ELFABRIO®▼ (PEGUNIGALSIDASE ALFA)

IMPORTANT INFORMATION:

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

Information for Patients, Caregivers and Healthcare Professionals

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

If you are a patient or carer please always refer to your healthcare team

This booklet fulfills the conditions of the marketing authorisation and has been approved by the HPRA.
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For healthcare professionals:
▼ 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. This will allow quick identification of new safety information.

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 Pharmacovigilance 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.

LIST OF ABBREVIATIONS

ADR	Adverse drug reaction
CVAD	Central venous access device (central Line)
HCP	Healthcare professional
HPRA	Health Products Regulatory Authority
IRR	Infusion-related reaction
IV	Intravenous
PF	Pre-Filled (Heparin syringe)
SmPC	Summary of Product Characteristics

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1. OBJECTIVE OF THIS GUIDE

The objective of this document is to provide relevant information for the Patient/Caregiver/Healthcare Professional (HCPs) to administer pegunigalsidase alfa at home and to prevent medication errors.

Administration of pegunigalsidase alfa at home may be considered for patients who are tolerating their infusions well.

The decision to transfer pegunigalsidase alfa treatment to the patient's home setting is made by the treating physician according to patient's preferences and medical status.

2. REQUIREMENTS FOR HOME INFUSION

2.1. Drug and Infusion Equipment Supplies

Treatment medicine, pre-medication and emergency treatment and supplies, as well as all necessary equipment will be provided to the patient's home according to local arrangements and regulations (hospital/pharmacy to the patient or to a third party with the appropriate prescription).

Transport from the pharmacy/warehouse must comply with the following details of the transport chain as well as compliance with the following activities:

- Temperature control of drug during transport from pharmacy/warehouse to patient's home.
- The temperature monitoring device must be checked to confirm the drug experienced no temperature deviation during the shipping process (it is considered a deviation if temperature <2 or >8 °C).

2.1.1. ELFABRIO (pegunigalsidase alfa)

Vials of pegunigalsidase alfa (20 mg or 5 mg vials), will be provided as a liquid in clear glass 10 ml or 2.5 ml vials closed with rubber stoppers and sealed with aluminium flip off cap. They must be stored in a clean refrigerator at a temperature of between +2 °C and +8 °C. Do not freeze or shake.

2.1.2. Infusion Equipment

- IV Pole
- Infusion pump
- Bio-waste container
- Alcohol wipes
- Non-sterile gloves
- 30 ml syringe
- 2 x Needle free valves
- 2 x 0.9% Sodium chloride 10 ml syringes
- IV catheter/Huber/extension set (as needed)
- IV Start Kit/Central Line Kit per access type
- Cadd In-line 0.2-micron IV tubing
- Vented vial access spike
- 18-gauge needle
- Tape
- 10 ml syringe
- 3 ml syringe
- Heparin 100 IU/ml PF 5ml/12 ml syringe (for central lines only)
- Hibiclens
- Sodium chloride 0.9% IV bag(s) according to the dilution needs
- Emergency Kit
- Tourniquet
- Pre-infusion medication (if applicable)

NOTE: This is the typical requirement for the infusion equipment but this may vary depending on local arrangements.

2.1.3. Pre-Infusion Treatment

Pre-treatment with antihistamines and/or corticosteroids, if administered in the hospital or other medical setting, 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.

2.1.4. Emergency Equipment and Medication

The Irish national emergency number and/or the treating physician must also be called if an infusion related reaction (IRR) occurs after completion of the infusion. Any IRR must be reported according to local rules and regulations.

- An available, rapid and reliable line of communication must be ensured to expedite emergency response in case immediate medical attention is required, as per indications reported in Section 5.2 and the Logbook (Section 3).
- In the event the patient experiences an adverse event (see Section 5.1) during or shortly after the infusion, the procedure indicated in Section 5.2 are to be followed. The infusion should be discontinued immediately and the treating physician should be contacted to seek advice. Subsequent infusions may need to occur in a hospital or other medical setting.

Emergency Kit will consist of:

- Airway
- Ambu Mask
- Pulse Oximeter
- 1000cc Hartman or Lactated Ringer's
- Antihistamine, as prescribed by the treating physician
- Any additional items per the treating physician's order (i.e., adrenaline, methylprednisolone)
- 2 IV 0.2 µm filters
- Any additional items per the treating physician's order.

NOTE: This is the typical requirement for the Emergency Kit but this may vary depending on local arrangements.

The **Emergency Kit** will be provided in a locked Emergency Box, adequately labelled.

