PART III: CONSUMER INFORMATION

Cerezyme®
Imiglucerase for injection

This leaflet is part III of a three-part "Product Monograph" published when CEREZYME® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about CEREZYME®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
CEREZYME® is used to treat patients with a confirmed diagnosis of non-neuronopathic (Type 1) or chronic neuronopathic (Type 3) Gaucher disease resulting in one or more of the following conditions:

- anaemia after exclusion of other causes, such as iron deficiency
- thrombocytopenia
- bone disease after exclusion of other causes such as Vitamin D deficiency
- hepatomegaly or splenomegaly

What it does:
Gaucher disease is a genetic disorder resulting in deficient ß-glucocerebrosidase activity. Therefore, glucocerebroside accumulates in the lysosomes of tissue macrophages in the liver, spleen, bone marrow and occasionally in lung and kidney. 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 deficient enzyme.

When it should not be used:
Do not use CEREZYME® if you are hypersensitive to imiglucerase or to any ingredient in the formulation or component of the container.

What the medicinal ingredient is:
Imiglucerase

What the important nonmedicinal ingredients are:
Mannitol, Polysorbate 80, Sodium citrates
For a full listing of nonmedicinal ingredients see Part 1 of the product monograph.

What dosage forms it comes in:
CEREZYME® is supplied as a sterile lyophilized powder for intravenous infusion.
CEREZYME® is supplied in a 20 mL vial containing either (red label) of imiglucerase.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions
Do not use CEREZYME® if you are severely hypersensitive to imiglucerase or to any ingredient in the formulation or if you have experienced severe hypersensitivity to imiglucerase.

Anaphylactoid reaction has been reported in less than 1% of the patient population. Further treatment with CEREZYME® should be conducted with caution.

In rare cases, pulmonary hypertension has also been observed during treatment with CEREZYME®. Pulmonary hypertension is a known complication of Gaucher disease, and has been observed both in patients receiving and not receiving CEREZYME®. No causal relationship with CEREZYME® has been established. Patients with respiratory symptoms should be evaluated for the presence of pulmonary hypertension. But, if you suffer with any shortness of breath you should tell your doctor.

BEFORE you use CEREZYME® talk to your doctor or pharmacist if:

- You have been treated with placental-derived ß-glucocerebrosidase (CEREDASE®, alglucerase injection) and have developed antibody or exhibited symptoms of hypersensitivity to placental-derived ß-glucocerebrosidase (CEREDASE®, alglucerase injection)
- You have had a severe hypersensitivity or anaphylactic reaction to administration of CEREZYME®
- You have any allergies to this drug or its ingredients or components of the container
- You are pregnant or plan to become pregnant or are breast-feeding.

INTERACTIONS WITH THIS MEDICATION

No formal interaction studies have been conducted. Please inform your doctor if you are using any other medicinal products, due to the potential risk of interference with the uptake of imiglucerase.

PROPER USE OF THIS MEDICATION

Usual dose:
Dosage should be individualized to each patient.

Treatment may be initiated from 2.5 units/kg of body weight 3 times a week up to 60 U/kg, 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).

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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects related to CEREZYME® administration have been reported in less than 15% of patients. Each of the following events occurred in less than 2% of the total patient population. Reported side effects include nausea, vomiting, abdominal pain, diarrhea, rash, fatigue, headache, fever, dizziness, chills, backache, and rapid heart rate. Because CEREZYME® therapy is administered by intravenous infusion, reactions at the site of injection may occur: discomfort, itching, burning, swelling or uninfected abscess. Symptoms suggestive of allergic reaction include anaphylactoid reaction (a serious allergic reaction), itching, flushing, hives, an accumulation of fluid under the skin, chest discomfort, shortness of breath, coughing, cyanosis (a bluish discoloration of the skin due to diminished oxygen), and low blood pressure. Approximately 15% of patients have developed immune reactions (antibodies); periodic monitoring by your physician is suggested.

If you exhibit such a reaction following the administration of CEREZYME®, you should immediately contact your doctor.

Pre-treatment with antihistamines and/or corticosteroids and reduced rate of infusion has allowed continued use of CEREZYME® in most patients.

This is not a complete list of side effects. For any unexpected effects while taking CEREZYME®, contact your doctor or pharmacist.

HOW TO STORE IT

Keep out of reach and sight of children.
Store under refrigeration at 2 ºC to 8 ºC. 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 4,936 patients (as of March 7, 2008), 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 Genzyme Canada.

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

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  Fax toll-free to 1-866-678-6789, or
  Mail to:
  Canada Vigilance Program
  Health Canada
  Postal Locator 0701D
  Ottawa, Ontario
  K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: http://www.genzyme.ca or by contacting the sponsor, Genzyme Canada, at: 1-877-220-8918

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