FABRAZYME® (AGALSIDASE BETA) HOME INFUSION GUIDE

FABRAZYME® HOME INFUSION GUIDE FOR HEALTHCARE PROFESSIONALS (HCPs)

Version No. 1.2, September 2026

sanofi

Fabrazyme® agalsidase beta

This guide is not intended to suggest or recommend home infusion therapy for any patient. The decision to provide treatment in the home setting is made by the treating physician, who knows the patient's current clinical status and previous infusion history, in consultation with the patient and/or his/her caregiver. This guide is solely to share information that might be helpful to healthcare professionals and their patients/caregivers when treated at home.

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1. OBJECTIVES AND GOALS

The objective of this document is to provide information and guidance to healthcare professionals (HCPs) for the management of patients receiving Fabrazyme® in the home setting, and to mitigate the following risks:

- Hypersensitivity reactions and
- Medication errors in the home infusion setting.

This guide covers patient evaluation and selection discussion of requirements and organisation of home infusion.

Fabrazyme® enzyme replacement therapy (ERT) is available for treatment of patients with Fabry disease and is generally well tolerated. To enhance convenience and improve patient's quality of life, ERT infusions may be transferred to the patient's home if specific requirements can be fulfilled. This increases comfort and flexibility of infusion schedule.

The decision to transfer Fabrazyme treatment to the patient's home setting is made by the treating physician and should take into account patient preferences and medical status.

The home infusion will take place under the responsibility of the treating physician.

It is the responsibility of the treating physician to provide the 'Home infusion guide for patients and their caregivers' to the patient/carer if the patient is eligible for home infusion treatment.

It is the responsibility of the treating physician to ensure safe administration of Fabrazyme®, to reduce and mitigate the risks of medication errors in the home and hypersensitivity reactions. This should be checked and documented by the treating physician.

The processes presented in this document serve as overall guidance but are subject to local medical practice and national rules and regulations.

2. INFORMATION FOR HCPs PRESCRIBING FABRAZYME®

2.1. Assessing patient eligibility for home infusion

Before making any arrangements for providing Fabrazyme® infusion at home, the treating physician overseeing the patient's clinical care must determine if the patient fulfils the following primary criteria for transfer of hospital-based infusion therapy to the patient's home setting:

- The patient is considered medically stable. A comprehensive evaluation must be completed before deciding on transfer of therapy.
- The patient must have received Fabrazyme® infusions in a controlled setting for several months. Documentation of a pattern of well tolerated infusions with no infusion-associated reactions (IARs), or mild IARs that have been controlled with pre-medication, is a prerequisite for transfer of therapy to the home.
- The patient must have a history of adherence to the prescribed infusion schedule.

2.2. Requirements and organisation of home infusion

Once the patient is considered eligible for home infusion based on the primary criteria, a further set of requirements must be considered to ensure that Fabrazyme® infusions can be safely, efficiently, and reliably delivered at the patient's home.

- The patient and/or caregiver(s) have been informed by the treating physician about the treatment to be provided at home, the associated risks, and the provision of medical assistance at home, like hypersensitivity reactions and medication errors, and must agree to the treatment at home.
- The patient and/or caregiver(s) have an understanding of the illness and are able to recognise adverse events like hypersensitivity reactions and medication errors and understand the procedure to be followed should these occur.
- The home environment must be conducive to home infusion therapy including a clean environment with electricity, water, telephone access, refrigeration, and physical space to support storage of Fabrazyme® and other infusion supplies.
- The patient has been informed that the infusion nurse will carry out the entire infusion procedure at the patient's home.
- The patient and/or the caregiver must receive the educational material 'Home infusion guide for patients and their caregivers' which includes information about the signs and symptoms of IARs and the recommended actions for their management.
- Patients experiencing serious adverse events should contact Triple Zero (000) in the case of an emergency. For all other adverse events, the patient/caregiver should immediately contact the treating physician or his/her medical designate. Events can occur during the infusion or up to several hours after the infusion has ended. Subsequent infusions may need to occur in a hospital or in another appropriate setting of outpatient care until no such adverse reaction is present at the discretion of the prescribing HCP or his/her medical designate.
- The patient must be physically and mentally able to undergo the infusions at home. The treating physician is responsible for the recommendation to receive Fabrazyme® infusions at home.
- The patient has venous access or a central venous access device that allows adequate infusion.
- Treatment and all necessary equipment will be provided according to local arrangements and regulations.