Should patients experience, or should the home infusion nurse or caregiver(s) identify, any adverse drug reaction (ADR) or any problem with the dilution and administration of pegunigalsidase alfa, they need to contact the treating physician immediately. Subsequent infusions may need to occur in a hospital or other medical setting at the discretion of the treating physician.

3. THE LOGBOOK

The Logbook is herewith attached as Appendix 1.

The Logbook serves as a means of communication for all involved in administering pegunigalsidase alfa in the home-setting.

The 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).

The Logbook must be kept at the patient's home and will be updated by the home infusion nurse/patient/caregiver(s) each time pegunigalsidase alfa 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 infusion volume, infusion rate, as well as any changes. The treating physician clearly states what must be done and which procedures are to be followed and what medications are to be administered in the event of a serious IRR, in line with current medical standards for emergency treatment. The contact details of the treating physician and the Irish National Emergency Number are documented in the Logbook ***(resource contact list)***.

The pegunigalsidase alfa dose required, frequency, 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, volume or infusion rate) must again be reported in the Logbook. It is important to keep this guide handy and review the method of administration regularly. This will ensure optimal practice as well as an effective way of communicating with the treating physician.

4. STEP BY STEP INSTRUCTIONS ON PREPARING AND ADMINISTERING PEGUNIGALSIDASE ALFA

Each administration of pegunigalsidase alfa should be recorded in the Logbook (Appendix 1). In case of any problems with the dilution and administration of pegunigalsidase alfa, the patient or caregiver(s) should contact the treating physician to determine appropriate action before starting or continuing with the infusion as detailed in the Logbook.

The infusion should always be administered in the presence of a caregiver knowledgeable about the infusion procedures and adequately trained on how to handle the situation in case of an IRR and medication errors, as assessed by the treating physician or home infusion nurse.

4.1. Drug Preparation and Administration – Process Flow Diagram

Preparation of Infusion Bag

- Prior to starting the preparation, confirm that all equipment is available to prepare the infusion bag
- Receive drug vials in a temperature controlled shipment
- Confirm shipping container is sealed and intact and check the temperature monitoring device for any alarm
- Allow vials to sit at room temperature (30 minutes) and check they are colourless and free of any visible particles
- Record batch number and expiration date for each of the vials in the Logbook
- Check the Logbook for dose and diluent specifications
- Proceed with drug preparation as described in the instructions
- Record dose, and date/time of preparation in the Logbook

Preparation for Administration of Drug Infusion

- Assess pre-medications
- Confirm contents and expiration dates of all items in the Emergency Kit
- Confirm the infusion pump is charged (check battery status and inform the treating physician when replacement is needed)
- Confirm dose settings on the infusion pump. Collect pre-infusion vital signs (within 10 minutes before the infusion)
- Insert IV catheter or prepare central venous access

Administration of Drug Infusion

- Prime the line with saline. The prime volume may differ based on specific pump/tubing used
- Connect primed tubing to prepared infusion bag and to IV/central venous access
- Administer infusion of pegunigalsidase alfa according to instructions. Record start time of infusion
- Collect vital signs every 30 minutes until end of infusion
- Monitor for signs of infusion reaction
- Empty infusion bag indicates end time of infusion and start time of clinical observation

Clinical Observation

- Flush the line with 20 ml of saline at the same infusion rate as the infusion
- Disconnect infusion tubing from the IV line
- Leave the cannula/central venous access clear
- Evaluate the infusion site to ensure there is no reaction
- Collect vital signs every 60 minutes and at the end of clinical observation
- Record end time of observation period
- Properly dispose of all used supplies, according to local procedures, in biohazard bag or sharps container as appropriate

4.2. Preparation of pegunigalsidase alfa infusion

If the patient/caregiver or HCP becomes aware that a mistake was made in the preparation and/or administration of pegunigalsidase alfa, the patient/caregiver or HCP should inform the treating physician, so he/she determines appropriate action.

Maintain strict asepsis while performing all preparation activities

1. Prepare a clean, flat, work area and lay out the requisites.
2. Keep the provided Emergency Kit nearby during the infusion.

Verify if the number of vials received is correct and the temperature monitoring device shows the correct information. **NOTE: IF THERE IS AN ALARM ON THE TEMPERATURE LOG, DO NOT START THE INFUSION. CALL THE HOME INFUSION ORGANISATION CONTACT IMMEDIATELY FOR FURTHER INSTRUCTION.**

3. Check lot numbers, expiration dates (do not use pegunigalsidase alfa after the labelled expiry date), and current prescription, then remove the correct number of boxes to prepare the prescribed dose. Vials are for single use only.
4. Allow the required number of vials to reach room temperature prior to dilution (approximately 30 minutes).
5. Wash hands with soap and water.
6. Prepare the infusion bag provided to initiate the process.
7. Remove the vials of pegunigalsidase alfa from their boxes, inspect vials. Do not use if cap is missing or broken. Do not use if medication is discoloured or contains particulate matter.
8. Ensure vials of pegunigalsidase alfa have been allowed to warm to room temperature. Do not heat vials with hot water or in the microwave.

