

# ELFABRIO®▼ (PEGUNIGALSIDASE ALFA)

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

## Logbook

IE version No. 1 December 2023

Adverse events should be reported to HPRA Pharmacovigilance, Website: [www.hpra.ie](http://www.hpra.ie). Adverse events should also be reported to Chiesi Limited on 1800 817459 (IE) or [PV.UK@Chiesi.com](mailto: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.

## Logbook for ELFABRIO Home Infusion

This Logbook is designed to assist with the administration of ELFABRIO. The Logbook should be kept as a record of when ELFABRIO is administered. Included within the Logbook are relevant information such as contact details for relevant healthcare professionals (HCPs) associated with the administration of ELFABRIO 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 ELFABRIO 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)

<b>Emergency number:</b>		
<b>CONTACT DETAILS</b>		
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)*

ELFABRIO administered since	Date (dd-mm-yyyy):
First ELFABRIO infusion at home	Date (dd-mm-yyyy):
ELFABRIO dosing regimen	
- Weight (kg)	
- Dose (mg)	
- Frequency (once every 2 weeks) Day of the week	
- Number of ELFABRIO vials to be used	
- Volume of ELFABRIO 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 ELFABRIO 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 ELFABRIO, and proper education on the use of emergency medications has been provided.
- The management of IRRs must be based on the severity of the reaction. For mild to moderate reactions, management should include slowing the infusion rate and treatment with medicinal products such as antihistamines, antipyretics and/or corticosteroids. If severe hypersensitivity reactions or anaphylactic reactions occur, immediately seek medical attention and stop the infusion. The Treating Physician will provide medical attention if required.
- Any patients experiencing adverse events 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.

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Patient's general health status - Describe any new health issues that you are currently experiencing prior to infusion, if any	
Dose (mg)	
Required ELFABRIO volume (ml)	
Number of ELFABRIO vials used	
Start time of preparation of infusion	
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**

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to Chiesi Limited on 1800 817459 (IE) or [PV.UK@Chiesi.com](mailto: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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