ELFABRIO®▼ (PEGUNIGALSIDASE ALFA)

IMPORTANT INFORMATION:
on minimising the risk of hypersensitivity reactions and medication errors in home settings

Logbook

This educational material is provided by Chiesi Limited as part of the Risk Management Plan for Elfabrio

IE Version No: 3.0 September 2026

Reporting of side effects
If you experience any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this material. You can also report side effects directly to the HPRA at www.hpra.ie or to Chiesi Limited on 1800 817459 (IE) or PV.UK@Chiesi.com.
By reporting side effects, you can help provide more information on the safety of this medicine.
▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may experience.

Logbook for Pegunigalsidase Alfa Home Infusion

This Logbook is designed to assist with the administration of pegunigalsidase alfa. The Logbook should be kept as a record of when pegunigalsidase alfa is administered. Included within the Logbook is relevant information such as contact details for relevant healthcare professionals (HCPs) associated with the administration of pegunigalsidase alfa and how and where to report adverse drug reactions (details of which are included on the front and back covers of this Logbook).

If you require additional/replacement copies of the Logbook or if you, or one of your healthcare team have any questions, please contact Chiesi at **medinfo.uk@chiesi.com** or **+44 161 488 5555**

Checklist for Home Infusion Organisation

- ☐ 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, and agrees to the treatment at home.
- ☐ The patient and/or caregiver(s) understand the illness and have been trained to recognise possible adverse events, including infusion-related reactions (IRRs) and understand the procedure to be followed in case they occur (i.e., notify symptoms suggestive of adverse drug reactions [ADRs] to the HCP for proper assessment and management).
- ☐ 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 pegunigalsidase alfa and other infusion supplies.
- ☐ Ensure that a HCP is available at all times during the home infusion and a specified time after infusion, as per national regulations. The patient should not be alone at home, but with a caregiver capable of stopping the infusion and giving the alert in the event of an IRR. The patient has been informed that the infusion should always be administered in the presence of the caregiver adequately trained on how to manage in case of ADRs, IRRs and medication errors in agreement with the local requirements for the implementation of the home infusion therapy.

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

Emergency number:

CONTACT DETAILS		
Patient	Name:	
	Date of birth:	
	Address:	
	City / Postcode:	
	Telephone:	
Patient's caregiver contact details	Name:	
	Address:	
	City / Postcode:	
	Telephone:	
Home infusion nurse	Name:	
	Organisation:	
	Address:	
	City / Postcode:	
	Telephone:	
Treating physician	Name:	
	Hospital:	
	Address:	
	City / Postcode:	
	Telephone:	
	Emergency number:	
Pharmacy	Name:	
	Address:	
	City / Postcode:	
	Telephone:	
Irish national emergency number		

Administration details *(to be completed by treating physician)*

Pegunigalsidase alfa administered since	Date (dd-mm-yyyy):	
First pegunigalsidase alfa infusion at home	Date (dd-mm-yyyy):	
Pegunigalsidase alfa dosing regimen		
- Weight (kg)		
- Dose (mg)		
- Frequency (once every 2 weeks or once every 4 weeks) and day of the week		
- Number of pegunigalsidase alfa vials to be used	10ml vials	2.5ml vials
- Volume of pegunigalsidase alfa to be used (ml)		
- Volume of 0.9% sodium chloride to be removed and discarded (ml)		
- Minimum total volume to be infused (ml) based on body weight <70 kg - 150 ml 70-100 kg - 250 ml >100 kg - 500 ml		
- Rate of infusion (ml/hr)		
Pre-treatment medication (if applicable)		
Reasons for pegunigalsidase alfa infusion at home		
Findings and actions from the initial interview		
Indicate support to be provided by home infusion nurse		

Infusion Session Form

(To be complete at each infusion session)

- The patient and/or caregiver(s) have been informed about the associated risks of home infusion of pegunigalsidase alfa, and proper education on the use of emergency medications has been provided.
- The management of infusion-related reactions (IRRs) should be based on the severity of the reaction. For mild to moderate reactions, the infusion rate may be reduced and, if needed, medications may be administered to help manage symptoms, such as allergy medicines (antihistamines), medicines to reduce fever (antipyretics), and/or steroids (corticosteroids) to control inflammation. If severe hypersensitivity reactions (including anaphylaxis) occur, the infusion should be stopped immediately and urgent medical attention sought.
- Any patients experiencing side effects during the home infusion need to immediately stop the infusion process and seek the attention of a healthcare professional. Subsequent infusions may need to occur in a clinical setting.

Date of Infusion	Date (dd-mm-yyyy)	
Patient's general health status - Describe any new health issues that you are currently experiencing prior to infusion, if any		
Dose (mg)		
Required pegunigalsidase alfa volume (ml)		
Number of pegunigalsidase alfa vials used	10ml vials	2.5ml vials
Preparation completion time		
Start time of infusion		
Duration of administration		
Infusion rate (ml/hr)		
End time of Observation Period		
Problems/Remarks related to the infusion, if any (including infusion related reaction(s), action taken, and outcome)		
Name of person responsible for infusion, and date - home infusion nurse - caregiver (if different from above)		

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Notes

Adverse events should be reported to HPRA Pharmacovigilance, Website: www.hpra.ie. Adverse events should also be reported to Chiesi Limited on 1800 817459 (IE) or PV.UK@Chiesi.com.
▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

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