VIMIZIM®

elosulfase alfa (rch)

What is in this leaflet

This leaflet answers some common questions about Vimizim.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of treating you with Vimizim against the benefits expected for you.

If you have any concerns about receiving this medicine, talk to your doctor, nurse or the hospital pharmacist.

Keep this leaflet while you are being treated with Vimizim.

You may need to read it again.

What Vimizim is used for

Vimizim is used to treat children and adults of all ages with MPS IVA (Mucopolysaccharidosis Type IVA, Morquio A Syndrome). 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.

How Vimizim works

This medicine contains an enzyme called elosulfase alfa. 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 MPS IVA patients.

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

Ask your doctor if you have any questions about why Vimizim has been prescribed for you.

Vimizim is available only with a doctor's prescription.

Use in Children

Vimizim is recommended for use in children and adults.

Before starting treatment with Vimizim

When you must not have it

Do not have Vimizim if you experience severe or life-threatening allergic reactions to elosulfase alfa or any of the other ingredients of Vimizim 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.

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.

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

Do not have Vimizim if the expiry date printed on the carton has passed.

The nurse or hospital pharmacist will check the expiry date before giving Vimizim to you.

Do not have Vimizim if the packaging is torn or shows signs of tampering.

The nurse or hospital pharmacist will check this for you.

Check with your doctor or pharmacist if you are not sure about any of the above.

Before you start treatment with Vimizim

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

Vimizim has not been studied in pregnant patients and should not be

given during pregnancy unless clearly necessary.

Tell your doctor if you are breastfeeding or wish to breastfeed during this time.

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

Tell your doctor if you have, or have had, any 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.

Your doctor may also give you additional medicines to prevent an allergic reaction or fever, and may also monitor you closely during your next treatment.

Tell your doctor if you are on a controlled sodium diet.

Each 5 mL vial of Vimizim contains 8 mg sodium.

Tell your doctor if you have an intolerance to certain sugars.

Each 5 mL vial contains 100 mg of sorbitol.

Tell your doctor if you have a fever or any respiratory conditions including sleep apnoea. Sleep apnoea is a condition where you temporarily stop breathing during your sleep.

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

If you have not told your doctor about any of the above, tell him/her before you start receiving Vimizim.

Taking other medicines

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

How to use Vimizim

How much to use

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.

How to use Vimizim

Your doctor or nurse will administer Vimizim to you.

The medicine has to be diluted before being given and should not be mixed with other products.

How long to use Vimizim for

Your doctor will decide how long you will receive Vimizim for.

If you miss a dose

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

While you are being treated with Vimizim

MPS IVA can cause pressure on the spinal cord.

Tell your doctor if you notice any of the following:

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

Things you must do

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

Before starting any new medicine, remind your doctor or pharmacist that you are receiving Vimizim.

Tell all the doctors, dentists and pharmacists who are treating you that you are receiving Vimizim.

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

Things you must not do

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.

Things to be careful of

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

This medicine may cause dizziness in some people. If you feel dizzy, do not drive or operate machinery.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are receiving Vimizim.

All medicines, including Vimizim, can have unwanted side effects. Sometimes they are serious, most of the time they are not.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor or nurse if you experience any of the following:

- Headache
- Nausea
- Vomiting
- Fever
- Chills
- Abdominal pain
- Diarrhoea
- Mouth and throat pain
- Stomach ache
- Dizziness
- Shortness of breath

- Muscle pain

These are the most common side effects of your medicine. Most side effects have occurred either during the infusion or within one day after the infusion.

Allergic reactions

Tell your doctor or nurse immediately if you experience any of the following side effects:

- 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.

These can be symptoms of an allergic reaction, which can be serious. 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.

Ask your doctor to answer any questions you may have.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

After being treated with Vimizim

Storage

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.

Product description

What it looks like

Vimizim is a clear, colourless to pale yellow solution. It is supplied in a 5 mL clear glass vial with a rubber stopper and aluminium seal. Each pack contains 1 vial.

Ingredients

The active ingredient in Vimizim is elosulfase alfa. Each 5 mL vial contains 5 mg elosulfase alfa.

The solution also contains the following inactive ingredients:

- sodium acetate trihydrate
- monobasic sodium phosphate monohydrate
- arginine hydrochloride
- sorbitol
- polysorbate 20
- water for injections

Vimizim solution does not contain any preservative.

Supplier

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

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