3. RESPONSIBILITIES OF HCPs PRESCRIBING FABRAZYME®

- The treating physician is responsible for the initiation of all necessary administrative actions which will allow the other parties involved (patient and/or caregiver(s), infusion nurse, pharmacy) to proceed.
- The treating physician is responsible for providing the patient with the educational material 'Home infusion guide for patients and their caregivers'. Distribution is only required where the treating physician decides that the patient is eligible for home infusion treatment.
- The treating physician is responsible for selection of the infusion rate and dose. The infusion rate of Fabrazyme® that was tolerated by the patient in a more controlled setting (e.g., in the hospital or other medical setting) must not be changed in the home setting, unless necessary due to safety considerations. Any changes in Fabrazyme® administration must be clearly documented.

- The home infusion will take place under the responsibility of the treating physician.
- It is the responsibility of the treating physician to ensure safe administration to the patient to avoid risks of medication errors and hypersensitivity reactions.
- Pre-infusion treatment, if administered in the hospital or other medical setting (e.g. antihistamines, paracetamol, ibuprofen, corticosteroids), must be provided based on the patient-specific prescription. This treatment must not be altered in the home setting, unless medically warranted at the discretion of the treating physician.
- Emergency treatment must be provided based on the patient-specific prescription Instructions and a documented emergency plan must be given to the infusion nurse prior to setting up home infusion.
- The treating physician must ensure that a rapid and reliable line of communication is available to expedite an emergency response in case immediate medical attention is required.
- Patients experiencing adverse events need to contact the treating physician or his/her medical designate immediately. Subsequent infusions may need to occur in a hospital or other medical setting at the discretion of the treating physician or his/her medical designate.
- Regular disease monitoring of the home-infused patient is the responsibility of the treating physician.
- Appropriate scheduling and monitoring of the infusions is the responsibility of the treating physician and infusion nurse.
- The treating physician is strongly encouraged to report any adverse events that occur during treatment with Fabrazyme®. To report an adverse event, refer to section 6 'Safety Reporting'.

4. INFORMATION REGARDING THE ADMINISTRATION OF FABRAZYME®

Instructions for use relating to the dose and method of administration for Fabrazyme® are detailed in the Fabrazyme® Product Information (PI), available from Sanofi (https://qr.medsinfo.com.au/tx/sw.cfm?h=swcfabra) or the Package Insert in the Fabrazyme® vial box. Further important information to be read in combination with the Fabrazyme® PI/package insert is detailed in the sections below.

4.1. Responsibilities of infusion nurse

- The infusion nurse will have a coordinating role alongside the treating physician and the patient and/or caregiver(s) in organising the treatment at home, and will establish with the treating physician, patient and/or caregiver(s) the level of support necessary in the home.
- The infusion nurse is qualified to give intravenous (IV) infusions, has been appropriately trained on the administration of Fabrazyme®, and is trained on the possible adverse events (including serious adverse events such as anaphylactoid reactions) and the actions to be taken should they occur.
- The infusion nurse will strictly follow the prescribed method of preparation and administration of Fabrazyme® as stated by the prescribing physician.
- The infusion nurse will strictly follow the prescribed dose and infusion rate of Fabrazyme® as stated by the prescribing physician.
- The infusion nurse records each administration of Fabrazyme®.
- Appropriate scheduling and monitoring of the infusions is the responsibility of the treating physician and infusion nurse.

- In the event of an IAR, the infusion nurse must discontinue the infusion and phone the treating physician and/or Triple Zero (000). The treating physician and/or Triple Zero (000) must also be phoned if an IAR occurs shortly after completion of the infusion. Reporting of adverse events helps ensure the ongoing safety of Fabrazyme®. To report an adverse event, refer to section 5 'Safety Reporting'.

