MYOZYME® *[my-oh-ZIME]*

Alglucosidase alfa-rch *[al-glue-co-SIDE-aze al-fa R.C.H]* 50 mg/10 mL, Powder for Concentrate for Solution for Infusion

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Myozyme.

It does not contain all the available information about Myozyme.

It does not take the place of talking to your treating physician or a trained health care professional.

All medicines have risks and benefits. Your treating physician has weighed the risks of you or your child having Myozyme against the benefits they expect it will have.

If you have any concerns about this medicine, ask your doctor or nurse.

Keep this leaflet.
You may need to read it again.

What it is used for

What Myozyme is used for

Myozyme is used to treat Pompe disease, a rare genetic disease in which the level of an enzyme called acid alfa-glucosidase is missing or is lower than in healthy individuals.

Myozyme is used as a replacement to the lack of or low levels of the enzyme. Myozyme contains the active ingredient alglucosidase alfa-rch. Alglucosidase alfa-rch is a type of protein.

Myozyme is available only with a doctor's prescription. Only the treating physician can start the treatment and supervise the ongoing treatment.

Myozyme is to be given only to the person for whom it has been prescribed.

How it works

Patients with Pompe disease do not produce enough of their own enzyme, acid alfa-glucosidase. The reduced acid alfa-glucosidase activity in patients results in the build up of glycogen in many parts of the body. Myozyme is an enzyme replacement therapy that is intended to restore a level of enzyme activity sufficient to remove the accumulated glycogen and to prevent further accumulation.

Pompe disease has been described under 2 forms: early-onset and late-onset. Your physician is in the best position to determine the risks and benefits of treatment with Myozyme and he will discuss it with you or your child.

Ask your treating physician if you have any questions about why it has been prescribed for you or your child.

This medicine is only available with a physician's prescription.

It is not addictive.

Before you are given Myozyme

When you or your child must not be given it

Do not take Myozyme if you or your child have a known, severe, life-threatening allergic reaction to any of the ingredients listed at the end of this leaflet.

Symptoms of a severe allergic reaction may include:

- shortness of breath, difficulty breathing
- skin rash, itching or hives
- very fast heart rate
- swelling of the face, lips or tongue
- symptoms of low blood pressure

Your treating physician may recommend to perform blood tests to monitor your or your child's body's response to Myozyme to make sure that it is working, especially if you or your child have experienced a loss of mobility since the last Myozyme infusion, to check your or your child's immune reaction to Myozyme active ingredient or if you have experienced certain side effects.

Tell your treating physician if you or your child have experienced loss in mobility since the last Myozyme infusion.

If you are not sure whether you or your child should have Myozyme, talk to your treating physician or nurse.

Before you or your child are given it

Tell your treating physician if you or your child have received Myozyme or another drug, and experienced any of the following conditions:

- life-threatening allergic reaction
- difficulty breathing

Tell your treating physician if you or your child have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

Tell your treating physician if you are pregnant or intend to become pregnant.
There is limited experience of the use of Myozyme in pregnant women. Your treating physician will discuss the possible risks and benefits of having Myozyme during pregnancy.

Tell your treating physician if you are breast-feeding or planning to breast-feed.
There is limited information available regarding the use of Myozyme in breastfeeding women. Myozyme may be found in breast milk. The continuation of treatment for Pompe disease during pregnancy and breast-feeding should be individualised. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you have not told your treating physician about any of the above, tell them before you or your child are given Myozyme.

Taking other medicines

Tell your treating physician or nurse if you or your child are receiving treatment with medicines that suppress your immune system,
Because you or your child have Pompe disease, there is a risk that you get a severe infection of your airways or lungs. Using these medicines to suppress the immune system may further increase this risk.

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

Tell your treating physician or nurse if you or your child are using other medicines as these medicines may be affected by Myozyme or may affect how well it works (different amounts of these medicines may be needed or different medicines may need to be taken). Your treating physician or nurse will advise you and decide whether or not to give you or your child Myozyme.

How Myozyme is given

How much to use

The recommended dosage for Myozyme is 20 mg/kg of body weight once every two weeks. Myozyme will be given to you or your child directly into the vein (intravenously) by a trained health care professional in a hospital or a clinic.

How to use it

Myozyme will be prepared and given to you or your child by a treating physician or a nurse.

