Fabrazyme® (agalsidase beta) Home Infusion Therapy:
Risk Minimisation Information for Patients

Manual for Patients with Fabry Disease who Receive
Home Infusion of Fabrazyme

Essential Non-Promotional information

Do not discard.

Version No. 1.2 (Ireland): May 2015

(Based on EMA approved version No. 1.1: 19 September 2011)

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

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 treating physician.
- 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 get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the patient information leaflet.

You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.
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1. YOUR DISEASE, TREATMENT AND HOME INFUSION

Together with your treating physician, you have decided to start home infusion therapy with Fabrazyme®. The objective of this document is to provide you with guidance on how to receive Fabrazyme at home. The processes presented in this document serve as overall guidance but are subject to local medical practice and national rules and regulations. Your treating physician will provide you with the details that are applicable to your situation.

1.1 Fabrazyme®

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. Fabrazyme is indicated in adults, children and adolescents aged 8 years and older.

Refer to the Package Leaflet of Fabrazyme for additional information (Appendix A).

1.2 Home Infusion

Currently, in some countries, 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 treating physician after initial infusions at the hospital to make sure you have no problems with the infusion.

Home infusion of Fabrazyme will make it possible for you to receive treatment within your own living environment which increases comfort and flexibility of infusion timing. This does not require spending time travelling to and from the hospital, and you will be able to follow a normal schooling program and/or organise social and professional activities more easily. Home infusion also facilitates arranging treatment around family and friends.

The home infusion will take place under the responsibility of your treating physician. Distribution of the educational material should only be executed if the treating physician decides that the patient is eligible for home infusion treatment. It is the responsibility of the treating physician to ensure a safe administration to the patient. This should be checked and documented by the treating physician.

An appropriately trained infusion nurse will teach and assist you and/or your caregiver(s) in the beginning to ensure optimal treatment. The level of support required for home infusion will be discussed and agreed by you and/or your caregiver(s) and your treating physician. Should you prefer additional support for your infusion at home (after agreement of your treating physician), the infusion nurse can provide further assistance.
Note: The dose and rate of the infusion while at home must follow the guidelines provided by your treating physician as noted in the Logbook (Appendix B), and must not be changed without the prior agreement of your treating physician and supervision of the infusion nurse.

1.3 Safety Assessments (side effects and medication errors)

The most common side effects experienced with Fabrazyme infusion (seen in more than 1 in 10 patients) are fever and chills. Other very common side effects include headache, abnormal feelings (like pins and needles) in hands and feet, nausea (feeling sick), vomiting and feeling cold. There have been reports of serious allergic reactions (frequency unknown). Side effects reported in children are similar to those seen in adult patients. For the full list of all side effects reported with Fabrazyme, see the Package Leaflet (Appendix A).

In the event that you do not feel well during the home infusion or within 24 hours after the infusion, you must immediately stop the medication. The treating physician, his/her medical designate, and/or the country-specific national emergency number (see instructions in the Logbook in Appendix B) must be contacted immediately. Subsequent infusions may need to occur in a clinical setting.

Any symptoms or side effects must also be recorded in the Logbook (Appendix B). In case of any problem with the preparation and/or administration of Fabrazyme, please contact the infusion nurse or the treating physician to determine appropriate actions before starting or continuing with the infusion.

In case you feel the treatment is not efficacious, please contact your treating physician.

2. ORGANISATION OF TREATMENT AT HOME

The organisation of treatment at home should be performed under the supervision of the treating physician. Your treating physician will be responsible for organising the treatment at home. The processes presented in this document serve as an overall guidance but are subject to local medical practice and national rules and regulations.

2.1 Patient

- You and/or your caregiver(s) have been informed by the treating physician 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.

- The home environment must be conducive to the provision of the 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.

- You have been informed that the infusion should always be administered in the presence of an adequately trained adult (infusion nurse or, if self-infusion skills have been acquired, an adult knowledgeable about the infusion procedures and adequately trained on what to do in case of an infusion-associated reaction and medication errors, as assessed by the treating physician or infusion nurse).

- The treating physician is responsible for training you and determining whether you are suitable to receive Fabrazyme infusions at home.

- You have accessible veins that allow an infusion needle to be inserted. When you have a central venous access device you should know how the infusion needle should be inserted into the septum.

- You and/or your caregiver(s) must agree that you receive the treatment at home.

- You and/or your caregiver have been adequately trained in the procedures of Fabrazyme preparation and infusion.

2.2 Treating Physician

- The treating physician is responsible for the initiation of all necessary administrative actions, and for overseeing the scheduling and monitoring of infusion activities, allowing the other parties involved (the nurse, patient and/or caregiver(s) and pharmacist) to proceed.

- The treating physician is responsible for determining the patient eligibility, the dose, the infusion rate, the pre-infusion treatment, and the emergency treatment, to be described in the Logbook. Any changes must be clearly communicated to the patient and/or caregiver(s) and described in the Logbook (Appendix B).