4.2. Pre-treatment and emergency treatment

- Appropriate pre-treatment should be provided based on the patient- specific prescription. Treatment administered in the hospital or other medical setting should not be altered in the home setting unless medically warranted at the discretion of the treating physician.
- Medications must be available to respond to an emergency situation, if necessary.
- In the event the patient experiences an adverse event like hypersensitivity reactions during or shortly after the infusion, the infusion should be discontinued immediately and the treating physician or his/her medical designate should be contacted to seek advice. Subsequent infusions may need to occur in a hospital or other medical setting.

4.3. Prescription

The Fabrazyme® dose, required reconstituted volume, infusion rate, premedication, emergency medication, as well as any changes will be determined by the treating physician. Any changes of this prescription (dose or infusion rate) must be documented.

4.4. Supplies

Supplied by the hospital/pharmacy to the patient or to a third party with the appropriate prescription:

- Vials of Fabrazyme® (5 mg or 35 mg per vial); must be stored in a clean refrigerator at a temperature of between 2°C and 8°C
- Sterile water for injection to reconstitute Fabrazyme®
- NaCl 0.9% solution, 2 x 250 mL for IV administration
- NaCl 0.9% solution, 2 x 50 mL to flush infusion line pre- and post-infusion
- Chlorhexidine 0.5% in alcohol 70% (antiseptic solution)
- Appropriate number of 2 mL, 10 mL and 50 mL syringes depending on dose of Fabrazyme®
- 3 x sterile hypodermic needles (1.1 x 40 mm)
- 1 x infusion needle
- In-line low protein-binding 0.2 micron filter
- Infusion-administration set (infusion line)
- Tape
- Sterile skin cleansing swabs
- Sharps bin
- Hand wash
- Tourniquet
- Additional requisites if using a venous access device: heparin, NaCl 0.9% solution, needles, syringes, dressing pack, sterile gloves, Gripper needle
- Pretreatment medication (if applicable)
- Emergency medication

4.5. Dose and method of administration

Information on dose and method of administration for Fabrazyme® are extensively detailed in the Fabrazyme® PI, available at Sanofi (https://qr.medsinfo.com.au/tx/sw.cfm?h=swcfabra) or the Package Insert in the Fabrazyme® vial box. Further important information to be read in combination with the Fabrazyme® PI/pack insert is detailed below.

- Therapy with Fabrazyme® should only be initiated or continued by a physician with expertise in the treatment of Fabry disease **(refer to PI Section 4.4. SPECIAL WARNINGS AND PRECAUTIONS FOR USE)**.
- If an IAR occurs during a Fabrazyme® infusion, decreasing the infusion rate, temporarily stopping the infusion and/or administration of antipyretics, antihistamines and/or steroids may ameliorate the symptoms **(Table 1)**. Patients who experience an IAR during a Fabrazyme® infusion should be treated with caution when Fabrazyme® is re-administered. If severe allergic or anaphylactoid reactions occur, immediate discontinuation of the administration of Fabrazyme® and current medical standards for emergency treatment are to be observed.

Table 1 - Managing Therapy for Patients Experiencing Infusion-Associated Reactions

Event Severity and Frequency	Single Mild to Moderate Event or Recurrent Mild to Moderate Event	Single Severe Event or Recurrent Moderate to Severe Event
Pre-Treatment Regimen	Approximately 1 hr prior to infusion: - Antihistamines - Paracetamol/Ibuprofen	Approximately 13 hrs, 7 hrs, and 1 hr prior to infusion: - Corticosteroids* Approximately 1 hr prior to infusion: - Antihistamines - Paracetamol/Ibuprofen
Infusion Rate	~ 0.15 mg/min (10 mg/hr)*	~ 0.15 mg/min (10 mg/hr)*

*If infusion proceeds without incident, consideration may be given to increasing infusion rates in a stepwise manner and to reducing premedication.

