PACKAGE LEAFLET: INFORMATION FOR THE USER

Cerezyme® 400 Units

powder for concentrate for solution for infusion
Imiglucerase

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Cerezyme is and what it is used for

Cerezyme contains the active substance imiglucerase and is used 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), a tendency to bleed easily (due to low numbers of platelets – a type of blood cell), spleen or liver enlargement or bone disease.

People with Gaucher disease have low levels of an enzyme called acid β-glucosidase. This enzyme helps the body control levels of glucosylceramide. Glucosylceramide is a natural substance in the body, made of sugar and fat. In Gaucher disease glucosylceramide levels can get too high.

Cerezyme is an artificial enzyme called imiglucerase - this can replace the natural enzyme acid β-glucosidase which is lacking or not active enough in patients with Gaucher disease.

The information in this leaflet applies to all patient groups including children, adolescents, adults and the elderly.

2. What you need to know before you are given Cerezyme

Do not use Cerezyme
- if you are allergic to imiglucerase or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before using Cerezyme:
- if you are treated with Cerezyme, you may experience an allergic reaction while you are being given the medicine or shortly after. If you experience a reaction like this, you should **tell your doctor immediately**. Your doctor may test if you have an allergic reaction to imiglucerase.
- some patients with Gaucher disease have high blood pressure in the lungs (pulmonary hypertension). The cause can be unknown, or it can be due to heart, lung or liver problems. It can occur whether the patient is treated with Cerezyme or not. But, if you suffer with any **shortness of breath** you should tell your doctor.

Other medicines and Cerezyme
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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Cerezyme should not be given as a mixture with other medicinal products in the same infusion (drip).

Pregnancy and breast-feeding
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. Cautious use of Cerezyme during pregnancy and breastfeeding is recommended.

Cerezyme contains sodium
This medicine contains 41 mg sodium (main component of cooking/table salt) per vial. This is equivalent to 2% of the recommended maximum daily dietary intake of sodium for an adult. It is administered in 0.9% sodium chloride intravenous solution. This should be taken into consideration by patients on a controlled sodium diet.

3. How Cerezyme is given

Instructions for proper use
Cerezyme is given through a drip into a vein (by intravenous infusion).

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.

Your dose will be specific to you. Your doctor will work out your dose based on how severe your symptoms are, and other factors. The recommended dose is 60 units/kg body weight given once every 2 weeks.

Your doctor will keep a close check on your response to your treatment, and may change your dose (up or down) until he/she finds the best dose to control your symptoms.

Once this dose is found your doctor will still keep a check on your responses to make sure you are using the right dose. This might be every 6 to 12 months.

There is no information on the effect of Cerezyme on brain-based symptoms of patients with chronic neuronopathic Gaucher disease. Therefore no special dosage regimen can be recommended.

The ICGG Gaucher Registry
You can ask your doctor to register your patient information into the "ICGG Gaucher Registry". The aims of this Registry are to increase the understanding of Gaucher disease and to check how well enzyme replacement therapy, like Cerezyme, works. This should lead to improvement in the safe and effective use of Cerezyme. Your patient data will be registered anonymously– nobody will know it is information about you.

If you use more Cerezyme than you should
There are no cases of overdose of Cerezyme reported.

If you forget to use Cerezyme
If you have missed an infusion, please contact your doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common (may affect up to 1 in 10 people):
- breathlessness
- coughing
- hives/ localised swelling of the skin or lining of the mouth or throat
- itching
- rash

Uncommon (may affect up to 1 in 100 people):
- dizziness
- headache
- a sensation of tingling, pricking, burning or numbness of the skin
- increased heart rate
- bluish skin
- flushing
- fall in blood pressure
- vomiting
- nausea
- abdominal cramping
- diarrhoea
- pain in the joints
- infusion site discomfort
- infusion site burning
- infusion site swelling
- injection site sterile abscess
- chest discomfort
- fever
- rigors
- fatigue
- backache

Rare (may affect up to 1 in 1,000 people):
- anaphylactoid reactions

Some side effects were seen primarily while patients were being given the medicine or shortly after. These have included itching, flushing, hives/localised swelling of the skin or lining of the mouth or throat, chest discomfort, increased heart rate, bluish skin, breathlessness, a sensation of tingling, pricking, burning or numbness of the skin, fall in blood pressure and backache. If you experience any of these symptoms, please **tell your doctor immediately**. You may need to be given additional medicines to prevent an allergic reaction (e.g. antihistamines and/or corticosteroids).