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

- The treating physician is responsible for setting up communication lines in case immediate medical attention is required. This should be checked and documented by the treating physician in the Logbook.

2.3 Pharmacy and Infusion Equipment

- Treatment and all necessary equipment will be provided according to local arrangements and regulations.
2.4 Infusion Nurse

- The infusion nurse will establish with the treating physician and the patient and/or caregiver(s) the level of support and coordination in organizing the treatment and in monitoring the safety at home during infusions.

- The infusion nurse is qualified to give intravenous (IV) infusions of Fabrazyme, and is knowledgeable of the possible side effects (including serious allergic reactions) and the actions to be taken should they occur.

- The infusion nurse will strictly follow the prescribed dose, method of preparation and administering Fabrazyme and the infusion rate of Fabrazyme.

- The infusion nurse will record each administration of Fabrazyme in the Logbook (Appendix B).

- In the event of an IAR, the infusion nurse must discontinue the infusion and phone the treating physician and/or the country-specific national emergency number described in the Logbook. The treating physician and/or the country-specific national emergency number must also be phoned if an IAR occurs shortly after completion of the infusion. Any IAR must be recorded in the Logbook (Appendix B).

2.5 Pre-treatment and Emergency Treatment

- If necessary, your treating physician will prescribe pre-treatment medication(s). Your treating physician will include the information on this medication in the Logbook.

- Your treating physician will prescribe medication(s) to respond to an emergency situation, if necessary. Your treating physician will include the information on this medication in the Logbook. This emergency medication should be available during the infusions at home.

2.6 The Logbook (Appendix B)

- The Logbook serves as a means of communication for everyone involved in administering Fabrazyme at home.

- The Logbook must be kept at your home and will be kept up to date by you, your caregiver(s), your treating physician and/or the infusion nurse.

- The prescribed dose and infusion rate of Fabrazyme as stated in the Logbook should be strictly followed. The treating physician is responsible for describing the dose and the infusion rate, as well as any changes.

- Each administration of Fabrazyme at home should be recorded in the Logbook.
• You and/or your caregiver(s) must take the Logbook along to the hospital at each appointment for a check-up and bring it home afterwards.

• The infusion nurse records the findings and actions from the initial interview. You, your caregiver(s) or the infusion nurse notes all relevant information from subsequent visits in the Logbook.

• In the Logbook, the treating physician must clearly state what has to be done and administered in the event of an infusion side effect. In case of any reaction to an infusion, the infusion needs to be stopped.

• Any infusion associated side effect and/or medication error should be recorded in the Logbook.

3. TRAINING ON PREPARATION AND ADMINISTRATION OF FABRAZYME

• The initial instructions will be given at the hospital. The level of support required for home infusion will be discussed and agreed by you and/or your caregiver(s) and your treating physician.

• Your treating physician is responsible for the organization of the home infusion and needs to agree upon the home infusion procedure.

• Should you prefer to carry out the procedure yourself or with the assistance of your caregiver(s), you and/or your caregiver(s) will receive training from the infusion nurse. The infusion nurse will explain and demonstrate the complete infusion procedure to you and/or your caregiver(s), including training in hand hygiene, proper disinfection and aseptic handling when preparing the infusion.

• At subsequent infusions, the infusion nurse will be present to assist, if required, until you and/or your caregiver(s) feel confident with the entire infusion procedure.

• While preparing and administering Fabrazyme, the procedures described in the Package Leaflet (Appendix A) and in this Manual must be closely followed.

• It is important to keep this guide handy and reread the instructions for administration regularly. This will ensure optimal practice.

• Each administration of Fabrazyme should be recorded in the Logbook (Appendix B).

• The infusion should always be administered in the presence of an adult knowledgeable about the infusion procedures and adequately trained on how to handle in case of an infusion-associated reaction and medication errors (as assessed by the treating physician or infusion nurse).
4. HOW DO I PREPARE AND ADMINISTER FABRAZYME?

4.1 Supplies
Supplied by the hospital/pharmacy to you or to a third party, and as prescribed by the treating physician.

- Vials of Fabrazyme (5 mg or 35 mg per vial); must be stored in a clean refrigerator at a temperature between +2°C and +8°C.
- Sterile water for injections to reconstitute Fabrazyme.
- 0.9% sodium chloride (NaCl) intravenous solution, 2 x 250 ml for IV administration.
- 0.9% sodium chloride (NaCl) intravenous 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 upon 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.
o Dressing pack.
o Sterile gloves.
o Gripper needle.

- Pre-treatment medication (if applicable)
- Emergency medication (See Logbook for instructions by treating physician).

## 4.2 Preparation

**NOTE:** The instructions for use (reconstitution, dilution and administration) can be found in the Package Leaflet (Appendix A). A detailed description is provided in this section.

1. Prepare a clean work area and lay out the supplies.

2. The vials of Fabrazyme must be removed from the refrigerator to reach room temperature approximately 30 minutes before preparation.

