PART III: CONSUMER INFORMATION

Fabrazyme®
Agalsidase Beta

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

ABOUT THIS MEDICATION

What the medication is used for:

Fabrazyme® is used to treat individuals with a confirmed diagnosis of Fabry Disease. Fabrazyme® reduces levels of globotriaosylceramide or GL-3, a fat substance, and slows the rate of progression of Fabry disease in the kidney, heart and brain.

The safety and efficacy of Fabrazyme® have not been studied in children below the age of 8 years.

What it does:

Fabry disease is a genetic disorder where the level of α-galactosidase activity [an enzyme that breaks down complex lipids (fats)] is absent or lower than normal. If you suffer from Fabry disease, GL-3 is not removed from the cells of your body and starts to accumulate in the walls of the blood vessels of your organs. Fabrazyme® is a form of human enzyme, α-galactosidase, produced by recombinant DNA technology. Fabrazyme® can help to treat some of the symptoms of Fabry Disease by replacing the deficient enzyme.

When it should not be used:
Do not use Fabrazyme® if you have experienced any life-threatening allergic reaction to agalsidase beta or to any ingredient in the medication.

What the medicinal ingredient is:
Agalsidase beta

What the important nonmedicinal ingredients are:
Mannitol, Sodium Phosphate Monobasic Monohydrate, Sodium Phosphate Dibasic Heptahydrate
For a full listing of nonmedicinal ingredients, see Part 1 of the product monograph.

What dosage forms it comes in:
Fabrazyme® is supplied as a sterile dry powder for intravenous infusion.

Fabrazyme® is supplied in a 20 mL vial containing either 35 mg (purple cap) or 5 mg (grey cap) of agalsidase.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions
As with any medication of this type, severe allergic reactions, including life-threatening ones, have been seen in patients receiving Fabrazyme.

Serious Warnings and Precautions:
As with any intravenous protein product, severe allergic reactions have been seen in patients receiving Fabrazyme® infusions. Reactions have included swelling of the face, mouth and throat, wheezing, low blood pressure, hives, difficulty swallowing, rash, shortness of breath, flushing, chest discomfort, itchiness, and nasal congestion. Interventions have included cardiopulmonary resuscitation (CPR), oxygen, fluids given through a catheter in a vein (intravenously), hospitalization and treatment with epinephrine, beta-adrenergic medicines to help with breathing, and steroids. Because of the potential for severe allergic reactions, appropriate medical support measures should be readily available when Fabrazyme® is administered.

It is expected that most individuals will develop antibodies upon treatment with enzyme replacement therapy. If you develop antibodies to agalsidase beta, you have a higher risk of allergic side effects (see SIDE EFFECTS AND WHAT TO DO ABOUT THEM). The antibodies are not likely to stop Fabrazyme® working and will decrease with time.

If you experience an allergic side effect following the administration of Fabrazyme®, you should immediately contact your physician. Your doctor can decrease the infusion rate and/or treat the symptoms with other medicines (antihistamines, ibuprofen, paracetamol and/or corticosteroids) to help reduce some of the side effects. If infusions proceed without further incident, consideration may be given to increasing the infusion rate in a stepwise manner and to reducing premedication.

If severe allergic or life-threatening reactions occur, immediate discontinuation of the administration of Fabrazyme® may be considered and an appropriate treatment will have to be initiated by your physician.

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

- You have had a severe allergic or life-threatening reaction to the administration of Fabrazyme®
- 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 agalsidase beta. Fabrazyme® should not be administered with certain medications including chloroquine, amiodarone, benoquin or gentamycin because of a theoretical risk that they may interfere with the activity of Fabrazyme®.

PROPER USE OF THIS MEDICATION

Usual dose:
The recommended dosage of Fabrazyme® is 1.0 mg/kg body weight administered every 2 weeks as an intravenous infusion.

Overdose:

There have been no reports of overdose with Fabrazyme®. Doses up to 3.0 mg/kg body weight have been tested in clinical trials.

Missed Dose:
If you have missed a Fabrazyme® infusion, please contact your doctor. The next dose will not be doubled to make up for the missed or partially administered dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, Fabrazyme® can have side effects. Patients with advanced Fabry disease may have heart problems, which may put them to a higher risk of severe complications from infusion reactions. These patients should be monitored closely during Fabrazyme® infusions.

In clinical trials, the following side effects were reported as being related to Fabrazyme® in a total of 134 patients by greater than 10% of individuals treated for a minimum of one infusion up to a maximum of 5 years: chills, temperature changed feeling, runny nose or seasonal allergies, fever, headache, tremor, nausea, pain of the extremities, swelling of the extremities, vomiting, high blood pressure, muscle pain, shortness of breath. Side effects were mostly mild or moderate in severity.

Approximately half of the individuals treated at 1 mg/kg initially experienced related side effects, on the day of the infusion. After up to 2 years of treatment, less than 37% of patients experienced infusion-associated reactions. These reactions consisted most often of fever and chills. Additional symptoms included allergic-like reactions with mild to moderate shortness of breath, throat tightness, chest tightness, difficulty in breathing, red face, itching, hives, runny nose or seasonal allergies, rapid breathing and/or wheezing, swelling of the face, swelling of the lips and throat, heart and blood vessel symptoms including high blood pressure, decreased blood pressure, increased heart rate, palpitations, stomach and bowel symptoms including abdominal pain, nausea, vomiting, infusion-related pain including pain of extremities and muscle pain, and headache.

Since Fabrazyme® has been released on the market, side effects which have been seen include: joint pain, weakness, redness of the skin, excessive sweating, increased tear production, reduced sensation of the mouth, palpitations, feeling hot and cold, fatigue (a lack of energy), musculoskeletal (muscle and bone) pain, swelling, runny nose and decreased oxygen. Since Fabrazyme® is administered into a vein (intravenously), some patients have had reactions at the site where Fabrazyme® was given. There was one report of a skin reaction due to inflammation of the small blood vessels of the skin.

A small number of patients have experienced allergic reactions which in some cases were considered life-threatening. Signs and symptoms of possible allergic reactions include localized rapid swelling often of the mouth and throat, hives, difficulty breathing and low blood pressure.

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

Pre-treatment with antihistamines, antipyretics, and/or corticosteroids can be used to manage infusion-associated reactions. A slower infusion rate should also be considered.

This is not a complete list of side effects. For any unexpected effects while taking Fabrazyme®, 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 Fabrazyme® does not contain any preservatives, vials must be used immediately after reconstitution.

The Fabry Registry, sponsored by Genzyme Corporation, has been established in order to better understand the variability and progression of Fabry disease, and to continue to monitor and evaluate safety and effectiveness of Fabrazyme®. You are encouraged to participate. Information regarding the registry program may be found at www.LSDregistry.net or by calling 1-800-745-4447. If you are interested in participating, please contact your doctor. You can only participate in the Registry through your doctor.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected side effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug, you may notify Canada Vigilance:

Online: www.healthcanada.gc.ca/medeffect
Toll free phone: 1-866-234-2345
Toll free fax: 1-866-678-6789
Postage Paid Mail: Canada Vigilance Program
Health Canada
AL 0701C
Ottawa, Ontario K1A 0K9

NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying Canada Vigilance. 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, Sanofi Genzyme, a division of sanofi-aventis Canada Inc., at: 1-877-220-8918.

This leaflet was prepared by Sanofi Genzyme, a division of sanofi-aventis Canada Inc.

Date of Revision: April 3, 2017

FABRAZYME® is a registered trademark of Genzyme Corporation.