NAGLAZYME®

galsulfase (rch) concentrated solution for injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Naglazyme.

It does not contain all the available information. It does not take the place of talking to your doctor or a trained health care professional.

All medicines have risks and benefits. Your doctor has weighed the risks of having Naglazyme against the benefits they expect it will have.

If you have any concerns about this medicine, ask your doctor or health care professional.

Keep this leaflet while you are being treated with Naglazyme.

You may need to read it again.

What Naglazyme is used for

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.

How it works

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

This medicine contains a recombinant enzyme called galsulfase-rch. 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 GAG in the body. This medicine may improve the symptoms of MPS VI.

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

Naglazyme is available only with a doctor's prescription.

Use in Children

Naglazyme is recommended for use in children and adults.

Before you are given Naglazyme

When you must not have it

Naglazyme should not be given if you have experienced severe or life-threatening allergic (hypersensitive) reactions to galsulfase-rch or any of the other ingredients of Naglazyme listed at the end of this CMI and re-administration of the medicine was not successful.

If you are treated with Naglazyme, you may develop infusion reactions. An infusion reaction is any side effect occurring during the infusion or shortly after (refer to Side Effects section). **When you experience such a reaction, you should immediately contact your health care professional.**

MPS VI disease can cause pressure on the upper spinal cord, which can occur while you are receiving Naglazyme. **Please talk to your health care professional if you experience muscle pain, numbness in your arms or legs, or any bowel or bladder problems.**

Before you start treatment with Naglazyme

Before Naglazyme administration, talk to your health care professional if:

- **you have a fever, or if you are having difficulty breathing before this medicine is given.**
- **you have kidney or liver insufficiency. This medicine has not been tested in patients with kidney or liver problems.**
- **you are pregnant or intend to become pregnant or are breastfeeding.**

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-rch is excreted in milk, therefore breast-feeding should be stopped during Naglazyme treatment.

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

Taking other medicines

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

Interaction studies with Naglazyme have not been conducted.

How Naglazyme is given

Naglazyme is administered once a week directly into the vein (intravenously) by a trained health care professional in a hospital or a clinic.

Your doctor or health care professional will decide on the dose that is most suitable.

An antihistamine may be administered prior to infusion of Naglazyme to minimise possible infusion reactions.

If you are given too much (overdose)

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.

While you are being given Naglazyme

Things you must do

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

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

Tell your doctors, dentists and pharmacists who treat you that you are taking this medicine.

Things to be careful of

Be careful driving or operating machinery 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. **Make sure you know how you react to Naglazyme before you drive a car or operate machinery.**

Side effects

Tell your doctor or health care professional as soon as possible if you do not feel well while you are taking Naglazyme.

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 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); swelling of the tongue and throat, and serious allergic reaction to this medicine (unknown frequency).

If you experience any reaction like this, tell your health care professional immediately. You may need to be given additional medicines to prevent an allergic reaction (e.g. antihistamines and/or corticosteroids) or to reduce fever (antipyretics).

The most common symptoms of infusion reactions include fever, chills, rash, hives and shortness of breath.

INFUSION REACTIONS AND SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN	
Symptom / effect	
Very Common (More than 1 in 10 people)	Sore Throat, Gastroenteritis, Poor Reflexes, Headache, Inflammation of the Eye, Cloudy Eyes, Poor Hearing, High Blood Pressure, Nasal Congestion, Bulging Belly Button, Vomiting, Nausea, Itching, Pain (Including Ear, Abdominal, Joint, Chest Pain), Malaise, Swollen Face, Fever
Common (Up to 1 to 10 people)	Tremor, Low Blood Pressure, Cough, Wheezing, Skin Redness, Asthma, Hives, Difficulty Breathing, Longer than Normal Gaps between Breaths
Unknown (unknown frequency)	Shock, Tingling, Decreased Heart Rate, Increased Heart Rate, Bluish Skin, Skin Paleness, Low Blood-Oxygen, Rapid Breathing, Swelling of Tongue and Throat, Serious Allergic Reactions

This is not a complete list of side effects. For any unexpected effects while taking Naglazyme, contact your doctor or health care professional.

After having Naglazyme

Storage

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

Product description

What it looks like

Naglazyme is a colourless to pale yellow, clear to slightly opalescent solution contained in a labelled 5 mL glass vial.

Ingredients

The active ingredient in Naglazyme is *N*-acetylgalactosamine 4-sulfatase (galsulfase-rch). Each vial contains 5 mg/5 mL galsulfase-rch.

The solution also contains the following inactive ingredients:

- sodium chloride
- monobasic sodium phosphate monohydrate
- dibasic sodium phosphate heptahydrate
- polysorbate 80
- water for injections.

Supplier

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:

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New Zealand: 0800 882 012

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Australian registration number

AUST R 125598

Date of preparation

This leaflet was prepared in March 2018.