- The recommended dosage is 1 mg/kg of Fabrazyme® per dose, infused every 2 weeks. Dosage should be individualised for each patient and small adjustments can be made to avoid discarding partially used vials.
- No dose adjustment is necessary for paediatric patients 8 - 16 years old. The safety and efficacy in patients younger than 8 years of age have not been evaluated. However, patients with Fabry disease younger than 8 years old may be treated with Fabrazyme® when clearly needed and after a careful risk/benefit analysis has been conducted by the physician.
- The initial infusion rate should be no more than 0.25 mg/min (15 mg/hr) to minimise the potential occurrence of IARs. After patient tolerance is established, the infusion rate may be increased gradually with subsequent infusions.

4.6. Instructions for use

Instructions for use are extensively detailed in the Fabrazyme® PI, available at Sanofi (https://qr.medsinfo.com.au/tx/sw.cfm?h=swcfabra), or the Package Insert in the Fabrazyme® vial box. Further important information to be read in combination with the Fabrazyme® PI/pack insert is detailed below.

1. Determine the number of vials for reconstitution based on the patient's body weight (kg) and the recommended dose of 1 mg/kg.
2. Using aseptic technique, reconstitute each vial with sterile water for Injection to yield a 5 mg/mL clear, colourless solution. The final concentration and administration volumes are provided in **Table 2** below:

Table 2 - Final Concentration and Administration Volumes

	5 mg Presentation	**35 mg Presentation**
Sterile water for reconstitution	1.1 mL	7.2 mL
Final volume of reconstituted product	1.1 mL	7.4 mL
Concentration after reconstitution	5 mg/mL	5 mg/mL
Extractable volume	1.0 mL	7.0 mL
Amount of enzyme within extractable volume	5 mg	35 mg

3. Visually inspect the reconstituted vials for particulate matter and discolouration. Do not use vials exhibiting particulate matter or discolouration. Fabrazyme® does not contain preservatives. Vials are for single use only.
4. Immediately withdraw reconstituted solution from each vial, and using aseptic technique, further dilute with 0.9% sodium chloride for Injection to a total volume based on the individual dose dispensed (see **Table 3** below). Total infusion volumes as low as 50 mL were used in the phase 1/2 trial.

Table 3 - Minimum Total Volume for Infusion Based on Individual Dose

Individual Patient Dose Dispensed (mg)	**Minimum Total Volume (mL)**
<35	50
35.1 to 70	100
70.1 to 100	250
>100	500

5. Administer the solution intravenously at an initial rate of no more than 0.25 mg/min. The diluted solution may be filtered through an in-line low protein-binding 0.2 µm filter during administration.
6. Fabrazyme® should not be infused in the same IV line with other products. Fabrazyme® does not contain any preservatives; therefore after dilution with saline in the infusion bag, the unused product should be discarded.

5. FABRAZYME® SAFETY PROFILE

Identified risks of treatment with Fabrazyme® include:

- Hypersensitivity reactions and
- Medication errors in the home infusion setting.

Information relating to the full safety profile of Fabrazyme® can be found in the PI, available at Sanofi (https://qr.medsinfo.com.au/tx/sw.cfm?h=swcfabra), or alternatively via the Therapeutic Goods Administration (TGA) Australian Register of Therapeutic Goods (ARTG) at: (https://www.tga.gov.au/resources/artg)

6. SAFETY REPORTING

To report adverse event(s) and/or pregnancy occurring in association with the use of Fabrazyme®:

Please contact Sanofi Medical Information*:

Phone: 1800 818 806 (Australia)

Fax: 1800 053 105 (Australia)

E-mail: MedInfo.Australia@sanofi.com

*or refer to the Patient Support Program specific pharmacovigilance reporting requirements for PSP nurses.

Alternately, you may report adverse events and/or pregnancy directly to the TGA:

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

7. FURTHER INFORMATION

Please refer to the Fabrazyme PI 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) for complete indication statements and further information about the approved use of Fabrazyme.

Fabrazyme® PI

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Sydney, Australia. www.sanofi.com.au.
MAT-AU-2502491-2.0 - 11/2026