sanofi

Fabrazyme® (agalsidase beta)
Home Infusion Therapy:

Mikilvægar öryggisupplýsingar

Í samráði við Lyfjastofnun

A Guide for Healthcare Professionals Treating Patients with Fabry Disease

ÚTGÁFA 3 (BYGGT Á UK VERSION NO. 2.0)

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

Útgáfa 3. Yfirfarið af Lyfjastofnun í júní 2021

Contents

Útgáfa 3. Yfirfarið af Lyfjastofnun í júní 2021

1. OBJECTIVES AND GOALS

The objective of this document is to **provide guidance to healthcare professionals for the management of patients receiving Fabrazyme® at home.** The process (described in detail below) will start with patient evaluation and selection, and discussion of requirements for home infusion. This is followed by the organisation of home infusion and training.

Enzyme replacement therapy is available for some of the lysosomal storage disorders and, to improve convenience and quality of life, **the intravenous treatment can be transferred to the patient's home if specific requirements can be fulfilled.**[1-3] Fabrazyme® infusion therapy is available for treatment of patients with Fabry disease and is generally well tolerated.[4-6]

If the requirements can be fulfilled, **the patient can receive treatment within the living environment which increases comfort and flexibility of infusion timing.** It avoids spending time travelling to and from the hospital, and patients will be able to follow a normal schooling program and organise social and professional activities more easily. Moreover, it reduces the constraints of hospital resources.[1]

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. 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 trying to avoid risks of medication errors 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. ASSESSING ELIGIBILITY FOR HOME INFUSION

Before making any arrangements, the 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.**

Útgáfa 3. Yfirfarið af Lyfjastofnun í júní 2021

3. REQUIREMENTS AND ORGANISATION OF HOME INFUSION

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

3.1 Patient

General

- 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 should always be administered in the presence of an adult,** i.e. the infusion nurse or, if self-infusion skills have been acquired, an adult knowledgeable about the infusion procedures and adequately trained on how to handle in case of an IAR and medication errors (as assessed by the treating physician or infusion nurse).

Medical

- 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.

3.2 Treating Physician

- 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 "Manual for patients with Fabry Disease who receive home infusion of Fabrazyme" (*Handbók fyrir sjúklinga með Fabry-sjúkdóm sem fá innrennslisgjöf með Fabrazyme heima*) and with the Logbook (*Dagbók fyrir innrennslisgjöf heima með Fabrazyme*).**
- **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 in the Logbook (Appendix 1).**
- **The home infusion will take place under the responsibility of the 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 in order to avoid risks of medication errors and hypersensitivity reactions'**. This should be checked and documented by the treating physician.
- **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 and should be described in the Logbook.** 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 and should be described in the Logbook.
- 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.

3.3 Pharmacy and Infusion Equipment

Treatment and all necessary equipment will be provided according to local arrangements and regulations.

3.4 Infusion Nurse

- The infusion nurse will have a **coordinating role** vis-à-vis the treating physician and the patient and/or caregiver(s) in organizing 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 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 in this Manual.
- The infusion nurse will strictly follow the prescribed dose and infusion rate of Fabrazyme as stated in the Logbook (Appendix 1).
- The infusion nurse **records each administration of Fabrazyme in the Logbook** (Appendix 1).
- **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 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 1).**

3.5 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. Proper education on the use of emergency medications must be provided by the treating physician to the patient and/or caregiver.
- **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. All adverse events, including medication errors, should be reported to Sanofi's Pharmacovigilance Department by the treating physician (reporting instructions are provided in this Manual in Section 7 Safety Reporting).**

3.6 The Logbook

- The Logbook serves as a **means of communication** for all involved in administering Fabrazyme in the home-setting.
- **The infusion nurse/patient/caregiver(s) will record the findings and actions from the initial interview** and all relevant information from subsequent visits in the Logbook.
- **A resource contact list** must be completed and available at home in the Logbook for the patient and/or caregiver(s) and the infusion nurse.
- The Logbook **must be kept at the patient's home** and will be updated by the infusion nurse/patient/caregiver(s) each time Fabrazyme is administered.
- The patient **must take the Logbook along to the hospital at each appointment** and bring it home afterwards.
- In the logbook, **the treating physician clearly states the dose, the required reconstituted volume, infusion rate, as well as any changes.** The treating physician clearly states what has to be done and which medications are to be administered in the event of a serious IAR in line with current medical standards for emergency treatment. The contact details of the treating physician and the country-specific national emergency number are documented in the Logbook (Appendix 1).