3. Check the expiry date printed on the bottom of the vial pack (do not use Fabrazyme after the labelled expiry date).

4. Verify if the number of vials received is correct.

5. Prepare only the number of vials required for one infusion.
   
   *Note:* The storage instructions as described in the instructions for use in the Package Leaflet must be followed (Appendix A).

### 4.3 Reconstituting Fabrazyme

1. Remove the flip-off cap from the Fabrazyme vial.

2. Disinfect the rubber stopper of the Fabrazyme vial with chlorhexidine and allow to air dry.

3. Open the sterile water for injection.

4. Draw the required amount (ml) of sterile water into the syringe.

   - For 35 mg vials, reconstitute each vial with 7.2 ml water for injection.
   - For 5 mg vials, reconstitute each vial with 1.1 ml water for injection.

5. Avoid forcefully ejecting the water for injection from the syringe onto the powder, to minimize foaming. This should be done by slow drop-wise addition of the water for
injection down the inside of the vial. Roll and tilt each vial gently. Do not invert, swirl or shake the vial.

6. Repeat the process for more Fabrazyme vials if required.

7. Small bubbles may appear after the mixing.

8. Let the solution settle for a few minutes to allow any bubbles present to disappear and to ensure that the powder is properly reconstituted.

9. After reconstitution, Fabrazyme must be inspected visually before use. The reconstituted solution must be a clear, colourless liquid and free from foreign matter. Because this is a protein solution, slight flocculation/cloudiness (in the form of thin translucent fibres) may occur occasionally after dilution.

10. If you notice any foreign matter or discolouration of the liquid, do not use the product and contact the infusion nurse and/or treating physician.

11. It is recommended that the vials be diluted promptly after reconstitution, to minimize protein particle formation over time.

12. Any unused product or waste material must be disposed of in accordance with local requirements.

4.4 Dilution

1. Disinfect the cap/opening of 1 or 2 bags of NaCl 0.9% solution using chlorhexidine and allow to air dry.

2. The volume of reconstituted Fabrazyme solution must be the same as the prescribed volume in the Logbook (Appendix B).

3. Insert the needle in the cap of the infusion bag and slowly withdraw a volume of NaCl 0.9% solution, equivalent to the volume of the reconstituted Fabrazyme solution to be added.

   For instance, if the prescribed reconstituted volume is 14 ml, remove 14 ml of NaCl solution from the bag of NaCl solution. Never remove more than half the content of the bag of NaCl solution to ensure that at least half the diluted solution consists of NaCl solution.

4. Remove the airspace within the infusion bag by withdrawing the air into a 50 ml syringe.
5. Slowly withdraw the reconstituted solution from each vial up to the total volume required.
   Do not use a filter needles. At the point when these quantities are withdrawn, the
   reconstituted product should not contain any foam.

6. Gently inject the total volume of the reconstituted Fabrazyme solution into the infusion
   bag of NaCl 0.9% solution.

7. Carefully mix this Fabrazyme solution by gently inverting or lightly massaging the
   infusion bag. Do not shake or excessively agitate the infusion bag.

8. The diluted solution should be filtered through an in-line low protein-binding 0.2 micron
   filter during administration.

4.5 Administration

4.5.1 Filling the Infusion Line

1. Remove the infusion system from the package and close it using the roller clamp.
   Connect the in-line filter to the infusion line.

2. Connect the spike in the NaCl 0.9% solution bag that does not contain Fabrazyme and fill
   the infusion system by holding the drip chamber upside down and opening the clamp.

3. Fill the entire system, remove any air bubbles that may be present and close the roller
   clamp.

4. Connect the infusion bag containing Fabrazyme to the y-system. Keep the clamp closed.

4.5.2 Inserting the Needle in the Vein

In case of self-infusion, the adult person present during the infusion session should have been
adequately trained (by the infusion nurse, treating physician, or his/her medical designate) on
the technique of needle insertion.

1. Ensure that some strips of tape are hanging ready for use and that the start of the infusion
   system is within reach. Place the chlorhexidine solution close by, along with some gauze.

2. Remove the needle from the packaging.

3. Sit down and rest one arm on the table (preferably on a clean cloth).

4. Apply the tourniquet, look for an appropriate vein, and disinfect the area where the needle
   is to be inserted and allow it to dry.
5. Pull the skin tight and insert the needle (with its eye facing upward) at a slight angle through the skin and into the vein. When the needle has entered the vein, a ‘flash’ of blood will be visible at the start of the tubing.

6. Insert the needle approximately 0.5 cm in the vein to ensure that it does not immediately pop out again. Use tape to keep the needle into place. Connect the system with filter to the needle.

7. Remove the tourniquet; the tube will now fill up with blood. If this does not happen, the needle is not positioned correctly in the vein. The process must then be repeated using a new needle. Open the clamp for NaCl 0.9% solution.

8. Adjust the infusion rate according to the prescription (see the Logbook, Appendix B) and open the valve. Sit down and relax while the infusion takes place. Keep the Logbook close in case information on emergency procedures are needed.

