim contains the active ingredient elosulfase alfa, which belongs to a group of medicines known as enzyme replacement therapies.

Elosulfase alfa is a recombinant version of a human enzyme produced by genetic engineering in Chinese Hamster Ovary (CHO) cells. It works by replacing the natural enzyme in patients with Mucopolysaccharidosis Type IVA (MPS IVA, also known as Morquio A Syndrome).

Vimizim is used to treat patients with MPS IVA. People with MPS IVA have either a low level, or reduced activity, of an enzyme called N-acetylgalactosamine-6-sulfatase (or GALNS), which breaks down specific substances (for example, keratan sulfate) in the body. As a result, these specific substances do not get broken down and processed by the body as they should. They accumulate in many tissues in the body, which causes the symptoms of MPS IVA.

Treatment with Vimizim has shown improvement in walking ability and reduction of the levels of keratan sulfate.

2. What should I know before I use Vimizim?

Warnings

You must not receive Vimizim if:

- you have experienced severe or life-threatening allergic reactions to elosulfase alfa, or any of the ingredients listed at the end of this leaflet, and your doctor is not able to control these reactions with medicines or

other measures such as slowing the rate of the infusion or temporarily stopping the infusion.

Always check the ingredients to make sure you can use this medicine.

Your doctor will tell you if you can have Vimizim or not.

Check with your doctor if you:

- have any other medical conditions, especially the following:
 - a severe allergic reaction to elosulfase alfa or any of the other ingredients of Vimizim
 - any severe side effects with previous Vimizim treatment
 - fever
 - any respiratory conditions including sleep apnoea (a condition where you temporarily stop breathing during your sleep)
- are on a controlled sodium diet, as each 5 mL vial of Vimizim contains 8 mg of sodium
- have an intolerance to certain sugars, as each 5 mL vial of Vimizim contains 100 mg of sorbitol
- have allergies to any other medicines, foods, preservatives or dyes.

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 breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Vimizim has not been studied in pregnant patients and should not be given during pregnancy unless clearly necessary.

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

It is not known if Vimizim passes into breast milk. Discuss with your doctor the risks and benefits of continuing to take Vimizim while breastfeeding.

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, naturopath or health food shop.

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

4. How am I given Vimizim?

How Vimizim is given

Your doctor or nurse will administer Vimizim to you as a drip into a vein (by intravenous infusion). The medicine has to be diluted before being given and should not be mixed with other products.

Your doctor or nurse may give you some medicines before your treatment to reduce allergic reactions and you may also be given medicines to help control any fever. Your doctor will decide how long you will receive Vimizim for.

How much is given

The dose you receive is based on your body weight. The recommended dose regimen is 2 mg/kg body weight administered once every week through a drip into a vein (by intravenous infusion).

Each infusion will take approximately 4 hours.

If you miss a dose

If you miss a dose, talk to your doctor or nurse and arrange another visit as soon as possible.

If you take too much Vimizim

Vimizim is administered under the supervision of a health care professional. He or she will check that the correct dose has been given and act accordingly if necessary.

5. What should I know while being treated with Vimizim?

Things you should do

Your condition MPS IVA can cause pressure on the spinal cord. **Call your doctor straight away if you experience:**

- back pain
- numbness or loss of feeling in parts of your body
- any bowel or bladder problems

When you are treated with Vimizim, you may develop infusion reactions. An infusion reaction is any side effect, including an allergic reaction, occurring during the infusion or within a day following infusion. **Call your doctor immediately if you think you are experiencing such a reaction.**

Some of the 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
- rash, itching or hives on the skin
- cough
- throat tightness

- bluish colour of skin
- abnormally low blood pressure
- chest discomfort
- gastrointestinal symptoms, such as nausea, stomach ache, dry heaves, and vomiting.

If you have an allergic reaction, your doctor may slow down, or stop your infusion. Your doctor may also give you additional medicines to manage any allergic reaction. Your doctor will decide when you can restart Vimizim treatment.

- Tell your doctor if you have sleep apnoea or use a CPAP machine. You may need to have it available during infusions.

Keep all appointments with your doctor and always discuss anything that worries you during or after treatment with Vimizim.

If you become pregnant while you are treated with Vimizim, tell your doctor immediately.

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

Things you should not do

Do not stop your treatment visits for Vimizim unless you have spoken to your doctor.

Your condition may worsen if you stop receiving Vimizim.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Vimizim affects you.

Vimizim may cause dizziness in some people. If you feel dizzy during or after your infusion, do not drive or operate machinery.

Looking after your medicine

Vimizim must be stored in a refrigerator at 2°C to 8°C, but it must not be frozen. The vial should be kept in the carton to protect it from light. Your doctor or pharmacist is responsible for storing Vimizim.

When to discard your medicine

Each vial of Vimizim should be used once only. The doctor or nurse will discard any unused portion and dispose of used vial.

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.

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>Infections related:</p> <ul style="list-style-type: none"> • ear infection, with symptoms such as earache, muffled hearing <p>Neurological related:</p> <ul style="list-style-type: none"> • headache • dizziness • drowsiness • feeling nervous or jittery <p>Respiratory related:</p> <ul style="list-style-type: none"> • shortness of breath <p>Gastrointestinal related:</p> <ul style="list-style-type: none"> • vomiting • nausea • diarrhoea • stomach ache <p>Skin related:</p> <ul style="list-style-type: none"> • hives • tingling or prickling (e.g. sensation of pins and needles) in skin • flushing (reddening) of skin <p>Musculoskeletal related:</p> <ul style="list-style-type: none"> • neck pain • muscle pain <p>General:</p> <ul style="list-style-type: none"> • fever • chills • infusion site pain • chest discomfort • mouth and throat pain • cloudiness in the eye 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Allergy related:</p> <ul style="list-style-type: none"> • anaphylactic reaction – a life threatening allergic reaction, which include the following symptoms: <ul style="list-style-type: none"> ○ shortness of breath ○ wheezing or difficulty breathing ○ swelling of the face, lips, tongue or other parts of the body ○ rash, itching or hives on the skin. 	<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. 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 Vimizim contains

Active ingredient (main ingredient)	5 mg elosulfase alfa in each vial (1 mg/mL)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • sodium acetate trihydrate • monobasic sodium phosphate monohydrate • arginine hydrochloride • sorbitol • polysorbate 20 • water for injections

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

What Vimizim looks like

Vimizim is a clear, colourless to pale yellow concentrated solution for injection in a clear glass vial containing 5 mL of solution. Each pack contains 1 vial. (Aust R 215523).

Who distributes Vimizim

Vimizim is supplied in Australia by:
BioMarin Pharmaceutical Australia Pty Ltd
119 Willoughby Road
Crows Nest, NSW 2065
Telephone (02) 8520 3255

Vimizim is supplied in New Zealand by:
Pharmacy Retailing (NZ) Limited t/a Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks 2022
Auckland
Telephone (09) 918 5100

For enquiries about Vimizim, contact medinfoasia@bmrn.com or call BioMarin: Australia: 1800 387 876

New Zealand: 0800 882 012

To report adverse events, contact drugsafety@bmrn.com
or call BioMarin:
Australia: 1800 387 876
New Zealand: 0800 882 012

This leaflet was prepared in December 2025.

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