# Naglazyme®

## 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 Naglazyme?

Naglazyme contains the active ingredient galsulfase. Naglazyme is used as an enzyme replacement therapy in patients with Mucopolysaccharidosis VI (MPS VI) storage disorder, a disease in which the enzyme level of *N*-acetylgalactosamine 4 sulfatase is absent or lower than normal.

For more information, see Section 1. Why am I using Naglazyme? in the full CMI.

### 2. What should I know before I use Naglazyme?

Do not use if you have ever had an allergic reaction to Naglazyme 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 Naglazyme? in the full CMI.

### 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.

### 4. How do I use Naglazyme?

- Naglazyme will be given to you by a healthcare professional as a drip into a vein (by intravenous infusion) over several hours.
- The dose you receive will depend on your body weight. The recommended dose regimen is 1 mg per kg of body weight.

More instructions can be found in Section 4. How do I use Naglazyme? in the full CMI.

### 5. What should I know while using Naglazyme?

| | |
|---|---|
| **Things you should do** | • Remind any doctor, dentist or pharmacist you visit that you are using Naglazyme.<br>• Keep all appointments with your doctor and always discuss anything that worries you during or after treatment with Naglazyme. |
| **Things you should not do** | • Do not stop going to your visits for treatment with Naglazyme.<br>• If you have missed a Naglazyme infusion, please contact your doctor. Your condition may worsen if you stop receiving Naglazyme. |
| **Driving or using machines** | • Be careful before you drive or use any machines or tools until you know how Naglazyme affects you. |
| **Looking after your medicine** | • Naglazyme will be stored under refrigeration (2°C - 8°C) in the hospital or pharmacy. |

For more information, see Section 5. What should I know while using Naglazyme? in the full CMI.

### 6. Are there any side effects?

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Side effects were mainly seen while patients were being given the medicine or shortly after ("infusion associated reactions"). The most serious side effects were swollen face and fever (very common); longer than normal gaps between breaths, difficulty breathing, asthma and hives (common); and swelling of the tongue and throat, and serious allergic reaction to this medicine (unknown frequency). The most common symptoms of infusion reactions include fever, chills, rash, hives and shortness of breath.
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.

# Naglazyme®

**Active ingredient:** *galsulfase-rch*

## Consumer Medicine Information (CMI)

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

**Where to find information in this leaflet:**



## 1. Why am I using Naglazyme?

**Naglazyme contains the active ingredient galsulfase.** Naglazyme is used as an enzyme replacement therapy in patients with Mucopolysaccharidosis VI (MPS VI) storage disorder, a disease in which the enzyme level of *N*-acetylgalactosamine 4 sulfatase is absent or lower than normal.

Patients with MPS VI disease do not produce enough of their own enzyme, *N*-acetylgalactosamine 4-sulfatase. The reduced or absent enzyme activity in patients results in the accumulation of substances called glycosaminoglycans (GAGs) in many tissues in the body.

Naglazyme replaces 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 GAG in the body. This medicine may improve the symptoms of MPS VI.

Naglazyme is recommended for use in children and adults.

## 2. What should I know before I use Naglazyme?

### Warnings

#### Do not use Naglazyme if:

- you have experienced severe or life-threatening allergic (hypersensitive) reactions to galsulfase, or any of the ingredients listed at the end of this leaflet and re-administration of the medicine was not successful.
- Always check the ingredients to make sure you can use this medicine.

#### Check with your doctor if you:

- have any other medical conditions, in particular if you:
  - have a fever, or if you are having difficulty breathing before this medicine is given.
  - have an underlying heart condition, please inform your doctor at any point while being treated with Naglazyme. They may adjust your infusion based on this information.
  - if you have muscle pain, numbness in your arms or legs, or any bowel or bladder problems as these may be caused by pressure on your spinal cord.
  - have kidney or liver insufficiency. This medicine has not been tested in patients with kidney or liver problems.
- are on a controlled sodium diet. Each vial of Naglazyme contains 18.5 mg sodium and is administered in sodium chloride 9 mg/mL solution for injection.
- have allergies to any other medicines, foods, preservative 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.

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

Naglazyme should not be given during pregnancy unless clearly necessary. Ask your doctor or health care professional for advice before taking any medicine. It is not known whether galsulfase is excreted in milk, therefore breastfeeding should be stopped during Naglazyme treatment.