4.5.3 Administration

- From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage and conditions are the responsibility of the user. The product diluted in NaCl 0.9% solution will retain chemical stability up to 24 hours if stored at a temperature between 2°C and 8°C and away from light.
- The Fabrazyme dose, infusion rate, as well as any changes, will be determined by the treating physician. The treatment must not be altered in the home setting, unless medically warranted at the discretion of the treating physician.
- After the Fabrazyme infusion has been completed, the system is flushed with NaCl 0.9% solution at the same rate, and the needle is then removed.

4.5.4 Preparation of the Fabrazyme infusion in case of a central venous access device

When you have a venous access device for the delivery of Fabrazyme, you and/or your caregiver(s) will be shown how to care for the device by the infusion nurse, if this has not already been demonstrated during hospital-based infusions.

Proper care of a venous access device involves regular irrigation with a drug called heparin to prevent clotting and attention to a sterile technique to keep the device free of infection. The following steps are necessary:

- When in use, cover site with transparent occlusive dressing. No dressing required when not in use.
- Flush with 5 ml NaCl 0.9% solution before and after each use.
- Flush with 5 ml heparin (100 U/ml) after each use.
5. **APPENDICES**

A. Fabrazyme Package Leaflet

B. Logbook
Appendix A. Fabrazyme Patient Information Leaflet

Package leaflet: Information for the user

Fabrazyme 35 mg powder for concentrate for solution for infusion
Agalsidase beta

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet
1. What Fabrazyme is and what it is used for
2. What you need to know before you use Fabrazyme
3. How to use Fabrazyme
4. Possible side effects
5. How to store Fabrazyme
6. Contents of the pack and other information

1. What Fabrazyme is and what it is used for

Fabrazyme contains the active substance agalsidase beta and is used as enzyme replacement therapy in Fabry disease, where the level of α-galactosidase enzyme activity is absent or lower than normal. If you suffer from Fabry disease a fat substance, called globotriaosylceramide (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 indicated for use as long-term enzyme replacement therapy in patients with a confirmed diagnosis of Fabry disease.

Fabrazyme is indicated in adults, children and adolescents aged 8 years and older.

2. What you need to know before you use Fabrazyme

Do not use Fabrazyme
If you have experienced an allergic anaphylactic reaction to agalsidase beta or if you are allergic (hypersensitive) to any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
If you are treated with Fabrazyme, you may develop infusion associated reactions. An infusion-associated reaction is any side effect occurring during the infusion or until the end of the infusion day (see section 4). If you experience a reaction like this, you should tell your doctor immediately. You may need to be given additional medicines to prevent such reactions from occurring.

Children and adolescents
No clinical studies have been performed in children 0-7 years old and therefore no dose can be recommended for this age group.
Other medicines and Fabrazyme
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Tell your doctor if you use any medicines containing chloroquine, amiodarone, benoquin or gentamicin. There is a theoretical risk of decreased agalsidase beta activity.

Pregnancy, breast-feeding and fertility
Use of Fabrazyme during pregnancy is not recommended. There is no experience with the use of Fabrazyme in pregnant women. Fabrazyme may get into breast milk. Use of Fabrazyme during breast-feeding is not recommended. Studies have not been performed to examine the effects of Fabrazyme on fertility.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
Do not drive or use machines if you experience dizziness, sleepiness, vertigo or fainting during or shortly after administration of Fabrazyme (see section 4). Talk to your doctor first.

3. How to use Fabrazyme
Fabrazyme is given through a drip into a vein (by intravenous infusion). It is supplied as a powder which will be mixed with sterile water before it is given (see information for Health Care Professionals at the end of this leaflet).
Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Fabrazyme is only used under the supervision of a doctor who is knowledgeable in the treatment of Fabry disease. Your doctor may advise that you can be treated at home provided you meet certain criteria. Please contact your doctor if you would like to be treated at home.

The recommended dose of Fabrazyme for adults is 1 mg/kg body weight, once every 2 weeks. No changes in dose are necessary for patients with kidney disease.

Use in children and adolescents
The recommended dose of Fabrazyme for children and adolescents 8 – 16 years is 1 mg/kg body weight, once every 2 weeks. No changes in dose are necessary for patients with kidney disease.

If you use more Fabrazyme than you should
Doses up to 3 mg/kg body weight have shown to be safe.

If you forget to use Fabrazyme
If you have missed an infusion of Fabrazyme, please contact your doctor.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.

In clinical studies side effects were mainly seen while patients were being given the medicine or shortly after (“infusion related reactions”). Severe life-threatening allergic reactions (“anaphylactoid
Very common symptoms (may affect more than 1 in 10 people) include chills, fever, feeling cold, nausea, vomiting, headache and abnormal feelings in the skin such as burning or tingling. Your doctor may decide to lower the infusion rate or give you additional medicines to prevent such reactions from occurring.

