PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

FABRAZYME®

Agalsidase Beta

Read this carefully before you start taking **Fabrazyme** 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 **Fabrazyme**.

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.

What is Fabrazyme used for?

- Fabrazyme is used to treat individuals with a confirmed diagnosis of Fabry Disease.

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

How does Fabrazyme work?

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, the fat substance globotriaosylcermaide, or 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.

What are the ingredients in Fabrazyme

Medicinal ingredients: Agalsidase beta

Non-medicinal ingredients: Mannitol, Sodium Phosphate Dibasic Heptahydrate, Sodium Phosphate Monobasic Monohydrate

Fabrazyme comes in the following dosage forms:

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.

Do not use Fabrazyme if:

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

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

- Have a severe allergic or life-threatening reaction to the administration of Fabrazyme.® Symptoms of this may include the following:
    - Swelling of the face, mouth and throat, or difficulty swallowing
    - Wheezing or shortness of breath
    - Low blood pressure
    - Hives
    - Rash
    - Flushing
    - Chest discomfort
    - Itchiness
    - Nasal congestion

  If you experience these symptoms, your health professional may stop or interrupt the infusion to treat the symptoms or wait for the symptoms to go away. Your health professional may also give you other medicines to treat the symptoms. In severe cases, cardiopulmonary resuscitation (CPR), oxygen, intravenous fluids, treatment with epinephrine or beta-adrenergic medicines to help with breathing, and hospitalization may be needed. Because of the potential for severe allergic reactions, appropriate medical support measures should be readily available when Fabrazyme is administered.
- Have any allergies to this drug or its ingredients or components of the container
- Are pregnant or plan to become pregnant or are breast-feeding

Other warnings you should know about:

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 **What are possible side effects from using Fabrazyme®?).**

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.

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 Fabrazyme:

- 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.

How to take Fabrazyme®:

Fabrazyme will be given to you by a health professional in a healthcare setting.

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.

If you think you, or a person you are caring for, have taken too much Fabrazyme, 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 Fabrazyme infusion, please contact your doctor. You do not need to make up for the missed or partially administered dose.

What are possible side effects from using Fabrazyme®?

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

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.

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.

Approximately half of the individuals treated at 1 mg/kg initially experienced related side effects, on the day of the infusion. The most common side effects with Fabrazyme include 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.

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.

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

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**	
VERY COMMON			
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.		√	
COMMON			
joint pain, weakness, redness of the skin, excessive sweating, increased tear production, reduced sensation of the mouth, palpitations, fatigue (a lack of energy),		√	

musculoskeletal (muscle and bone)			
RARE			
Localized rapid swelling often of the mouth and throat, hives, difficulty breathing and low blood pressure			√

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.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 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.

If you want more information about Fabrazyme®:

- 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 http://www.sanofi.ca, or by calling 1-800-265-7927.

The Fabry Registry 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.

This leaflet was prepared by sanofi-aventis Canada Inc.

This information is current up to the time of the last revision date shown below, but more current information may be available from the manufacturer.

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