

## CEREZYME®

[serah-ZIME]

Imiglucerase-rch [im-e-glue-sar-aze R.C.H] 400 U, Powder for Solution for Infusion

### 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 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 Cerezyme against the benefits they expect it will have.

**If you have any concerns about this medicine, ask your treating physician or nurse.**

**Keep this leaflet.**

You may need to read it again.

#### What Cerezyme is used for

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  $\beta$ -glucocerebrosidase in the body does not work properly.

#### How it works

Patients with Gaucher disease do not produce enough of their own active enzyme,  $\beta$ -glucocerebrosidase. The reduced  $\beta$ -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 use 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 treating physician or nurse.**

**Before you or your child are given it**

**Tell your treating physician if you or your child have received Cerezyme or another drug and experienced any of the following:**

- 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 or your child have previously had surgery to remove the spleen.**

**Tell your treating physician 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.

**Tell your treating physician if you are breast-feeding or plan to breast feed.**

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

#### Taking other medicines

**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.**

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

#### 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.

Your treating physician 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.

Your treating physician is trained to work out the correct dose and to contact the Australian Poisons Information Centre (telephone 13 11 26), or the New Zealand National Poisons Centre (telephone 0800 POISON or 0800 764 766) in case of an overdose.

**Things you or your child must 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.

#### After having Cerezyme

**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.

#### 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 treating physician 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 treating physician or nurse to answer any questions you may have.**

**Tell your treating physician or pharmacist if you notice any of the following and they worry you:**

- nausea
- vomiting

These are mild to moderate side effects of Cerezyme.

**Tell your treating physician or nurse immediately 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
- stomach ache or cramp
- diarrhoea
- rash or hives
- tiredness
- dizziness

These may be serious side effects of Cerezyme, 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 Cerezyme

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.

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## Product Description

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### *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

#### **Other ingredients:**

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

### *Supplied by*

#### **In Australia this product is registered by:**

sanofi-aventis australia Pty Ltd  
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#### **AUST R 74277**

#### **In New Zealand this product is registered by:**

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