List of other side effects:

Common (may affect up to 1 in 10 people):
- chest pain
- difficulty in breathing
- pallor
- itching
- abnormal tear secretion
- feeling weak
- tinnitus
- nasal congestion
- diarrhoea
- redness
- muscle pain
- increased blood pressure
- sudden swelling of the face or throat
- oedema in extremities
- vertigo
- stomach discomfort
- muscle spasms
- sleepiness
- increased heart beat
- abdominal pain
- back pain
- rash
- low heart rate
- lethargy
- syncope
- cough
- abdominal discomfort
- swelling face
- joint pain
- decreased blood pressure
- chest discomfort
- face oedema
- exacerbated difficulty in breathing
- muscle tightness
- fatigue
- flushing
- pain
- throat tightness
- dizziness
- palpitations
- decreased sensitivity to pain
- burning sensation
- wheezing
- urticaria
- pain at the extremities
- nasopharyngitis
- hot flush
- feeling hot
- hyperthermia
- decreased mouth sensitivity
- musculoskeletal stiffness

Uncommon (may affect up to 1 in 100 people):
- tremor
- itching eyes
- ear swelling
- bronchospasm
- runny nose
- heart burn
- skin discomfort
- musculoskeletal pain
- rhinitis
- influenza-like illness
- malaise
- low heart rate due to conduction disturbances
- increased sensitivity to pain
- upper respiratory tract congestion
- red rash
- (mottled purplish) skin discoloration
- coldness of the extremities
- injection site blood clotting
- skin discoloration
- oedema

Not known (frequency cannot be estimated from the available data):
- lower blood oxygen levels
- serious inflammation of the vessels

In some patients initially treated at the recommended dose, and whose dose was later reduced for an extended period, some symptoms of Fabry disease were reported more frequently.
Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed below. By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

Ireland
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafty@hpра.ie

5. How to store Fabrazyme

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label after ‘EXP’. The expiry date refers to the last day of that month.

Unopened vials
Store in a refrigerator (2°C – 8°C).

Reconstituted and diluted solutions
The reconstituted solution cannot be stored and should be promptly diluted. The diluted solution can be held for up to 24 hours at 2°C – 8°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Fabrazyme contains
- The active substance is agalsidase beta, one vial contains 35 mg.
- The other ingredients are:
  - Mannitol
  - Sodium phosphate monobasic, monohydrate
  - Sodium phosphate dibasic, heptahydrate.

What Fabrazyme looks like and contents of the pack
Fabrazyme is supplied as a white to off-white powder. After reconstitution it is a clear, colourless liquid, free from foreign matter. The reconstituted solution must be further diluted. Package sizes: 1, 5 and 10 vials per carton. Not all pack sizes may be marketed.
Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder
Genzyme Europe B.V., Gooimeer 10, NL-1411DD Naarden, The Netherlands

Manufacturer
Genzyme Ltd., 37 Hollands Road, Haverhill, Suffolk CB9 8PU, United Kingdom

Genzyme Ireland Ltd., IDA Industrial Park, Old Kilmeaden Road, Waterford, Ireland
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Instructions for use – reconstitution, dilution and administration

The powder for concentrate for solution for infusion has to be reconstituted with water for injections, diluted with 0.9% sodium chloride intravenous solution and then administered by intravenous infusion.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage and conditions are the responsibility of the user. The reconstituted solution cannot be stored and should be promptly diluted; only the diluted solution can be held for up to 24 hours at 2ºC -8ºC.

Use Aseptic Technique

1. Determine the number of vials to be reconstituted based on the individual patient's weight and remove the required vials from the refrigerator in order to allow them to reach room temperature (in approximately 30 minutes). Each vial of Fabrazyme is intended for single use only.

Reconstitution

2. Reconstitute each vial of Fabrazyme 35 mg with 7.2 ml water for injections. Avoid forceful impact of the water for injections on the powder and avoid foaming. This is done by slow drop-wise addition of the water for injection down the inside of the vial and not directly onto the lyophilized cake. Roll and tilt each vial gently. Do not invert, swirl or shake the vial.

3. The reconstituted solution contains 5 mg agalsidase beta per ml, and appears as a clear colourless solution. The pH of the reconstituted solution is approximately 7.0. Before further dilution, visually inspect the reconstituted solution in each vial for particulate matter and discoloration. Do not use the solution if foreign particles are observed or if the solution is discoloured.

4. After reconstitution it is recommended to promptly dilute the vials, to minimise protein particle formation over time.
5. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

**Dilution**

6. Prior to adding the reconstituted volume of Fabrazyme required for the patient dose, it is recommended to remove an equal volume of 0.9% sodium chloride intravenous solution, from the infusion bag.

7. Remove the airspace within the infusion bag to minimize the air/liquid interface.

8. Slowly, withdraw 7.0 ml (equal to 35 mg) of the reconstituted solution from each vial up to the total volume required for the patient dose. Do not use filter needles and avoid foaming.

9. Then slowly inject the reconstituted solution directly into the 0.9% sodium chloride intravenous solution (not in any remaining airspace) to a final concentration between 0.05 mg/ml and 0.7 mg/ml. Determine the total volume of sodium chloride 0.9% solution for infusion (between 50 and 500 ml) based on the individual dose. For doses lower than 35 mg use a minimum of 50 ml, for doses 35 to 70 mg use a minimum of 100 ml, for doses 70 to 100 mg use a minimum of 250 ml and for doses greater than 100 mg use only 500 ml. Gently invert or lightly massage the infusion bag to mix the diluted solution. Do not shake or excessively agitate the infusion bag.