4. TRAINING ON PREPARATION AND ADMINISTERING FABRAZYME

In principle, the initial instructions will be given in the hospital and the level of support required from the infusion nurse in the home setting will be discussed and agreed by the treating physician and the patient and/or caregiver(s).

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

The infusion nurse will carry out the entire procedure for the first infusions at the patient's home. Subsequently, should the patient then prefer to carry out the procedure him/herself, or with the assistance of a caregiver, the following conditions must be followed:

- **The patient and/or caregiver(s) will receive adequate training from the infusion nurse on how the infusion is being prepared and administered.** The infusion nurse will explain and demonstrate the complete infusion procedure to the patient and/or caregiver(s), including training in hand hygiene, proper disinfection and aseptic handling when preparing the infusion.
- At subsequent visits, **the infusion nurse will be present to assist, if required, until the patient and/or caregiver(s) feels confident with the entire infusion procedure.**
- While reconstituting and administering Fabrazyme, **the procedures described** in the Fabrazyme Summary of Product Characteristics and in **section 5 "Administration of Fabrazyme infusions" of this document must be adhered to,** and each administration of Fabrazyme should be recorded in the Logbook (Appendix 1).

- **If self-infusion skills have been acquired, 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 IAR and medication errors, as assessed by the treating physician or infusion nurse.
- **In the event of any IAR, the infusion must be immediately discontinued and the patient or caregiver(s) must phone the treating physician or his/her medical designate. In the case of an emergency, refer to the emergency details in the Logbook (Appendix 1). The same procedure must be followed if an IAR occurs shortly after completion of the infusion.**

5. ADMINISTRATION OF FABRAZYME

Instructions for use relating to the reconstitution, dilution and administration can be found in the Summary of Product Characteristics (SmPC). A detailed description is provided in this section.

5.1 Prescription

The Fabrazyme dose, required reconstituted volume, infusion rate, premedication, emergency medication, as well as any changes will be determined by the treating physician. The prescription must be written in the Logbook (Appendix 1). Any changes of this prescription (dose or infusion rate) must again be reported in the Logbook.

5.2 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 (as described in Logbook)

5.3 Preparations

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

1. Prepare a clean work area and lay out the requisites.
2. The vials with 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 SmPC must be followed.

5.3 STEP 1: Preparation of the materials

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

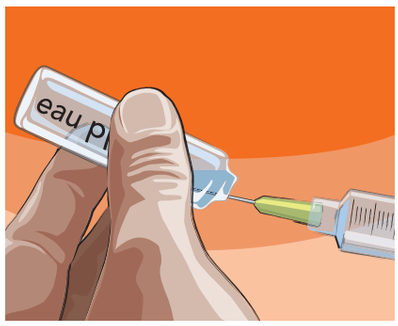
   For 35 mg vials, reconstitute each vial with 7.2 ml water for injection.
   For 5 mg vials, reconstitute each vial with 1.1 ml water for injection.
5. Avoid forcefully ejecting the water for injections from the syringe onto the powder, to minimize foaming. This should be done by slow drop-wise addition 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 (described as thin translucent fibres) may occur occasionally after dilution.
10. If foreign matter or discolouration of the liquid is noticed, the product must not be used and the infusion nurse and/or treating physician must be informed.
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.

5.5 Dilution

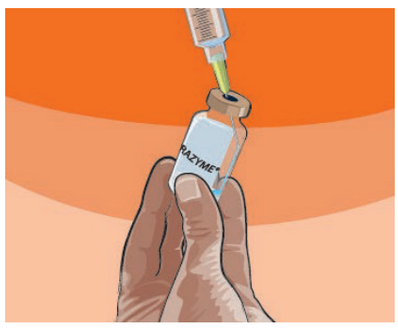
1. Disinfect the cap/opening of 1 or 2 bags of NaCl 0.9% solution using chlorhexidine and allow to air dry.
2. The volume of reconstituted Fabrazyme solution must be the same as the prescribed volume in the Logbook (Appendix 1).
3. Insert the needle in the cap of the infusion bag and slowly withdraw 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 (2 x 7 ml) 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.

5.4 STEP 2: Disinfect the vial



5.4 STEP 4: Draw the required amount of sterile water into the syringe

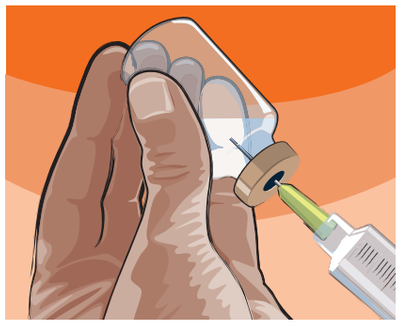


5.4 STEP 5: Avoid forcefully ejecting the water for injections from the syringe

5.5 STEP 3: Slowly withdraw the required volume of NaCl 0.9% solution, equivalent to the volume of the reconstituted Fabrazyme

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.

