

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

CEREZYME®

Imiglucerase for injection

Read this carefully before you start taking **Cerezyme** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Cerezyme**.

Serious Warnings and Precautions

- A trained healthcare professional will supervise and monitor your treatment with Cerezyme.
- An allergic reaction, which can be life-threatening, may occur when you receive Cerezyme or shortly after. This may be more likely to happen if:
 - you have been treated with a medical treatment called “enzyme replacement therapy”,
 - after extended use of Cerezyme, or
 - if you have a history of mild or moderate reactions to imiglucerase or Cerezyme (e.g., eczema, itching, flushing, rash, etc.).

Approximately 15% of patients have developed an allergic reaction. If you have an allergic reaction, immediately contact your healthcare professional. They may stop your treatment, modify your dose, and/or add other medications before or during your treatment. This may include medications such as antihistamines and/or corticosteroids. They may also perform tests to evaluate your allergic reaction.

See the **Serious side effects and what to do about them** table below for more information on this serious side effects.

What is Cerezyme used for?

Cerezyme is used to treat patients with a confirmed diagnosis of non-neuronopathic (Type 1) or chronic neuronopathic (Type 3) Gaucher disease. The non-neurological Gaucher disease may result in one or more of the following conditions:

- anemia, after exclusion of other causes, such as iron deficiency
- thrombocytopenia (reduced blood platelets count)
- bone disease (such as weakened bones and increased risk of fracture), after exclusion of other causes, such as Vitamin D deficiency
- hepatomegaly (liver enlargement) or splenomegaly (spleen enlargement)

How does Cerezyme work?

Gaucher disease is a rare genetic disorder in which the body is deficient in an enzyme called β -glucocerebrosidase. This enzyme breaks down a fatty substance called glucocerebroside. In Gaucher disease, glucocerebroside becomes high in the tissue macrophages in the liver, spleen, bone marrow and occasionally in lung and kidney, because this enzyme is missing. Cerezyme is a form of β -glucocerebrosidase produced by recombinant DNA technology. Cerezyme can help to treat some of the symptoms of Gaucher disease by replacing the natural enzyme that is missing in Gaucher disease.

What are the ingredients in Cerezyme?

Medicinal ingredient: Imiglucerase.

Non-medicinal ingredients: mannitol, nitrogen, polysorbate 80, and sodium citrates (disodium hydrogen citrate and trisodium citrate).

Cerezyme comes in the following dosage forms:

Cerezyme is supplied as a sterile lyophilized powder for intravenous infusion.

Cerezyme is supplied in a 20 mL vial containing 400U (red label) of imiglucerase.

Do not use Cerezyme if:

- you are severely allergic to imiglucerase, any of the other ingredients in Cerezyme, or any component of the container.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Cerezyme. Talk about any health conditions or problems you may have, including if you:

- have been treated with placental-derived β -glucocerebrosidase (alglucerase injection) and have developed antibody or exhibited symptoms of hypersensitivity to placental-derived β -glucocerebrosidase (alglucerase injection) .
- have had any allergic reactions to the administration of imiglucerase, the medicinal ingredient of Cerezyme.
- are pregnant or plan to become pregnant or are breast-feeding.
- You experience any shortness of breath, before or after starting Cerezyme. Your doctor will evaluate if this is a sign of a condition called pulmonary hypertension, a condition that occurs rarely with Gaucher disease, whether or not patients are on Cerezyme.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Cerezyme:

Studies to test how Cerezyme interacts with other drugs have not been done. Please inform your doctor if you are using any other medicinal products, due to the potential risk of interference with the uptake of imiglucerase.

How to take Cerezyme:**Usual dose:**

Dosage should be individualized to each patient.

Your healthcare professional will prescribe you the dose that is suitable for you.

Treatment may be initiated at a dose of 2.5 units/kg of body weight 3 times a week up to 60 U/kg of body weight administered as frequently as once every two weeks.

If Cerezyme is to be administered in a home care environment, it is suggested that the health care professional be trained and prepared for the possibility of an allergic-type reaction.

Overdose:

There have been no reports of obvious toxicity for doses up to 240 U/kg (every two weeks). In the event of an overdose, stop the infusion immediately and monitor the patient closely in a hospital setting for the development of infusion-associated reactions.

If you think you, or a person you are caring for, have taken too much Cerezyme, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you have missed a Cerezyme infusion, please contact your doctor. It is important to have your infusion on a regular basis to avoid the accumulation of glucocerebroside. The total dose administered each month should remain substantially unchanged.

What are possible side effects from using Cerezyme?

These are not all the possible side effects you may have when taking Cerezyme. If you experience any side effects not listed here, tell your healthcare professional.

Common (may affect up to 1 in 10 people):

- shortness of breath
- 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
- flushing
- vomiting
- nausea
- abdominal cramping/pain
- diarrhea
- pain in the joints
- You may experience allergic reaction some of which may be severe and may include symptoms such as itching, swelling of mouth and/or throat, chest discomfort, shortness of breath and, fall in blood pressure.
- infusion site discomfort
- infusion site burning
- infusion site swelling
- injection site uninfected abscess
- fever

- rigors
- fatigue
- backache

Frequency Unknown:

- chills
- infusion site itching
- rapid heartbeat

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE			
Allergic reaction: itching, flushing, hives, swelling, chest discomfort, shortness of breath, coughing, bluish skin, low blood pressure, or increased heart rate.			X

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Keep out of reach and sight of children.

Store under refrigeration at 2°C to 8°C. Do not use after the expiration date on the vial.

Since Cerezyme does not contain any preservative, after reconstitution, vials should be promptly diluted and not stored for subsequent use.

International Collaborative Gaucher Group (ICGG) Registry

The ICGG Registry is a longitudinal prospective study that includes over ~6900 patients (as of October 4, 2023), with Gaucher disease from around the world. The Registry was established to assist physicians in the treatment and management of patients with Gaucher disease.

Treatment centres involved with Registry enrolled patients are required to collect data on a regular basis.

In Canada, the ICGG Annual Report is made available at the beginning of each year. This report details the data collected in the seven provinces with Gaucher patients. The Canadian Annual Report is available upon request through sanofi-aventis Canada.

Information regarding the registry program may be found by calling (800) 745-4447. If you are interested in participating, please contact your doctor.

If you want more information about Cerezyme:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website (www.sanofi.ca), or by calling 1-800-265-7927.

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