**Administration**

10. It is recommended to administer the diluted solution through an in-line low protein-binding 0.2 µm filter to remove any protein particles which will not lead to any loss of agalsidase beta activity. The initial infusion rate should be no more than 0.25 mg/min (15 mg/hour) to minimise the potential occurrence of infusion-associated reactions. After patient tolerance is established, the infusion rate may be increased gradually with subsequent infusions.
Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If this medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet
1. What Fabrazyme is and what it is used for
2. What you need to know before you use Fabrazyme
3. How to use Fabrazyme
4. Possible side effects
5. How to store Fabrazyme
6. Contents of the pack and other information

1. What Fabrazyme is and what it is used for

Fabrazyme contains the active substance agalsidase beta and is used as enzyme replacement therapy in Fabry disease, where the level of α-galactosidase enzyme activity is absent or lower than normal. If you suffer from Fabry disease, a fat substance, called globotriaosylceramide (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 indicated for use as long-term enzyme replacement therapy in patients with a confirmed diagnosis of Fabry disease.

Fabrazyme is indicated in adults, children and adolescents aged 8 years and older.

2. What you need to know before you use Fabrazyme

Do not use Fabrazyme
If you have experienced an allergic anaphylactic reaction to agalsidase beta or if you are allergic (hypersensitive) to any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
If you are treated with Fabrazyme, you may develop infusion associated reactions. An infusion-associated reaction is any side effect occurring during the infusion or until the end of the infusion day (see section 4). If you experience a reaction like this, you should tell your doctor immediately. You may need to be given additional medicines to prevent such reactions from occurring.

Children and adolescents
No clinical studies have been performed in children 0-7 years old and therefore no dose can be recommended for this age group.
Other medicines and Fabrazyme
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Tell your doctor if you use any medicines containing chloroquine, amiodarone, benoquin or gentamicin. There is a theoretical risk of decreased agalsidase beta activity.

Pregnancy, breast-feeding and fertility
Use of Fabrazyme during pregnancy is not recommended. There is no experience with the use of Fabrazyme in pregnant women. Fabrazyme may get into breast milk. Use of Fabrazyme during breast-feeding is not recommended. Studies have not been performed to examine the effects of Fabrazyme on fertility.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
Do not drive or use machines if you experience dizziness, sleepiness, vertigo or fainting during or shortly after administration of Fabrazyme (see section 4). Talk to your doctor first.

3. How to use Fabrazyme
Fabrazyme is given through a drip into a vein (by intravenous infusion). It is supplied as a powder which will be mixed with sterile water before it is given (see information for Health Care Professionals at the end of this leaflet).
Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Fabrazyme is only used under the supervision of a doctor who is knowledgeable in the treatment of Fabry disease. Your doctor may advise that you can be treated at home provided you meet certain criteria. Please contact your doctor if you would like to be treated at home.

The recommended dose of Fabrazyme for adults is 1 mg/kg body weight, once every 2 weeks. No changes in dose are necessary for patients with kidney disease.

Use in children and adolescents
The recommended dose of Fabrazyme for children and adolescents 8 – 16 years is 1 mg/kg body weight, once every 2 weeks. No changes in dose are necessary for patients with kidney disease.

If you use more Fabrazyme than you should
Doses up to 3 mg/kg body weight have shown to be safe.

If you forget to use Fabrazyme
If you have missed an infusion of Fabrazyme, please contact your doctor.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.

In clinical studies side effects were mainly seen while patients were being given the medicine or shortly after (“infusion related reactions”). Severe life-threatening allergic reactions (“anaphylactoid
reactions”) have been reported in some patients. If you experience any serious side effect, you should contact your doctor immediately.

Very common symptoms (may affect more than 1 in 10 people) include chills, fever, feeling cold, nausea, vomiting, headache and abnormal feelings in the skin such as burning or tingling. Your doctor may decide to lower the infusion rate or give you additional medicines to prevent such reactions from occurring.

List of other side effects:

Common (may affect up to 1 in 10 people):
- chest pain
- difficulty in breathing
- pallor
- itching
- abnormal tear secretion
- feeling weak
- tinnitus
- nasal congestion
- diarrhoea
- redness
- muscle pain
- increased blood pressure
- sudden swelling of the face or throat
- oedema in extremities
- vertigo
- stomach discomfort
- muscle spasms
- sleepiness
- increased heart beat
- abdominal pain
- back pain
- rash
- low heart rate
- lethargy
- syncope
- cough
- abdominal discomfort
- swelling face
- joint pain
- decreased blood pressure
- chest discomfort
- face oedema
- exacerbated difficulty in breathing
- muscle tightness

Uncommon (may affect up to 1 in 100 people):
- tremor
- itching eyes
- red eyes
- ear pain
- throat pain
- fast breathing
- itchy rash
- feeling hot and cold
- difficulty swallowing
- infusion site pain
- infusion site reaction
- ear swelling
- bronchospasm
- runny nose
- heart burn
- skin discomfort
- musculoskeletal pain
- rhinitis
- influenza-like illness
- malaise

Not known (frequency cannot be estimated from the available data):
- lower blood oxygen levels
- serious inflammation of the vessels

In some patients initially treated at the recommended dose, and whose dose was later reduced for an extended period, some symptoms of Fabry disease were reported more frequently.
Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed below. By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

Ireland
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
E-mail: medsafety@hpra.ie

5. How to store Fabrazyme

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label after ‘EXP’. The expiry date refers to the last day of that month.