## 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.

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

## 4. How do I use Naglazyme?

### How Naglazyme is given

Naglazyme is administered once a week directly into the vein (intravenously) by a trained health care professional in an appropriate setting able to manage infusion-related reactions.

Your doctor or nurse may give you some medicines before your treatment to minimise possible infusion reactions (e.g. antihistamines and/or medicine to reduce fever).

### How much is given

The dose you receive is based on your body weight. The recommended dose regimen is 1 mg per kg of body weight administered once every week through a drip into a vein (by intravenous infusion). Your doctor or health care professional will decide on the dose that is most suitable.

Each infusion will take at least 4 hours.

### If you miss a dose

**If you have missed a Naglazyme infusion at the usual time, talk to your doctor or nurse and arrange another visit as soon as possible.**

### If you take too much Naglazyme

Naglazyme 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 using Naglazyme?

### Things you should do

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

It is important to have the Naglazyme infusion at the appropriate time to make sure the medicine has the best chance of providing treatment for the condition.

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

When you are treated with Naglazyme, you may develop infusion reactions. An infusion reaction is any side effect, including an allergic reaction, occurring during the infusion or shortly after (refer to Side Effects section). **Call your doctor immediately when you experience such a reaction.**

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 reactions. Your doctor will decide when you can restart Naglazyme treatment.

### Things you should not do

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

Your condition may worsen if you stop receiving Naglazyme.

### Looking after your medicine

Naglazyme must be stored in the fridge at 2°C to 8°C. Do not freeze or shake. Your doctor or pharmacist is responsible for storing Naglazyme.

Naglazyme should not be given if the expiry date printed on the carton has passed.

### Driving or using machines

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

The effect of Naglazyme on your ability to drive a car or operate machinery has not been studied.

### Looking after your medicine

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

Your doctor or pharmacist is also responsible for disposing of any unused Naglazyme properly.

### When to discard your medicine

Each vial of Naglazyme 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 |
|---|---|
| **General body related:**<br>• Poor reflexes<br>• Headache<br>• Fever<br>• Chills<br>• Bulging belly button<br>• Joint or chest pain<br>• Generally feeling unwell<br>• Rash or hives<br>• High blood pressure<br>• Tremor<br><br>**Gastrointestinal related:**<br>• Inflammation of the stomach and intestine, with symptoms like nausea, vomiting, cramps, diarrhoea<br>• Stomach ache<br><br>**Eye related:**<br>• Itchy, red eyes with discharge<br>• Cloudy eyes<br><br>**Respiratory related:**<br>• Sore throat<br>• Blocked nose<br>• Cough | **Speak to your doctor if you have any of these less serious side effects and they worry you.** |

| | |
|---|---|
| **Ear related:**<br>• Ear pain<br>• Poor hearing | |

## Serious side effects

| Serious side effects | What to do |
|---|---|
| **Allergic reaction related:**<br>• Signs of a sudden life-threatening allergic reaction e.g. 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<br>• Symptoms of shock, e.g. rapid, shallow breathing, cold, clammy skin, a rapid, weak pulse, dizziness, weakness and fainting<br><br>**Other infusion reaction related:**<br>• Low blood pressure<br>• Tingling<br>• Low blood oxygen, e.g. bluish skin, skin paleness<br>• Skin redness<br>• Slower or faster heart rate than normal<br>• Rapid breathing or longer than normal gaps between breaths | **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.** |

**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 Naglazyme contains

| | |
|---|---|
| **Active ingredient (main ingredient)** | 5 mg galsulfase in each vial (1 mg/mL) |
| **Other ingredients (inactive ingredients)** | • sodium chloride<br>• monobasic sodium phosphate monohydrate<br>• dibasic sodium phosphate heptahydrate<br>• polysorbate 80<br>• water for injections |
| **Potential allergens** | N/A |

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

## What Naglazyme looks like

Naglazyme is a colourless to pale yellow, clear to slightly opalescent concentrated solution for injection in a clear glass vial containing 5 mL of solution. Each pack contains 1 vial. (Aust R 125598).

## Who distributes Naglazyme

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

Naglazyme 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 Naglazyme, 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 September 2025.

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