   At the point when these quantities have been drawn, the reconstituted product should not contain any foam.
6. Gently inject the total volume of the reconstituted Fabrazyme solution into the 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.



5.5 STEP 5: Slowly withdraw the reconstituted solution from each vial up to the total volume required

5.5 STEP 5: The reconstituted product should not contain any foam

5.6 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.

5.7 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 close by along with some gauzes.
2. Remove the infusion needle from the packaging.
3. Have the patient sit down and rest one arm on the table (preferably on a clean cloth).
4. Apply the tourniquet 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 (Logbook, Appendix 1) and open the valve. Sit down and relax while the infusion takes place.

5.8 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 if stored up to 24 hours 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 removed.

5.9 Preparation of the Fabrazyme infusion in case of venous access device

When the patient has a venous access device for the delivery of Fabrazyme, the patient and/or 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 home care of a venous access device involves regular irrigation with heparin to prevent clotting and attention to a sterile technique to keep the device free of infectious agents.

The patient and/or caregiver(s) will be informed of the following necessary steps:

- When in use, cover site with transparent occlusive dressing. No dressing is 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.

6. FABRAZYME SAFETY INFORMATION

Please refer to section 4 of the current Summary of Product Characteristics (SmPC) for complete information on the safety of Fabrazyme.

7. SAFETY REPORTING

An adverse event (AE) is defined as a y untoward physical, psychological or behavioral occurrence in a patient administered a medicinal product which does not necessarily have to have a causal relationship with this treatment. A serious adverse event (SAE) involves an occurrence defined as having at least one of the following outcomes or characteristics:

- Results in death.
- Is life-threatening (any event in which the patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe).
- Required in-patient hospitalisation or prolongation of an existing hospitalisation.
- Results in persistent or significant disability/incapacity (any adverse event that resulted in a substantial disruption of a person's ability to conduct normal life functions).
- Is a congenital anomaly/birth defect.
- Is an important medical event (any event that, based upon appropriate medical judgement, may jeopardise the patient and may require medical or surgical intervention to prevent one of the outcomes listed above).

Tilkynning aukaverkana: Tilkynna skal mistök við lyfjagjöf og allar aukaverkanir sem grunur er um að tengist lyfinu til Lyfjastofnunar, sjá leiðbeiningar og vefeyðublöð á vef stofnunarinnar: www.lyfjastofnun.is. Með því að tilkynna aukaverkanir er hægt að hjálpa til við að auka upplýsingar um öryggi lyfsins. Einnig er hægt að tilkynna aukaverkanir til fulltrúa Genzyme á Íslandi hjá Vistor hf. í síma 535 7000 eða senda tölvupóst á netfangið safety@vistor.is.

If the patient becomes aware that a mistake was made in the preparation and/or administration of the drug, the patient or infusion nurse should inform the treating physician to determine appropriate action. Any medication errors should be reported as a spontaneous report to Genzyme by the treating physician.

8. FURTHER INFORMATION

Please refer to the Summary of Product Characteristics (SmPC) for complete indication statements and further information about the approved use of Fabrazyme. Other detailed information on Fabrazyme is available at the following website: The European Medicines Agency (EMA) (see http://www.ema.europa.eu).

9. REFERENCES

1 Cousins A, Lee P, Rorman D, *et al* (2008) Home-based infusion therapy for patients with Fabry disease. *Br J Nurs* 17:653-7.

2 Hughes DA, Milligan A, Mehta A (2007) Home therapy for lysosomal storage disorders. *Br J Nurs* 16:1384, 6-9.

3 Parini R, Pozzi K, Di Mauro S, *et al* (2010) Intravenous enzyme replacement therapy: hospital vs home. *Br J Nurs* 19:892-4, 6-8.

4 Banikazemi M, Bultas J, Waldek S, *et al* (2007) Agalsidase-beta therapy for advanced Fabry disease: a randomized trial. *Ann Intern Med* 146:77-86.

5 Eng CM, Guffon N, Wilcox WR, *et al* (2001) Safety and efficacy of recombinant human alpha-galactosidase A-replacement therapy in Fabry's disease. *N Engl J Med* 345:9-16.

