

## 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 Myozyme?

Myozyme contains the active ingredient alglucosidase alfa-rch. Alglucosidase alfa-rch is a type of protein. 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.

For more information, see Section [1. Why am I using Myozyme?](#) in the full CMI.

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

Do not use if you have ever had an allergic reaction to alglucosidase alfa-rch 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 Myozyme?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Myozyme and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Myozyme?

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.

More instructions can be found in Section [4. How do I use Myozyme?](#) in the full CMI.

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

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using Myozyme.</li><li>• Keep appointments with your treating physician or clinic.</li><li>• Have any tests when your treating physician says to.</li><li>• Call your doctor straight away if you or your child have experienced loss in mobility since the last Myozyme infusion.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how Myozyme affects you.</li><li>• Make sure that you know how you react to Myozyme before you do anything else that may be dangerous if you are dizzy, light-headed, tired or drowsy.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Myozyme should be stored in the hospital or clinic pharmacy under refrigeration at 2°C - 8°C.</li><li>• After reconstitution and dilution, Myozyme should be protected from light.</li></ul>

For more information, see Section [5. What should I know while using Myozyme?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects include nausea, feeling hot, headache, sleepiness, fainting, burning sensation and increased tear production. Serious side effects include dizziness and light headedness, 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 and swelling of the face.

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.

## Consumer Medicine Information (CMI)

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

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

1. [Why am I using Myozyme?](#)
2. [What should I know before I use Myozyme?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use Myozyme?](#)
5. [What should I know while using Myozyme?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

## 1. Why am I using Myozyme?

**Myozyme contains the active ingredient alglucosidase alfa-rch.** Alglucosidase alfa-rch is a type of protein.

**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 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 Myozyme 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.

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

### Warnings

#### Do not use Myozyme if:

- You or your child are allergic to alglucosidase alfa-rch, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you or your child can use this medicine.

#### Check with your doctor if you or your child:

- have any other medical conditions
- take any medicines for any other condition
- have allergies to any other medicines and/or any other substances such as foods, preservatives or dyes
- have experienced loss in mobility since the last Myozyme infusion

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.

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

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.

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.

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

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.**

**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

### **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.

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

**Some medicines may interfere with Myozyme and affect how it works.**

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.

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

### **4. How do I use Myozyme?**

**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.
- Follow the instructions provided and use Myozyme until your doctor tells you to stop.

**When to use Myozyme**

- Myozyme is given by infusion once every two weeks

**How to use Myozyme**

- 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.
- 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.
- 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.

**If you or your child forget to use Myozyme**

Myozyme should be used regularly at the same time every two weeks. It is important that you go to all your appointments to make sure your treatment works. If you miss any appointments, call your doctor as soon as possible to reschedule your appointment. Your doctor will decide how the treatment will continue.

**If you use too much Myozyme**

There have been no reported overdoses of Myozyme.

Your treating physician is trained to work out the correct dose and to phone the Poisons Information Centre (by calling 13 11 26 in Australia or 0800 764 766 in New Zealand), in case of an overdose. If you have any concerns, ask your doctor.

### **5. What should I know while using Myozyme?**

**Things you or your child should 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.

## Call your doctor straight away if you or your child:

- have experienced loss in mobility since the last Myozyme infusion.

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

## Driving or using machines

**Be careful before you drive or use any machines or tools 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.

## Looking after your medicine

- 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.

Follow the instructions in the carton on how to take care of your medicine properly.

**Keep it where young children cannot reach it.**

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 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
<b>General:</b> <ul style="list-style-type: none"><li>• Headache</li><li>• Nausea</li><li>• Sleepiness</li><li>• Fainting</li><li>• Burning sensation</li></ul> <b>Other:</b> <ul style="list-style-type: none"><li>• Increased tear production</li><li>• Feeling hot</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

## Serious side effects

Serious side effects	What to do
<b>Allergic related-reaction:</b> <ul style="list-style-type: none"><li>• Difficulty breathing, wheezing or coughing</li><li>• Fast breathing</li><li>• Itchy rash, hives, itching or rash</li><li>• Swelling of the face</li><li>• Increased sweating</li><li>• Fever or high temperature</li><li>• Flushing or redness of the skin</li></ul> <b>Heart related:</b> <ul style="list-style-type: none"><li>• Fast heart beat/rate</li></ul> <b>Infusion site-related:</b> <ul style="list-style-type: none"><li>• Redness, swelling or pain around infusion site</li></ul> <b>Skin-related:</b> <ul style="list-style-type: none"><li>• Bluish tinged skin</li><li>• Pale skin</li><li>• Severe skin reactions</li></ul> <b>Other:</b> <ul style="list-style-type: none"><li>• Dizziness and light headedness</li><li>• Vomiting or retching, cramps</li><li>• Irritability or agitation</li></ul>	<b>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.</b>

**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](http://www.tga.gov.au/reporting-problems) in Australia or in New Zealand at <https://pophealth.my.site.com/carmreportnz/s/>. 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 Myozyme contains

<b>Active ingredient (main ingredient)</b>	Alglucosidase alfa-rch
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• Mannitol</li><li>• Monobasic sodium phosphate monohydrate</li><li>• Dibasic sodium phosphate heptahydrate</li></ul>

	<ul style="list-style-type: none"> <li>• Polysorbate 80</li> </ul>
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**Do not take this medicine if you are allergic to any of these ingredients.**

### **What Myozyme 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. (Aust R 136005).

### **Who distributes Myozyme**

Distributed in Australia by:

sanofi-aventis australia Pty Ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Freecall: 1800 818 806

Email: [medinfo.australia@sanofi.com](mailto:medinfo.australia@sanofi.com)

Distributed in New Zealand by:

Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics

PO Box 62027

Sylvia Park Auckland 1644

Freecall: 0800 283 684

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