4.3. Dilution of pegunigalsidase alfa

The recommended dose should be diluted in 0.9% sodium chloride, to a total volume based on patient body weight. The recommended dose and infusion volume are detailed in the Logbook (Appendix 1).

NOTE: In some specific cases, pegunigalsidase alfa may be prepared at the pharmacy and shipped (in a cooler box) under temperature-controlled conditions (2 – 8 °C) with a temperature monitoring device to the patient's location for administration.

1. Remove the protective flip off cap from the pegunigalsidase alfa vials, and aseptically wipe each rubber seal with an alcohol pad, using one pad for each vial, and allow to dry.
2. Wipe the injection port of the IV bag of 0.9% sodium chloride with an alcohol pad and allow to dry.
3. Attach an 18-gauge needle to the needle free valve.
4. Remove needle cap and insert the needle into the IV bag injection port.
5. Secure the connection of the needle-free valve to injection port of the IV bag with tape.
6. Cleanse the valve with a new alcohol pad and allow to dry completely.
7. Prior to adding pegunigalsidase alfa to the 0.9% sodium chloride IV bag, an equal volume of sodium chloride must be removed from the IV bag.

Example (for once every 2 weeks):

- Patient weight is 80 kg
- Patient prescribed dose is 1 mg/kg = 80 mg
- Pegunigalsidase alfa vial concentration is 20 mg/10 ml or 5 mg / 2.5 ml (2 mg/ml)
- An 80 kg patient would receive 40 ml of pegunigalsidase alfa and need 40 ml of sodium chloride removed from the IV bag prior to adding pegunigalsidase alfa

Example (for once every 4 weeks):

- Patient weight is 80 kg
- Patient prescribed dose is 2 mg/kg = 160 mg
- Pegunigalsidase alfa vial concentration is 20 mg/10 ml or 5mg / 2.5 ml (2 mg/ml)
- An 80 kg patient would receive 80 ml of pegunigalsidase alfa and need 80 ml of sodium chloride removed from the IV bag prior to adding pegunigalsidase alfa

8. Attach 30 ml syringe to needle free valve/clave and remove appropriate amount of 0.9% sodium chloride from IV bag, discard in the trash.
9. Attach a vented vial access spike to a sterile 10 ml syringe (and 3 ml syringe as needed).

10. Remove the protective cap of the vented vial access spike. While holding the vial of pegunigalsidase alfa firmly on the table, insert the spike into the centre of the rubber seal.
11. Invert the vial and withdraw the contents into the syringe.
12. Unscrew the syringe from the spike and attach the syringe directly to the needle free valve at the injection port of the IV bag. Slowly inject the medication into the IV bag. Do NOT inject in the airspace within the infusion bag.
13. Reattach the syringe to the spike and remove the spike from the empty vial. Now insert it into the next vial of pegunigalsidase alfa, while maintaining aseptic technique.
14. Repeat these steps until the total calculated dose of pegunigalsidase alfa has been transferred into the IV bag.

NOTE: calculated volume may require removal of less than maximum volume (10 ml or 2.5 ml - depending on which vial used) from the last vial used for the infusion (partial vial use).

15. Remove the needle free valve and 18-gauge needle from the injection port and dispose of in the bio-waste receptacle.
16. Discard all pegunigalsidase alfa vials in the bio-waste container and document any amount of medication discarded in the Logbook.
17. Gently invert IV bag to mix the solution, avoiding vigorous shaking or agitation

4.4. Administration

Diluted solutions of pegunigalsidase alfa should be used immediately. If immediate use is not possible, the diluted solution may be stored for up to 24 hours in the refrigerator (2 °C – 8 °C) or 8 hours at room temperature (stored below 25 °C), away from light.

If medication cannot be used during these time frames it must be discarded. IMMEDIATELY CONTACT the treating physician's emergency line.

Time of preparation should be the time when the infusion preparation is finished and ready to be administered to the patient.

The pegunigalsidase alfa 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.

Infusion will be administered intravenously (IV) using a pre-programmed pump over a specified time period. The pump may be pre-set by the treating physician's team before the first home infusion.

NOTE: Settings on the pump will remain the same as programmed infusion settings. Monitor the pump screen display that indicates the amount infused. Note it in the Logbook (Appendix 1).

