

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 CEREZYME?

CEREZYME contains the active ingredient imiglucerase-rch. Cerezyme is used as enzyme replacement therapy to treat patients who have a confirmed diagnosis of Type I or Type 3 Gaucher disease.

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

2. What should I know before I use Cerezyme?

Do not use if you have ever had an allergic reaction to Cerezyme 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 Cerezyme?](#) in the full CMI.

3. What if I am taking other medicines?

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

For more information, see Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Cerezyme?

- Cerezyme is given through a drip into a vein (intravenously) by a trained healthcare professional in a hospital, or in a clinic.
- Your doctor may advise that you can be treated at home provided you meet certain criteria. Please contact your doctor if you would like to be treated at home.
- Your treating physician will decide on the dose and frequency of infusion that is most suitable.

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

5. What should I know while using Cerezyme?

Things you should do	<ul style="list-style-type: none">• Keep appointments with your treating physician or clinic.• Have any tests when your treating physician says to.• Remind any nurse, doctor or pharmacist you visit that you are using Cerezyme.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine without speaking to your healthcare professional.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how Cerezyme affects you.
Looking after your medicine	<ul style="list-style-type: none">• Cerezyme will usually be stored in the hospital or clinic pharmacy refrigeration at 2°C - 8°C.• Reconstituted and diluted Cerezyme should be protected from light.

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

6. Are there any side effects?

Side effects include nausea & vomiting. Serious side effects include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, local reaction around the injection site such as redness, itchiness, tenderness, pain or discomfort, warmth, burning or stinging, swelling or the formation of hard lumps or scars, flushing or redness of the skin, headaches, stomach ache or cramp, diarrhoea, rash or hives, tiredness, dizziness.

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.

Cerezyme (serah-ZIME)

Active ingredient(s): Imiglucerase-rch [im-e-glue-sar-aze R.C.H] 400 U, Powder for Solution for Infusion

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using Cerezyme?

Cerezyme contains the active ingredient imiglucerase.

Cerezyme is used as enzyme replacement therapy to treat patients who have a confirmed diagnosis of Type I or Type 3 Gaucher disease, who show signs of the disease such as: anaemia (low number of red blood cells), low numbers of platelets (a type of blood cell) which can lead to a tendency to bleed, spleen or liver enlargement or bone disease. Gaucher disease is a disease in which the enzyme β -glucocerebrosidase in the body does not work properly.

Patients with Gaucher disease do not produce enough of their own active enzyme, β -glucocerebrosidase. The reduced β -glucocerebrosidase activity in patients results in the accumulation of a fatty substance in the body called glucocerebroside.

Cerezyme is an enzyme replacement therapy that is intended to restore a level of enzyme activity enough to remove the built up glucocerebroside and to prevent further build up.

2. What should I know before I use Cerezyme?

Warnings

Do not use Cerezyme if you or your child:

- have a known, severe, life-threatening allergic reaction to Cerezyme, or any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, skin rash, itching or hives.

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

Check with your doctor if you or your child:

- have received Cerezyme or another drug and experienced life-threatening allergic reaction or difficulty breathing.
- have any allergies to any other medicines or any other substances, such as foods, preservatives, or dyes.
- have previously had surgery to remove the spleen.

If you are treated with Cerezyme, you may experience infusion associated reactions (IARs) or an allergic reaction while you are being given the medicine or shortly after. The IARs or allergic reaction is any side effect occurring during the infusion or until the end of the infusion day. See additional information under Section [6. Are there any side effects?](#)

Your doctor may modify the administration of Cerezyme and may add medication before or during the infusion to prevent the IARs or allergic reaction. In addition, your doctor may perform tests to evaluate your allergic reaction.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor 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 no information available regarding the use of Cerezyme in pregnant women. Your treating physician will discuss the possible risks and benefits of having Cerezyme during pregnancy.

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

It is not known whether Cerezyme passes into breast milk. Your treating physician will discuss the possible risks and benefits of having Cerezyme during breastfeeding.

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.

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

No studies have been carried out on drug interactions.

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

4. How do I use Cerezyme?

How Cerezyme is given

Cerezyme is given through a drip into a vein (intravenously) by a trained Healthcare professional in a hospital, or in a clinic. The infusion can last 1 or 2 hours.

It is supplied as a powder which will be mixed with sterile water before it is given.

Cerezyme is only used under the supervision of a doctor who is knowledgeable in the treatment of Gaucher disease. Your doctor may advise that you can be treated at home provided you meet certain criteria. Please contact your doctor if you would like to be treated at home.

A Home Infusion Guide for Patients/Carers is available to provide home infusion information related to Cerezyme. Please ask your doctor for more information.

Your treating physician will decide on the dose and frequency of infusion that is most suitable.

If you are given too much Cerezyme

There have been no reported overdoses of Cerezyme.

Your treating physician is trained to work out the correct dose.

If you think that you have been given too much Cerezyme, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 in Australia or 0800 764 766 in New Zealand), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Cerezyme?

Things you or your child should do

- **Keep appointments with your treating physician or clinic.** It is important to have the infusion with Cerezyme at the appropriate times to make sure the medicine has the best chance of providing effective treatment for the condition.
- **Have any tests when your treating physician says to.** Your treating physician may wish to test your or your child's body's response to Cerezyme to make sure that it is working.

Remind any doctor, nurse or pharmacist you visit that you are using Cerezyme.

Things you or your child should not do.

- Do not stop using this medicine without speaking to your healthcare professional.

Driving or using machines

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

Cerezyme is unlikely to have any effect on your ability to drive a car or operate machinery. Make sure that you know how you react to Cerezyme 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

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

Storage

Cerezyme will usually be stored in the hospital or clinic pharmacy refrigeration at 2°C - 8°C.

Reconstituted and diluted Cerezyme should be protected from light.

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
<ul style="list-style-type: none">• nausea• vomiting	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Nervous system-related: <ul style="list-style-type: none">• tiredness• dizziness• headaches Skin-related: <ul style="list-style-type: none">• local reaction around the injection site such as redness, itchiness, tenderness, pain or discomfort, warmth, burning or	Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of

Serious side effects	What to do
<p>stinging, swelling or the formation of hard lumps or scars</p> <ul style="list-style-type: none"> • rash or hives • flushing or redness of the skin <p>Gut-related:</p> <ul style="list-style-type: none"> • stomach ache or cramp • diarrhoea <p>Others:</p> <ul style="list-style-type: none"> • Swelling of the face, lips, tongue or other parts of the body • Temporary high blood pressure <p>Signs of allergic reaction:</p> <ul style="list-style-type: none"> • Itching, swelling of mouth and/or throat • Chest discomfort • Shortness of breath, wheezing or difficulty breathing • Fall in blood pressure 	<p>these serious side effects.</p> <p>These may be serious side effects of Cerezyme, which may require urgent medical attention</p>

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 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 Cerezyme contains

Active ingredient (main ingredient)	imiglucerase
Other ingredients (inactive ingredients)	sodium citrate dihydrate, mannitol, citric acid monohydrate and polysorbate 80

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

What Cerezyme looks like

Cerezyme is a white to off-white powder before it is prepared for infusion and a clear, colourless solution after it has been prepared for infusion (AUST R 74277).

Who distributes Cerezyme

Distributed in Australia by:

sanofi-aventis australia pty ltd
International Tower 3, Level 23
300 Barangaroo Avenue
Sydney NSW 2000
Freecall: 1800 818 806
Email: 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
Email: medinfo.australia@sanofi.com

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