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the contact details listed below. By reporting side effects you can help provide more information on the safety of this medicine.

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

Malta
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

United Kingdom (Northern Ireland)
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How Cerezyme is stored

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date printed on the labelling after the letters "EXP". The expiry date refers to the last day of that month.

Unopened vials:
Store in a refrigerator (2°C – 8°C)

The following information is intended for healthcare professionals only:

Instructions for use – reconstitution, dilution and administration
Each vial of Cerezyme is for single use only. After reconstitution, each vial of Cerezyme contains 400 units of imiglucerase in 10.0 ml (40 units per ml).

Determine the number of vials to be reconstituted based on the individual patient's dosage regimen and remove the vials from the refrigerator.

Use Aseptic Technique

Reconstitution
Reconstitute each vial with 10.2 ml water for injections; avoid forceful impact of water for injections on the powder and, by mixing gently, avoid foaming of the solution. The reconstituted volume is 10.6 ml. The pH of the reconstituted solution is approximately 6.2.

After reconstitution it is a clear, colourless liquid, free from foreign matter. The reconstituted solution must be further diluted. Before further dilution, visually inspect the reconstituted solution in each vial for foreign particles and discoloration. Do not use vials exhibiting foreign particles or discoloration. After reconstitution, promptly dilute vials and do not store for subsequent use.

Dilution
The reconstituted solution contains 40 units imiglucerase per ml. The reconstituted volume allows accurate withdrawal of 10.0 ml (equal to 400 units) from each vial. Withdraw 10.0 ml reconstituted solution from each vial and combine the withdrawn volumes. Then dilute the combined volumes with 0.9% sodium chloride intravenous solution to a total volume of 100 to 200 ml. Mix the infusion solution gently.

Administration
It is recommended to administer the diluted solution through an in-line low protein-binding 0.2 µm filter to remove any protein particles. This will not lead to any loss of imiglucerase activity. It is recommended that the diluted solution be administered within 3 hours. The product diluted in 0.9% sodium chloride intravenous solution will retain chemical stability if stored up to 24 hours at 2°C and 8°C under protection from light; but microbiological safety will depend on the reconstitution and dilution having been performed aseptically.

Cerezyme contains no preservatives. Any unused product or waste material should be disposed of in accordance with local requirements.

Diluted solution:
It is recommended that Cerezyme is used immediately after it has been mixed with sterile water. The mixed solution in the vial cannot be stored and should be promptly diluted in an infusion bag; only the diluted solution can be held for up to 24 hours if it is kept cool (2°C – 8°C) and in the dark.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Cerezyme contains
- The active substance is imiglucerase. Imiglucerase is a modified form of the human enzyme acid β-glucosidase produced by recombinant DNA technology. One vial contains 400 units of imiglucerase. After reconstitution, the solution contains 40 units of imiglucerase per ml.
- The other ingredients are: mannitol, sodium citrate, citric acid monohydrate and polysorbate 80.

What Cerezyme looks like and contents of the pack
Cerezyme, 400 Units, is presented as a powder for concentrate for solution for infusion (in a vial, pack size of 1, 5 or 25). Not all pack sizes may be marketed.

Cerezyme is supplied as a white to off-white powder. After reconstitution it is a clear, colourless liquid, free from foreign matter. The reconstituted solution must be further diluted.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Sanofi B.V.,
Paasheuvelweg 25, 1105 BP, Amsterdam, The Netherlands

Manufacturer
Genzyme Ireland Limited, IDA Industrial Park,
Old Kilmeaden Road, Waterford, Ireland

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

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Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu/. There are also links to other websites about rare diseases and treatments.

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