Unopened vials
Store in a refrigerator (2°C – 8°C).

Reconstituted and diluted solutions
The reconstituted solution cannot be stored and should be promptly diluted. The diluted solution can be held for up to 24 hours at 2°C – 8°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Fabrazyme contains
- The active substance is agalsidase beta, one vial contains 5 mg.
- The other ingredients are:
  - Mannitol
  - Sodium phosphate monobasic, monohydrate
  - Sodium phosphate dibasic, heptahydrate.

What Fabrazyme looks like and contents of the pack
Fabrazyme is supplied as a white to off-white powder. After reconstitution it is a clear, colourless liquid, free from foreign matter. The reconstituted solution must be further diluted.
Package sizes: 1, 5 and 10 vials per carton. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
**Marketing authorisation holder**
Genzyme Europe B.V., Gooimeer 10, NL-1411DD Naarden, The Netherlands

**Manufacturer**
Genzyme Ltd., 37 Hollands Road, Haverhill, Suffolk CB9 8PU, United Kingdom

Genzyme Ireland Ltd., IDA Industrial Park, Old Kilmeaden Road, Waterford, Ireland
For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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Luxembourg/Luxemburg
Sanofi Belgium

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Sanofi Malta Ltd
Tel: +356 21493022

Date:
May 2015

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CODE: GZUK.FABR.14.11.0195 (1)
Instructions for use – reconstitution, dilution and administration

The powder for concentrate for solution for infusion has to be reconstituted with water for injections, diluted with 0.9% sodium chloride intravenous solution and then administered by intravenous infusion.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage and conditions are the responsibility of the user. The reconstituted solution cannot be stored and should be promptly diluted; only the diluted solution can be held for up to 24 hours at 2°C -8°C.

Use Aseptic Technique

1. Determine the number of vials to be reconstituted based on the individual patient's weight and remove the required vials from the refrigerator in order to allow them to reach room temperature (in approximately 30 minutes). Each vial of Fabrazyme is intended for single use only.

Reconstitution

2. Reconstitute each vial of Fabrazyme 5 mg with 1.1 ml water for injections. Avoid forceful impact of the water for injections on the powder and avoid foaming. This is done by slow drop-wise addition of the water for injection down the inside of the vial and not directly onto the lyophilized cake. Roll and tilt each vial gently. Do not invert, swirl or shake the vial.

3. The reconstituted solution contains 5 mg agalsidase beta per ml, and appears as a clear colourless solution. The pH of the reconstituted solution is approximately 7.0. Before further dilution, visually inspect the reconstituted solution in each vial for particulate matter and discoloration. Do not use the solution if foreign particles are observed or if the solution is discoloured.

4. After reconstitution it is recommended to promptly dilute the vials, to minimise protein particle formation over time.
5. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

**Dilution**

6. Prior to adding the reconstituted volume of Fabrazyme required for the patient dose, it is recommended to remove an equal volume of 0.9% sodium chloride intravenous solution, from the infusion bag.

7. Remove the airspace within the infusion bag to minimize the air/liquid interface.

8. Slowly, withdraw 1.0 ml (equal to 5 mg) of the reconstituted solution from each vial up to the total volume required for the patient dose. Do not use filter needles and avoid foaming.

9. Then slowly inject the reconstituted solution directly into the 0.9% sodium chloride intravenous solution (not in any remaining airspace) to a final concentration between 0.05 mg/ml and 0.7 mg/ml. Determine the total volume of sodium chloride 0.9% solution for infusion (between 50 and 500 ml) based on the individual dose. For doses lower than 35 mg use a minimum of 50 ml, for doses 35 to 70 mg use a minimum of 100 ml, for doses 70 to 100 mg use a minimum of 250 ml and for doses greater than 100 mg use only 500 ml. Gently invert or lightly massage the infusion bag to mix the diluted solution. Do not shake or excessively agitate the infusion bag.

