

CEREZYME[®]

Imiglucerase-rch 200 U and 400 U, Powder for Injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Cerezyme[®].

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 you or your child having Cerezyme[®] 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 Cerezyme[®] is used for

Cerezyme[®] is used as enzyme replacement therapy in Type I Gaucher disease, a disease in which the enzyme β -glucocerebrosidase in the body does not work properly.

How it works

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.

Before you are given Cerezyme[®]

When you or your child must not be given it

Do not take Cerezyme[®] if you or your child have a known, severe, life-threatening allergic reaction to:

- Cerezyme[®]
- 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 doctor or nurse.

Before you or your child are given it

Tell your doctor if you or your child have reacted to previous treatments with any of the following:

- life-threatening allergic reaction
- difficulty breathing

Tell your doctor if you or your child have allergies to:

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

Tell 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 doctor will discuss the possible risks and benefits of having Cerezyme[®] during pregnancy.

Tell your doctor if you are breast-feeding.

It is not known whether Cerezyme[®] passes into breast milk. Your doctor will discuss the possible risks and benefits of having Cerezyme[®] during breast-feeding.

Taking other medicines

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

Some medicines and Cerezyme[®] may interfere with each other. No studies have been carried out on drug interactions.

How Cerezyme[®] is given

Cerezyme[®] will be given to you or your child directly into the vein (intravenously) in a hospital, in a clinic or in your home.

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

If you are given too much (overdose)

There have been no reported overdoses of Cerezyme®.

Things you or your child must do

Keep appointments with your doctor 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.

After having Cerezyme®

Have any tests when your doctor says to.

Your doctor may wish to test your or your child's body's response to Cerezyme® to make sure that it is working.

Things to be careful of

Be careful driving or operating machinery 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.

Side effects

Tell your doctor or nurse as soon as possible if you or your child do not feel well after having Cerezyme®.

Cerezyme® may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, but most of the time they are not. You or your child may need urgent medical treatment if you notice some side effects.

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

Tell your doctor or pharmacist if you notice any of the following:

- 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
- nausea
- vomiting
- stomach ache or cramp
- diarrhoea
- rash
- tiredness
- dizziness

Storing Cerezyme®

Cerezyme® will usually be stored in the hospital or clinic pharmacy.

However, if you are storing Cerezyme® at home **before** it has been prepared for infusion, place it in the refrigerator (2°C – 8°C) but do not freeze it.

If you are storing Cerezyme® at home **after** it has been prepared for infusion, place it in the refrigerator (2°C – 8°C) but do not freeze it. **It is important that Cerezyme® that has been prepared for infusion is used within 24 hours.**

If you notice particles in the solution that has been made for you at the hospital, do not infuse and contact your doctor or pharmacist immediately.

Product Description

What it 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.

Ingredients

Active ingredient: Imiglucerase-rch

Other ingredients: sodium citrate dihydrate, mannitol, citric acid monohydrate and polysorbate 80.

Supplied by

In Australia this product is registered by:

Genzyme Australasia Pty Ltd
Suite 2.02, 21 Solent Crt
Baulkham Hills NSW 2153

Phone: +61 2 8852 3900

AUST R 68331 and 74277

In New Zealand this product is registered by:

Medra Services Limited
PO Box 115
Fielding
New Zealand

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