

NAGLAZYME[®]

Concentrated Solution for Intravenous Infusion
Galsulfase (1mg/1 ml)

What is in this leaflet

1. What Naglazyme is used for
2. How Naglazyme works
3. Before you use Naglazyme
4. How to use Naglazyme
5. While you are using Naglazyme
6. Side effects
7. Storage and disposal of Naglazyme
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Naglazyme is used for

Naglazyme is used to treat patients with Mucopolysaccharidosis VI (MPS VI, Maroteaux-Lamy syndrome), a rare lysosomal storage disease (LSD).

People with MPS VI disease have either a low level or no level of activity of an enzyme called *N-acetylgalactosamine 4-sulfatase*, which breaks down specific substances (glycosaminoglycans) in the body. As a result, these substances do not get broken down and processed by the body as they should. They accumulate in many tissues in the body, leading to a progressive disorder with multiple organ and tissue involvement.

How Naglazyme works

This medicine contains a recombinant enzyme called galsulfase. This can replace the natural enzyme which is lacking in MPS VI patients. Treatment has been shown to improve walking and stair-climbing ability, and to reduce the levels of glycosaminoglycans in the body.

Before you use Naglazyme

- When you must not use it

Your doctor will tell you if you should not be treated with Naglazyme.

- Before you start to use it

Tell your doctor if you have or have had any medical conditions, especially if you:

- Have ever had an allergic reaction to galsulfase or any other ingredients of Naglazyme.
- Have sleep apnea (a condition in which breathing stops for a short time or becomes shallow during sleep)
- Have heart disease
- Have lung disease or breathing problems
- Have a fever, cough, or cold
- Are pregnant or planning to become pregnant.
- Are breast-feeding or planning to breast-feed

- Taking other medicines

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

How to use Naglazyme

Naglazyme will be given to you or your child directly into the vein (intravenously) by a doctor in a hospital or a clinic. Each infusion will be given over at least 4 hours.

You may be given additional medications to prevent side effects that may occur soon after you receive Naglazyme.

- How much to use

The recommended dosage regimen is 1 mg/kg body weight. Your doctor or nurse will calculate the dose based on your weight.

- When to use it

Your doctor or nurse will administer Naglazyme to you once weekly.

- How long to use it

Continue your treatment with Naglazyme for as long as your doctor tells you that you should.

- If you forget to use it

If you have missed a Naglazyme infusion, please contact your doctor or nurse.

- If you use too much (overdose)

Naglazyme is administered under the supervision of a doctor or nurse. He or she will check that the correct dose has been given and act accordingly if necessary.

While you are using it

- Things you must do

Tell your doctor immediately if you experience back pain, numbness in your arms or legs, or any bowel or bladder problems. MPS VI disease can cause pressure on the spinal cord. This can occur while you are receiving Naglazyme.

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

If you become pregnant during your treatment with Naglazyme, tell your doctor immediately.

NAGLAZYME[®]

Concentrated Solution for Intravenous Infusion
Galsulfase (1mg/1 ml)

- Things you must not do

Do not stop going to your visits for treatment with Naglazyme without checking with your doctor.

- Things to be careful of

An antihistamine may be administered prior to infusion of Naglazyme to minimise possible infusion reactions and some of these medicines are known to produce drowsiness. Be careful driving or operating machinery until you know how this medication affects you.

Side effects

Like all medicines, Naglazyme can cause side effects, although not everybody gets them.

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

Tell your doctor or pharmacist if you notice any of the following:

- Shortness of breath, wheezing or difficulty breathing
- Swelling of the face, lips, tongue, or other parts of the body
- Rash, hives or itching
- Chest pain
- Flushing or redness of the skin
- Stomach ache
- Nausea,
- Vomiting
- Headache
- Joint pain
- Ear pain
- Red, itchy, or irritated eyes
- Fever
- Chills

This is not a complete list of side effects. If you have any unexpected effects while taking Naglazyme, talk to your doctor or You may report side effects or adverse drug reactions directly to

the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

Storage and disposal of Naglazyme

- Storage

Naglazyme will be stored under refrigeration (2°C - 8°C) in the hospital or pharmacy.

- Disposal

Your doctor or nurse will dispose of the medicine properly

Product description

- What it looks like

Naglazyme is supplied as a clear to slightly opalescent and colourless to pale yellow solution in 5 mL glass vials.

- Ingredients

Active Ingredient: Galsulfase

Inactive Ingredients: sodium chloride, sodium phosphate monobasic monohydrate, sodium phosphate dibasic heptahydrate, polysorbate 80 and water for injection.

MAL Number:

MAL 12075023ARZ

Manufacturer and Product Registration Holder

Manufacturer:

BioMarin[®] Pharmaceutical Inc.
46 Galli Drive
Novato, CA 94949 USA

Product Registration Holder:

Pharm-D Sdn. Bhd. (535448-K)
No 8B, Jalan 1/137C,
Bedford Business Park,
Off Jalan Kelang Lama,
58000 Kuala Lumpur.
General line: +603-7770 7918
Fax line : +603-7770 1918

Date of revision

11 May 2016

Serial Number

BPFK(R4/2)110516/00128

Naglazyme is a registered trademark of BioMarin Pharmaceutical Inc., USA

v3