**Administration**

10. It is recommended to administer the diluted solution through an in-line low protein-binding 0.2 µm filter to remove any protein particles which will not lead to any loss of agalsidase beta activity. The initial infusion rate should be no more than 0.25 mg/min (15 mg/hour) to minimise the potential occurrence of infusion-associated reactions. After patient tolerance is established, the infusion rate may be increased gradually with subsequent infusions.
Appendix B. Logbook

Logbook for Fabrazyme® Home Infusion

General data *(to be completed by treating physician)*

<table>
<thead>
<tr>
<th>CONTACT DETAILS</th>
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</thead>
<tbody>
<tr>
<td>Patient</td>
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<tr>
<td>Name:</td>
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<tr>
<td>Birth Date:</td>
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<tr>
<td>Address:</td>
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<td>Zip / City:</td>
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<td>Telephone:</td>
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<tr>
<td>Contact details of patient’s caregiver</td>
<td></td>
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<tr>
<td>Name:</td>
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<td>Address:</td>
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<td>Zip / City:</td>
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<td>Telephone:</td>
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<tr>
<td>Nurse</td>
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<td>Name:</td>
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<td>Organisation:</td>
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<td>Zip / City:</td>
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<td>Telephone:</td>
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<tr>
<td>Treating physician</td>
<td></td>
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<tr>
<td>Name:</td>
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<tr>
<td>Hospital:</td>
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<td>Address:</td>
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<td>Zip / City:</td>
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<td>Telephone:</td>
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<td>Emergency number</td>
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<tr>
<td>Pharmacy</td>
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<tr>
<td>Name:</td>
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<td>Address:</td>
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<td>Zip / City:</td>
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<td>Telephone:</td>
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<tr>
<td>Administration details <em>(to be completed by treating physician)</em></td>
<td></td>
</tr>
<tr>
<td>---------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Fabrazyme administered since Date (dd-mmm-yyyy):</td>
<td></td>
</tr>
<tr>
<td>First infusion at home Date (dd-mmm-yyyy):</td>
<td></td>
</tr>
<tr>
<td>Fabrazyme dosing regimen - Dose</td>
<td></td>
</tr>
<tr>
<td>- Frequency</td>
<td></td>
</tr>
<tr>
<td>- Rate of infusion</td>
<td></td>
</tr>
<tr>
<td>- Required reconstituted volume (ml)</td>
<td></td>
</tr>
<tr>
<td>- Total volume in infusion bag (ml)</td>
<td></td>
</tr>
<tr>
<td>Pre-treatment medication (if applicable)</td>
<td></td>
</tr>
<tr>
<td>Reasons for Fabrazyme infusion at home</td>
<td></td>
</tr>
<tr>
<td>Findings and actions from the initial interview</td>
<td></td>
</tr>
<tr>
<td>Indicate support to be provided by infusion nurse at home</td>
<td></td>
</tr>
</tbody>
</table>
### Necessary actions in the event of a serious infusion-associated reaction
*(to be completed by treating physician)*

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. <strong>Stop the infusion</strong></td>
<td></td>
</tr>
<tr>
<td>2. <strong>Call the national emergency number</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Telephone number</td>
</tr>
<tr>
<td>3. <strong>Call the physician</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Telephone number</td>
</tr>
<tr>
<td></td>
<td>- Telephone number (24hr)</td>
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<tr>
<td></td>
<td>- Name of physician</td>
</tr>
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<td></td>
<td>- Name of clinic</td>
</tr>
<tr>
<td></td>
<td>- Address</td>
</tr>
<tr>
<td><strong>Emergency medication, including dose</strong></td>
<td></td>
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<tr>
<td><strong>Patient’s contact person to be notified</strong></td>
<td></td>
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<tr>
<td></td>
<td>- Name</td>
</tr>
<tr>
<td></td>
<td>- Telephone number</td>
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</tbody>
</table>
Complete this form for every infusion session

- The patient and/or caregiver(s) have been informed about the associated risks of home infusion of Fabrazyme, and proper education on the use of emergency medications has been provided.
- In the event of any infusion-associated reaction, the infusion must be immediately discontinued
- Necessary actions in the event of a serious infusion-associated reaction, including emergency contact details, are described in the Logbook. Keep this information readily available during the infusion procedure.

### Infusion data

<table>
<thead>
<tr>
<th>Date of infusion</th>
<th>Date (dd-mmm-yyyy):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient’s general health status - Describe any new health issues that you are currently experiencing prior to infusion, if any</td>
<td></td>
</tr>
<tr>
<td>Dose</td>
<td></td>
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<tr>
<td>Required reconstituted volume (ml)</td>
<td></td>
</tr>
<tr>
<td>Number of vials used</td>
<td>5 mg vials:</td>
</tr>
<tr>
<td>35 mg vials:</td>
<td></td>
</tr>
<tr>
<td>Duration of administration</td>
<td></td>
</tr>
<tr>
<td>Rate of administration</td>
<td></td>
</tr>
<tr>
<td>Problems/Remarks related to the infusion, if any (including infusion-associated reaction(s), action taken, and outcome)</td>
<td></td>
</tr>
<tr>
<td>Name of person responsible for infusion, and date</td>
<td></td>
</tr>
<tr>
<td>- Nurse</td>
<td></td>
</tr>
<tr>
<td>- Caregiver (if different from above)</td>
<td></td>
</tr>
</tbody>
</table>