Myozyme will be reconstituted, diluted and should be protected from light before it is given to you or your child. It is given as a drip through a needle placed into a vein (intravenous infusion), usually in the arm. This takes approximately 4 hours.

A few patients have had an allergic reaction to Myozyme. Your or your child's treating physician or nurse will check for allergic reactions during the infusion. Your or your child's treating physician may decide to check for allergic reactions some time after the infusion. You may need to be given pre-treatment medicines to prevent an allergic reaction (e.g. antihistamines and/or corticosteroids) or to reduce fever (antipyretics).

In studies, doctors have used medicines to suppress the immune system to reduce the production of antibodies. Because you or your child have Pompe disease, there is a risk that you could get a severe infection of your airways or lungs. Using these medicines to suppress the immune system may further increase this risk.

Infusion with Myozyme should start as soon as possible after the medicine has been reconstituted and diluted. If not used immediately, the solution must be stored at 2°C - 8°C and infused within 24 hours of reconstitution and dilution.

You may be at an increased risk of an infusion associated reaction (IAR), if you are given Myozyme at a higher dose or infusion rate than recommended. If you experience IARs you should tell your doctor immediately.

When it is given

Myozyme is given by infusion once every 2 weeks.

How long to use it

It is important to continue treatment with Myozyme unless your treating physician tells you or your child to stop.

If you are given too much (overdose)

There have been no reported overdoses of Myozyme.

Your treating physician is trained to work out the correct dose and to contact the New Zealand National Poisons Centre (telephone 0800 POISON or 0800 764 766) in case of an overdose.

While you are being given Myozyme

Things you or your child must do

Keep appointments with your treating physician or clinic.
It is important to have the infusion with Myozyme at the appropriate times to make sure the medicine has the best chance of providing treatment for the condition.

Have any tests when your treating physician says to.
Your treating physician may recommend to perform blood tests to monitor your or your child's

body's response to Myozyme to make sure that it is working, especially if you or your child have experienced a loss of mobility since the last Myozyme infusion and to check your or your child's immune reaction to Myozyme active ingredient.

Tell your treating physician if you or your child have experienced loss in mobility since the last Myozyme infusion.

Things to be careful of

Be careful driving or operating machinery until you know how Myozyme affects you.
The effect of Myozyme on your ability to drive a car or operate machinery has not been studied. Make sure that you know how you react to Myozyme before you drive a car or operate machinery or do anything else that may be dangerous if you are dizzy, light-headed, tired or drowsy.

Side effects

Tell your treating physician or nurse as soon as possible if you or your child do not feel well after having Myozyme.
All medicines may have unwanted side effects. Sometimes they are serious, but most of the time they are not. Your treating physician has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects.
You or your child may not experience any of them.

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

Tell your treating physician or nurse as soon as possible if you notice any of the following and they worry you:

- nausea
- feeling hot
- headache
- sleepiness
- fainting
- burning sensation
- increased tear production

These are mild to moderate side effects of Myozyme.

Tell your treating physician or nurse immediately if you notice any of the following:

- dizziness and lightheadedness
- bluish tinged skin
- fast heart beat/rate
- fever or high temperature
- itchy rash, hives, itching or rash
- flushing or redness of skin
- pale skin
- redness, swelling or pain around infusion site
- severe skin reactions
- difficulty breathing, wheezing or coughing
- fast breathing
- vomiting or retching, cramps
- irritability or agitation
- increased sweating
- swelling of the face

These may be serious side effects of Myozyme, which may require urgent medical attention.

Tell your treating physician if you notice anything else that is making you or your child feel unwell.
Other side effects not listed above may occur.

Storing Myozyme

Myozyme should be stored in the hospital or clinic pharmacy under refrigeration at 2°C - 8°C.

After reconstitution and dilution, Myozyme should be protected from light.

Product Description

What it looks like

Myozyme is supplied in a clear glass vial and is a white to off-white powder before it is prepared for infusion and a clear, colourless to pale yellow solution when it is prepared for infusion, which may contain particles.

Ingredients

Active ingredient: alglucosidase alfa

Other ingredients: mannitol, monobasic sodium phosphate monohydrate, dibasic sodium phosphate heptahydrate and polysorbate 80.

Supplier

Distributed in New Zealand by:
Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics
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