PART III: CONSUMER INFORMATION

Naglazyme®

Galsulfase for injection

This leaflet is part III of a three-part "Product Monograph" published when Naglazyme® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Naglazyme. Contact your health professionalif you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

Naglazyme is used to treat patients with MPS VI disease (Mucopolysaccharidosis VI). People with MPS VI disease have either a low activity level, or no activity level, of an enzyme called N-acetylgalactosamine 4-sulfatase, which breaks down specific substances (glycosaminoglycans or GAG) 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, which causes the symptoms of MPS VI.

Patients being treated with Naglazyme are supervised by doctors who have experience with metabolic diseases.

What it does:

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

When it should not be used:

If you have experienced severe or life-threatening allergic (hypersensitive) reactions to galsulfase or any of the other ingredients of Naglazyme and re-administration of the medicine was not successful.

What the medicinal ingredient is:

The active substance is galsulfase. Galsulfase is recombinant human N-acetylgalactosamine 4-sulfatase produced by genetically engineered Chinese Hamster Ovary (CHO) cells.

What the important nonmedicinal ingredients are: The nonmedical ingredients are: sodium chloride, sodium phosphate monobasic monohydrate, sodium phosphate dibasic heptahydrate, polysorbate 80, water for injection. For a full listing of nonmedicinal ingredients see Part 1 of the product monograph.

What dosage forms it comes in:

One ml of Naglazyme contains 1 mg galsulfase. One 5 mL vial contains 5 mg galsulfase.

WARNINGS AND PRECAUTIONS

If you are treated with Naglazyme, you may develop infusion-associated reactions. An infusion associated reaction is any side effect occurring during the infusion or until the end of the infusion day (see side effects and what to do about them). When you experience such a reaction, you should immediately contact your health professional.

If you have an allergic reaction your health professional may slow down, or stop your infusion. Your health professional may also give you additional medicines to manage any allergic reactions.

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

Naglazyme should not be given during pregnancy unless clearly necessary. Ask your health professional for advice before taking any medicine. It is not known whether galsulfase is excreted in milk, therefore precaution should be exercised if breast-feeding. Ask your health professional for advice before taking any medicine.

BEFORE you use Naglazyme talk to your health professional if:

- You have experienced severe or life-threatening allergic (hypersensitive) reactions to galsulfase or any of the other ingredients of Naglazyme and re-administration of the medicine was not successful.
- 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 taking or have recently taken any other medicines, including medicines obtained without a prescription.
- You are pregnant, planning to become pregnant, or breastfeeding.

INTERACTIONS WITH THIS MEDICATION

Please tell your health professional if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Interactions studies with Naglazyme have not been conducted.

PROPER USE OF THIS MEDICATION

Usual dose:
Your health professional will administer Naglazyme to you. The dose you receive is based on your body weight. The recommended dose is 1 mg / kg body weight administered once every week through a drip into a vein (intravenously) using an infusion set with a 0.2 µm in-line filter. Each infusion will take approximately 4 hours. For the first hour the infusion rate will be slow (approximately 2.5% of the total solution), with the remaining volume (approximately 97.5%) being taken over the next 3 hours.

Overdose:
Naglazyme is administered under the supervision of a health professional, he or she will check that the correct dose has been given and act accordingly if necessary.

Missed Dose:
If you have missed a Naglazyme infusion, contact your health professional. If you have any further questions on the use of this medicine, ask your health professional.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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); 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 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 associated reactions include fever, chills, rash, hives and shortness of breath.

INFUSION ASSOCIATED REACTIONS AND SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your health professional
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	Yes
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	Yes
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	Yes

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

HOW TO STORE IT

Keep out of the sight and reach of children.
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. The expiry of Naglazyme is 3 years from the date of manufacture.
Store in a refrigerator (2°C - 8°C).

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca / medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
    - Fax toll-free to 1-866-678-6789, or
    - Mail to:
      Canada Vigilance Program
      Health Canada
      Postal Locator 0701D
      Ottawa, Ontario
      K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca / medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be provided by contacting the sponsor, BioMarin Pharmaceutical (Canada) Inc, at: 1-877-597-6744

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