Fabrazyme® (agalsidase beta)
Home Infusion Therapy:

Logbook for agalsidase beta Home Infusion

Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme. You can report via:

- The Yellow Card website www.mhra.gov.uk/yellowcard
- The free Yellow Card app available from the Apple App Store or Google Play Store
- Some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.

When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine.

Suspected adverse reactions should also be reported to SANOFI on Tel: 0800 090 2314. Alternatively, send via e-mail to **UK-drugsafety@sanofi.com**.

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

MAT-GB-2100395(v1.0). Date of preparation: March 2021.
MHRA approval date: March 2021.

Contact details (to be completed by treating physician)

Emergency Number:

Patient	
Name:	
Date of birth:	
Address:	
Postcode/City:	
Telephone:	

Patient's Caregiver	
Name:	
Address:	
Postcode/City:	
Telephone:	

Pharmacy	
Name:	
Address:	
Postcode/City:	
Telephone:	

Treating physician	
Name:	
Hospital:	
Address:	
Postcode/City:	
Telephone:	
Emergency:	

Nurse	
Name:	
Organisation:	
Address:	
Postcode/City:	
Telephone:	

Administration details (to be completed by treating physician)

Date of first administration:	(DD-MM-YYYY):
First infusion at home:	(DD-MM-YYYY):

Agalsidase beta dosing regimen	
Dose:	
Frequency:	
Rate of infusion:	
Required reconstituted volume (ml):	
Total volume in infusion bag (ml):	
Pre-treatment medication: (if applicable)	
Reasons for agalsidase beta infusion at home:	
Findings and actions from the initial interview:	
Indicate support to be provided by infusion nurse at home:	

Necessary actions in the event of a serious infusion-associated reaction or hypersensitivity reaction

(to be completed by treating physician)

1. Stop the infusion

2. Call the emergency services: 999

3. Call your physician	
Telephone number:	
Telephone number (24hr):	
Name of physician:	
Name of clinic:	
Total volume in infusion bag (ml):	
Address:	

4. Emergency medication	
Medication, including dose:	

5. Patient's contact person to be notified	
Name:	
Telephone:	

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Indicate support to be provided by infusion nurse at home:	

5. Patient's contact person to be notified	
Date of infusion:	(DD-MM-YYYY):
Nurse:	
Caregiver (if different from above):	

Complete this form for every infusion session

- The patient and/or caregiver(s) have been informed about the associated risks of home infusion of agalsidase beta, 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 this Logbook. Keep this information readily available during the infusion procedure.

Date of first administration:	(DD-MM-YYYY):
First infusion at home:	(DD-MM-YYYY):

Dose	
Required reconstituted volume (ml):	
Number of vials used:	5mg vials:
	35mg vials:
Duration of administration:	
Rate of administration:	
Problems/Remarks related to the infusion, if any (including infusion-associated reaction(s), action taken, and outcome):	
Indicate support to be provided by infusion nurse at home:	

5. Patient's contact person to be notified	
Date of infusion:	(DD-MM-YYYY):
Nurse:	
Caregiver (if different from above):	

CERTIFICATE FOR NON-PROMOTIONAL ITEMS (PMCPA)

Version:	0 . 3
Document Number:	MAT-GB-2100395
Document Name:	UK Fabrazyme Risk Minimization Plan Patient Log Book
Country:	United Kingdom
Product:	Fabrazyme
Material Type:	Mail / e-mail
Material Intent:	Non-Promotional
Certification Type:	Certification
Audience:	Consumer / Patient, Healthcare Professionals
Additional Audience:	To be distributed to patients by HCPs treating Fabry Disease (metabolic specialists)
Intended Use:	External Use
Method of Dissemination:	Print, Pro-active
Material Owner:	Emily Goffin

I have examined the final form of the material and in my belief it is in accordance with the requirements of the relevant regulations relating to advertising and this Code, and is a fair and truthful representation of the facts.

Role	Signature
Carla Starita - Medical	Date: 24-Mar-2021 17:56:01 GMT+0000