4.4.1. Procedure

- Remove the protective cap from the 0.2-micron Cadd administration tubing spike and insert into the infusion port of the IV bag containing pegunigalsidase alfa.
- Hang IV bag on IV pole and attach Cadd Cassette to pump.
- Obtain IV access.
- Prime the tubing and connect to the patient to start infusion. DO NOT prime fluid with the tubing connected to the patient.
- **Ensure medication is administered at infusion rate as prescribed by the treating physician.**
- The patient should be sat down and relaxed while the infusion takes place.
- Should any alarm occur, resolve the problem as per pump specific instructions
  - In case of "air in line", stop the infusion, disconnect the line from the patient and gently tap the line to move all bubbles close to the end of the line (to limit any drug wasting) and prime the line to ensure all air is removed.
  - If the pump shows a "down occlusion" alarm, check whether the tubing or needle has become blocked or kinked. If the blockage cannot be resolved, do not try to force fluid through the line. Insert a new needle at a different site and remove the blocked needle.
- In the case of a hypersensitivity reaction to the medication, or emergency, refer to Section 5.1 and Section 5.2.
- The pump will alarm at the end of the infusion. An empty infusion bag indicates the end time of infusion and the start time of the clinical observation period (see Section 4.3).

NOTE: Do not remove the IV access at this time.

- Flush the infusion line with 20 ml of saline.
- Once the pump indicates 20 ml has been infused, manually stop the pump.
- Remove the infusion tubing from the patient's IV cannula or Central Venous Access Device (CVAD).

NOTE: The IV access should remain in place throughout the end of infusion monitoring period.

At the end of the infusion, ***all IV bags and administration tubing*** can be disposed of into the household trash unless contaminated with visible blood. ***Contaminated tubing and IV needles*** should be disposed of into the bio-waste container.

4.4.2. Measurement of Vital Signs

Vital signs (blood pressure, body temperature, respiratory rate, and heart rate) will be collected at least 10 minutes pre-infusion, every 30 minutes during infusion and at end of the infusion.

During the post-dosing clinical observation period, vital signs will be collected every 60 minutes and at the end of the visit/observation period.

4.5. Observation Period

The patient should be observed for two hours after the infusion in case of IRR.

5. PEGUNIGALSIDASE ALFA SAFETY INFORMATION: INFUSION RELATED REACTION (IRR)

Pegunigalsidase alfa has been shown to have good tolerability, however, being an IV protein product, hypersensitivity reactions including severe ones cannot be ruled out and these are commonly known as IRRs.

IRRs defined as any related adverse events with onset after start of infusion and up to 2 hours after end of infusion have been reported (see also section 4.8 of SmPC).

5.1. Identification

IRRs, including severe hypersensitivity reactions or anaphylactic reactions can occur following treatment with pegunigalsidase alfa. The most commonly observed symptoms of IRRs with pegunigalsidase alfa were hypersensitivity, itching, feeling sick, shivering, feeling cold, dizziness, and muscular pain.

Symptoms of hypersensitivity and serious allergic reactions include tightening of the airways causing difficulty breathing (bronchospasm), swelling of the face, mouth and throat, wheezing, low blood pressure, hives, difficulty swallowing, rash, shortness of breath, flushing, chest discomfort, itchiness, sneezing and nasal congestion.

5.2. Treatment and Management

Any patients experiencing adverse events during the home infusion need to immediately stop the infusion process and seek the attention of a HCP. Subsequent infusions may need to occur in a clinical setting.

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/immune response. If severe hypersensitivity reactions (including anaphylaxis) occur, the infusion should be stopped immediately and urgent medical attention sought.

6. CALL FOR REPORTING

Reporting suspected side effects is important. See page 1 for reporting information. It allows continued monitoring of the benefit/risk balance of the medicinal product. 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.***

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

7. FURTHER INFORMATION

Please refer to the Summary of Product Characteristic or the Patient Information leaflet for complete indication statements and further information about the approved use of pegunigalsidase alfa. Patients can refer to the Patient Package Leaflet (PIL) for further information. Other detailed information on pegunigalsidase alfa is available at the following ***website: The European Medicines Agency (EMA) (see http://www.ema.europa.eu).***

8. APPENDIX 1 – LOGBOOK

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.

Logbook for pegunigalsidase alfa Home Infusion

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	10 ml vials	2.5 ml 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/immune response. If severe hypersensitivity reactions (including anaphylaxis) occur, the infusion should be stopped immediately and urgent medical attention sought.
- 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.

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	10 ml vials	2.5 ml 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)		

Notes

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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