6 Germain DP, Waldek S, Banikazemi M, *et al* (2007) Sustained, long-term renal stabilization after 54 months of agalsidase beta therapy in patients with Fabry disease. *J Am Soc Nephrol* 18:1547-57.

10. APPENDICES

10.1 Logbook (*Dagbók fyrir innrennslisgjöf heima með Fabrazyme*)

Appendix 10.1

Dagbók fyrir innrennslisgjöf heima með Fabrazyme®

Samskiptaupplýsingar (sem meðferðarlæknir fyllir út)

Neyðarnúmer:

Sjúklingur	
Nafn:	
Fæðingardagur:	
Heimilisfang:	
Póstnr./Staður:	
Sími:	

Umönnunaraðili sjúklings	
Nafn:	
Heimilisfang:	
Póstnr./Staður:	
Sími:	

Apótek	
Nafn:	
Heimilisfang:	
Póstnr./Staður:	
Sími:	

Meðferðarlæknir	
Nafn:	
Sjúkrahús:	
Heimilisfang:	
Póstnr./Staður:	
Sími:	
Neyðarnúmer:	

Hjúkrunarfræðingur	
Nafn:	
Stofnun:	
Heimilisfang:	
Póstnr./Staður:	
Sími:	

Upplýsingar um lyfjagjöf (sem meðferðarlæknir fyllir út)

Fabrazyme gefið síðan:	Dags. (DD-MM-ÁÁÁÁ):
Fyrsta innrennslisgjöf heima:	Dags. (DD-MM-ÁÁÁÁ):

Skammtaáætlun fyrir Fabrazyme	
Skammtar:	
Tíðni:	
Innrennslishraði:	
Rúmmál af blöndu sem þarf (ml):	
Heildarrúmmál í innrennslispoka (ml):	
Lyf fyrir undirbúningsmeðferð (ef við á):	
Ástæður fyrir innrennslisgjöf með Fabrazyme heima:	
Niðurstöður og aðgerðir úr fyrsta viðtali:	
Lýsið stuðningi sem meðferðarhjúkrunarfræðingur þarf að veita heima:	

Nauðsynlegar aðgerðir við alvarlegum aukaverkunum vegna innrennslisgjafar

(meðferðarlæknir fyllir út)

1. Stöðvið innrennslisgjöf

2. Hringið í neyðarnúmer	
Símanúmer:	

3. Hringið í lækninn	
Símanúmer:	
Símanúmer (sólarhringsvakt):	
Nafn læknis:	
Nafn stofnunar:	
Heimilisfang:	

4. Neyðarlyf	
Neyðarlyf, ásamt skammti:	

5. Aðstandandi sjúklings sem þarf að láta vita	
Nafn:	
Símanúmer:	

Útgáfa 3. Yfirfarið af Lyfjastofnun í júní 2021

Fylla skal eyðublaðið út í hvert skipti sem innrennslisgjöf fer fram

- Sjúklingur og/eða umönnunaraðili hafa verið upplýstir um áhættu sem tengist innrennslisgjöf með Fabrazyme heima og rétta notkun neyðarlyfja.
- Ef upp koma einhver viðbrögð vegna innrennslisgjafar **skal stöðva hana þegar í stað.**
- Nauðsynlegar aðgerðir við alvarlegum viðbrögðum vegna innrennslisgjafar, **þ.m.t. upplýsingar um hvert skal snúa sér í neyðartilvikum,** eiga að koma fram í dagbókinni. Hafið upplýsingarnar tiltækar meðan á innrennslisgjöf stendur.

Skammtar	
Rúmmál af blöndu sem þarf (ml):	
Fjöldi hettuglasa sem er notaður:	5 mg hettuglös:
	35 mg hettuglös:
Tímalengd lyfjagjafar:	
Innrennslishraði:	
Vandamál/athugasemdir varðandi innrennslisgjöf ef við á (þ.m.t. viðbrögð vegna innrennslisgjafa(r), aðgerðir og niðurstöður):	
Almennt heilsufar sjúklings — Lýsið öllum breytingum á heilsufari sem koma upp fyrir innrennslisgjöf, ef einhverjar:	

Nafn þess sem er ábyrg(ur) fyrir innrennslisgjöf	
Dags. innrennslisgjafar:	Dags. (DD-MM-ÁÁÁÁ):
Hjúkrunarfræðingur:	
Umönnunaraðili (ef annar en hér að framan):	

Appendix 10.2

Adverse Event Form

Sjá leiðbeiningar og vefeyðublöð á vef Lyfjastofnunar, www.lyfjastofnun.is.

Útgáfa 3. Yfirfarið af Lyfjastofnun í júní 2021.