FABRAZYME® (AGALSIDASE BETA) HOME INFUSION GUIDE

FABRAZYME® HOME INFUSION GUIDE FOR PATIENTS AND THEIR CAREGIVERS

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- Read all of this information carefully before you start home infusion.
- Keep this information in an easily accessible place; you may need to read it again.
  - If you have further questions, ask your doctor or infusion nurse.
  - This medicine has been prescribed for you. Do not pass it on to others even if their symptoms are the same as yours as it may harm them.
  - If you experience any side effects, you and/or your caregiver must notify your doctor or infusion nurse.

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Fabrazyme® agalsidase beta

1. YOUR DISEASE, TREATMENT AND HOME INFUSION

Together with your doctor, you have decided to start home infusion therapy with Fabrazyme®. This guide provides you with information on how you will receive Fabrazyme® at home, but it does not replace the advice from your healthcare team. If you have any questions or concerns about Fabrazyme® home infusions, please talk to your doctor. Your doctor will provide you with the details that are applicable to your situation.

1.1. Fabry disease and treatment

Patients with Fabry disease have low or absent levels of an enzyme called alpha-galactosidase A. This enzyme is normally responsible for the breakdown of a fatty substance (globotriaosylceramide) and, as a result, abnormal deposits of this substance develop in blood vessel walls and other tissues throughout the body.

The main presenting childhood symptoms of Fabry disease in males include episodes of pain and burning sensations in the hands and feet, gastro-intestinal symptoms, skin rash and a decreased ability to sweat. Disease manifestations in adulthood are generally dominated by cardiac, renal and/or neurologic symptoms. In females, the course of the disease is variable, frequently – but not always – less severe than in affected males.

Fabrazyme® is an artificially produced enzyme called 'agalsidase beta' which is intended to replace the natural enzyme alpha-galactosidase A that is lacking or not active enough in patients with Fabry disease. Fabrazyme® is used for the long-term treatment of patients who have a confirmed diagnosis of Fabry disease.

Talk to your healthcare professional about treatment with Fabrazyme® and refer to the Fabrazyme® Consumer Medicine Information (CMI), available at Sanofi (https://qr.medsinfo.com.au/tx/sw.cfm?h=swcfabra), or alternatively via the Therapeutic Goods Association (TGA) Australian Register of Therapeutic Goods (ARTG) (https://www.tga.gov.au/resources/artg) for additional information.

1.2. What can I expect from treatment with Fabrazyme® at home?

In Australia, people suffering from Fabry disease and treated with Fabrazyme® may receive their infusions at home. **The decision to receive home treatment should be made by you and your doctor after initial infusions at the hospital to make sure home infusions are suitable for you.**

Home infusion of Fabrazyme® allows you to receive your treatment in the comfort of your own home, on a day suitable for you. It saves time commuting and spent at the hospital and allows you to schedule your infusions around your daily life commitments with school, social and professional activities more easily. Home infusions are the responsibility of your doctor. **Your doctor will discuss home infusions with you and assess your suitability to receive infusions at home before referring you to the home nursing program.**

It is the responsibility of your doctor to ensure safe administration of Fabrazyme®.

Home infusions will be given by home infusion nurses who are trained experts in enzyme replacement therapy infusions.

1.3. Before you can start home infusions

- You and/or your caregiver(s) have been informed by your doctor about the treatment to be provided at home, the associated risks, the possible complications, and the provision of medical assistance at home.
- You and/or your caregiver(s) have an understanding of Fabry disease and are able to recognise side effects and understand the procedures to be followed should they occur.

- Your home is safe and suitable for the home infusion nurse to give you the infusions including a clean environment with electricity, water, telephone access, refrigeration, and physical space to support storage of Fabrazyme® and other infusion supplies.
- You have been informed that the infusion should always be administered by an appropriately trained infusion nurse.
- Your doctor will confirm that you are physically and mentally able to undergo the infusions at home and have not experienced any side effects to treatment that cannot be managed with pre-infusion medication. If necessary, your doctor will prescribe pre-treatment medication.
- You and/or your caregiver(s) must agree that you receive the treatment at home.
- You can commit to regular infusions and appointments at your home.

2. HOW ARE FABRAZYME'S® SIDE EFFECTS MANAGED WITH HOME INFUSION?

Like all medicines, Fabrazyme® treatment may have unwanted side effects, although not everybody gets them. Side effects were mainly seen while patients were being given the medicine or shortly after, which is referred to as "infusion-associated reactions (IARs)". You may be at risk of developing these side effects. It is important you understand these risks and how to monitor for them.

Some patients have experienced infusion related side effects in the form of flu-like symptoms, which lasted for a few days after the infusion was given. Some patients have also experienced adverse reactions several hours after the infusion ended.

Some of these IARs were serious or life-threatening. Life threatening reactions, including very severe generalised allergic reactions and anaphylactic shock, have been reported in some patients.

If you have any of these serious side effects during the infusion, tell your Infusion nurse straight away. If it is after your infusion, call your doctor straight away, or call Triple Zero (000):

- Sudden signs of allergy such as rash, itching or hives on the skin
- Swelling of the face, lips, tongue or other parts of the body
- Shortness of breath, wheezing or trouble breathing
- Respiratory failure (inability of the lungs to work properly)

Your doctor will decide how to continue with the treatment, or if you need to receive pre-treatment medication to reduce the chance of some of these side effects (e.g. antihistamines, corticosteroids and/or antipyretics). In some instances, your doctor may decide to continue treatment at the hospital for a period of time, or even go back to infusions in the hospital permanently.

It is possible that your doctor has decided to give you other medicines to prevent mild and moderate side effects.

If you have a severe side effect during an infusion, your infusion nurse will stop the infusion and follow the guidance provided by your doctor.

For the full list of side effects reported with Fabrazyme®, see the Fabrazyme® Consumer Medicine Information, available at Sanofi (https://qr.medsinfo.com.au/tx/sw.cfm?h=swcfabra), or alternatively via the TGA ARTG (https://www.tga.gov.au/resources/artg).

Fabrazyme® CMI

If you feel unwell during the home infusion, your infusion nurse may immediately stop your infusion.

Depending on the severity of the reaction, the infusion nurse may immediately contact Triple Zero (000), or the treating doctor and/or their medical designate.

If an IAR occurs shortly after your infusion ends, the infusion nurse may also immediately contact Triple Zero (000), the treating doctor and/or their medical designate.

Subsequent infusions may need to occur in the hospital.

3. SAFETY REPORTING

If you experience any side effects, ensure to inform your infusion nurse and your doctor.

You may also report any side effects you experience during your treatment with Fabrazyme® directly to Sanofi Medical Information at:

Phone: 1800 818 806 (Australia)
Fax: 1800 053 105 (Australia)
E-mail: MedInfo.Australia@sanofi.com

Alternately, you may report any side effects you experience during your treatment with Fabrazyme® directly to the TGA at:

TGA (Australia)

Phone: 1800 044 114
Fax: +61 2 6232 8392
E-mail: adr.reports@tga.gov.au
Online reporting at: https://aems.tga.gov.au

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