PART III: PATIENT MEDICATION INFORMATION
READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

VIMIZIM
(elosulfase alfa)

Read this carefully before you start taking **Vimizim** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Vimizim**.

Serious Warnings and Precautions

- Vimizim may cause severe or life-threatening allergic reactions.
- Tell your doctor or nurse immediately if you experience any of the following symptoms: shortness of breath, coughing, wheezing or trouble breathing, swelling of the face, lips, tongue or other parts of the body, tightness in the throat, chest pain, bluish skin, flushing, rash, itching, or hives.
- Tell your doctor if you have a fever, cough, or cold. These conditions may worsen the symptoms of an allergic reaction.

What is Vimizim used for?
Vimizim is used to treat patients with MPS IVA (Mucopolysaccharidosis Type IVA, Morquio A Syndrome).

People with MPS IVA do not have enough of an enzyme called N-acetylgalactosamine-6-sulfatase, which breaks down specific substances in the body (for example keratan sulfate). As a result, these substances build-up in many tissues in the body which causes the symptoms of MPS IVA.

How does Vimizim work?
This medicine is an enzyme called elosulfase alfa. It can replace the missing enzyme in MPS IVA patients. Treatment with Vimizim in MPS IVA patients has shown improvement in walking ability and reduction in levels of keratan sulfate in the body.

What are the ingredients in Vimizim?
Medicinal ingredients: elosulfase alfa
Nonmedicinal ingredients: L-arginine hydrochloride, polysorbate 20, sodium acetate trihydrate, sodium phosphate monobasic monohydrate, sorbitol, and water for injection.

Vimizim comes in the following dosage forms:
Vimizim is supplied as a concentrated solution for intravenous infusion. One mL of Vimizim contains 1 mg elosulfase alfa. A 5 mL vial contains 5 mg elosulfase alfa.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Vimizim. Talk about any health conditions or problems you may have,

including if you:

- Have ever had an allergic reaction to elosulfase alfa or any other ingredients of Vimizim.
- Have a fever, cough, or cold
- Are pregnant or planning to become pregnant.
- Are breast-feeding or planning to breast-feed

Other warnings you should know about:

- Tell your doctor immediately if you have neck or back pain, numb or weak arms or legs, or any bowel or bladder problems. These symptoms may be caused by pressure on your spinal cord, which is a medical emergency.
- Vimizim given to test animals passes into their unborn babies. Vimizim has not been studied in pregnant patients. Vimizim should not be given during pregnancy unless clearly necessary. Female patients who could become pregnant while taking Vimizim should use two forms of effective birth control.
- Vimizim given to test animals passes into their breast milk. It is not known if Vimizim passes into human breast milk. You and your doctor should discuss the risks and benefits of taking Vimizim while breastfeeding.
- In animal studies, Vimizim had no effects on their sperm quality, but it is not known if Vimizim affects human sperm.

Tell your health professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines. Studies to test how Vimizim interacts with other medicines have not been done.

How to take Vimizim:

Vimizim is given through a drip into a vein (intravenous infusion). Each infusion takes approximately 4 hours and is supervised by a health professional in case you have a reaction to Vimizim.

Before treating you with Vimizim, your doctor will give you medicine to help prevent allergic reactions. If you have an allergic reaction during your Vimizim treatment, your doctor may slow down or stop the infusion and may give you additional medicines to treat the reaction. You and your doctor will decide whether to continue treatment with Vimizim.

Usual dose:

The dose you receive is based on your body weight. The recommended dose regimen is 2 mg/kg body weight given once every week.

Overdose:

Vimizim is administered under the supervision of a health professional, who will check that the correct dose has been given and treat any overdose.

If you think you have been given too much Vimizim, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:
If you have missed a Vimizim treatment, contact your health professional. If you have any other questions about this medicine, ask your health professional or pharmacist.

What are possible side effects from using Vimizim?
These are not all the possible side effects you may feel when using Vimizim. If you experience any side effects not listed here, contact your health care professional.

Like all medicines, this medicine can cause side effects. Most side effects are mild to moderate and generally are associated with the infusion; however some side effects may be serious and may need treatment. Most side effects happened during the treatment or up to one day later, but some happen up to 6 days later. Side effects may include:

- Headache
- Nausea
- Vomiting (throwing up)
- Fever
- Chills
- Stomach ache
- Diarrhea
- Mouth and throat pain
- Dizziness
- Muscle pain

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Severe allergic reactions (signs and symptoms may include wheezing, shortness of breath, coughing, throat tightness, chest pain, hives, turning red or blue and feeling hot)		√	√
Shortness of breath	√		
Enlarged tonsils (difficulty swallowing or sore throat)	√		
Pressure or swelling on the spinal cord (neck or back pain, numbness in your arms or legs, or any bowel or bladder problems)		√	√
Serious skin infection that may spread to the bloodstream (redness, pain, swelling or blistering of the skin or high fever)		√	√
Weakness or looseness in joints	√		

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects
You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.
3 ways to report:

- Online at MedEffect;
- By calling 1-866-234-2345 (toll-free);
- By completing a Patient Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program
    Health Canada, Postal Locator 0701E
    Ottawa, ON
    K1A 0K9

Postage paid labels and the Patient Side Effect Reporting Form are available at MedEffect.
NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:
Unopened vials: Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Store in the original package in order to protect from light.
Do not take this medicine after the expiry date which is stated on the vial after EXP. The expiry date refers to the last day of that month.

Keep out of the sight and reach of children

If you want more information about Vimizim:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for health professionals and includes this Patient Medication Information by visiting the Health Canada website; or by calling BioMarin Pharmaceutical (Canada) Inc, at 1-877-597-6744

This leaflet was prepared by BioMarin Pharmaceutical (Canada) Inc.

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