Elfabrio Home Infusion Nursing Order Form

Please fax completed form to Chiesi Total Care℠ staff at 1-636-355-3610.

PATIENT INFORMATION

Patient Name (Last, First) _____

Social Security # _____ - _____ - _____ Sex: ☐ Male ☐ Female Date of Birth _____/_____/_____ (mm/dd/yyyy)

Address _____ City _____ State _____ ZIP _____

Primary Phone (Required) _____ Cell Phone _____ Language: ☐ English ☐ Other _____

MEDICAL INFORMATION

Diagnosis: ☐ Fabry (-Anderson) disease E75.21

Height _____ inches or _____ cm Weight _____ lb or _____ kg Allergies: ☐ None ☐ Specify _____

Prior Therapies _____

Current Medications _____

History of Infusion-Related Reactions _____

ELFABRIO® (PEGUNIGALSIDASE ALFA-IWXJ) 20 mg/10 mL ORDER

Total Dose (mg) Per Infusion _____

Directions _____

_____

Quantity (1-month supply) _____

Number of Refills _____

Infusion Rate (mL/hour) _____

The recommended dosage is 1 mg/kg of body weight every 2 weeks, administered as an intravenous infusion.

NURSING ORDERS

- The recommended dose is 1 mg/kg of body weight
  - – Number of vials per infusion (round up to a whole # if the calculated # of vials is a fraction) = Patient dose (mg) ÷ 20 mg (contents of 1 vial)
  - – Dilute per label instructions
  - – Infusion duration is calculated individually, with a minimum infusion duration of 90 minutes

Recommended Infusion Rate for Initial Elfabrio IV Infusions Based on Patient's Actual Weight:

Patient's Actual Weight	Total Infusion Volume	Infusion Rate
up to 70 kg	150 mL	0.83 mL/min (50 mL/h)
70 - 100 kg	250 mL	1.39 mL/min (83 mL/h)
>100 kg	500 mL	2.78 mL/min (167 mL/h)

- **Infusion rate may be increased if the patient tolerates the initial 4-6 Elfabrio infusions. Infusion rate may be slowed in case of hypersensitivity reaction or an infusion-associated reaction**

- Vital sign monitoring:

  DBP _____ SBP_____ Heart Rate _____

- Intravenous access and flush orders:
  - ☐ Sodium chloride 0.9% flushes PRN
  - ☐ Peripheral IV line:
    - – Recommend to place distally on the dominant arm
    - – Postinfusion: sodium chloride 0.9% _____
  - ☐ Implanted port:
    - – Postinfusion upon de-access: sodium chloride 0.9% _____ and heparin (100 units/mL) _____
  - ☐ Central line:
    - – Postinfusion: sodium chloride 0.9% _____ and heparin (_____ units/mL) or sodium citrate (_____ units/mL)

PHYSICIAN/OFFICE INFORMATION

Physician's Name (Print) _____ Practice/Group Name _____

Address _____ Suite _____

City _____ State _____ ZIP_____

Office Contact Person _____ Office Phone _____

Emergency Cell Phone _____ Office Fax _____

License # _____ NPI # _____

For more information, visit hcp.elfabrio.com.

PP-EF-0315 V1.0

Please see Important Safety Information for Elfabrio, including Boxed Warning concerning hypersensitivity reactions including anaphylaxis, on page 4 of this form and accompanying Full Prescribing Information.

Please call Chiesi Total Care℠ at 1-833-656-1056 if you have any questions regarding this form.

Elfabrio Home Infusion Nursing Order Form (cont'd)

MEDICATION ORDERS

Select medication(s) needed for this administration:

☐ EMLA™ Cream
- ☐ Premedication dose _____
- Physician Directions _____
- Quantity _____ Refills _____

☐ Methylprednisolone
- ☐ Premedication dose _____
- ☐ Allergic reaction dose _____
- Physician Directions _____
- Quantity _____ Refills _____

☐ PO Acetaminophen
- ☐ Premedication dose _____
- ☐ Allergic reaction dose _____
- Physician Directions _____
- Quantity _____ Refills _____

☐ Famotidine
- ☐ Premedication dose _____
- ☐ Allergic reaction dose _____
- Physician Directions _____
- Quantity _____ Refills _____

☐ Diphenhydramine
- ☐ Premedication dose _____
- ☐ Allergic reaction dose _____
- Physician Directions _____
- Quantity _____ Refills _____

☐ Albuterol sulfate inhalation aerosol for oral inhalation
- ☐ Premedication dose _____
- ☐ Allergic reaction dose _____
- Physician Directions _____
- Quantity _____ Refills _____

☐ Epinephrine auto-injector
- Physician Directions _____
- Quantity _____ Refills _____

☐ Other: _____
- ☐ Premedication dose _____
- ☐ Allergic reaction dose _____
- Physician Directions _____
- Quantity _____ Refills _____

☐ Emergency kit:
- Epinephrine auto-injector
- PPE for administering CPR

MANDATORY OFFICE CHECKLIST

☑ Please confirm that you have completed each of the following steps:

☐ The patient has had successful infusions in an outpatient setting

☐ The patient is medically stable and safe for home infusion therapy

☐ The patient has been prescribed an epinephrine auto-injector

☐ The patient lives in an area where emergency medical services are available

By signing below, I certify that I am the prescribing provider mentioned above, that I am part of the Chiesi Total Care℠ Program, that the therapy described above is medically necessary, and that all the medical necessity information is true, accurate, and complete. The patient's records contain supporting documentation that substantiates the utilization and medical necessity of the products marked above. I provide permission to use my personal information and the personal information of the patient provided above to facilitate this request and complete any regulatory or legal requirements associated with this request. I understand that the personal information provided herein may be shared with Chiesi, successors, and their agents and service providers as needed to support this request. I also attest that I have obtained the patient's authorization to release the above information and such other personal information as may be necessary for the Chiesi Total Care Program and/or their agents and service providers. If the patient is 18 years old or younger, I attest that I have obtained permission from the patient's legal guardian. If my patient is eligible for free product, I understand that receiving free product is not contingent on any purchase obligations. I also understand that no free product may be submitted for reimbursement to any payer, including Medicare and Medicaid; nor may I bill any payer for administration of such product. I understand that any falsification, omission, or concealment of material fact may result in criminal liability.

X _____

Treating Physician's Signature **Date**

Please see Important Safety Information for Elfabrio, including Boxed Warning concerning hypersensitivity reactions including anaphylaxis, on page 4 of this form and accompanying Full Prescribing Information.

Please call Chiesi Total Care℠ at 1-833-656-1056 if you have any questions regarding this form.

Elfabrio Home Infusion
Nursing Order Form (cont'd)

ADDITIONAL PHYSICIAN ORDERS

Please see Important Safety Information for Elfabrio, including Boxed Warning concerning hypersensitivity reactions including anaphylaxis, on page 4 of this form and accompanying Full Prescribing Information.

Please call Chiesi Total Care℠ at 1-833-656-1056 if you have any questions regarding this form.

Elfabrio Home Infusion
Nursing Order Form (cont'd)

Indication
Elfabrio® (pegunigalsidase alfa-iwxj) is indicated for the treatment of adults with confirmed Fabry disease.

Important Safety Information

WARNING: HYPERSENSITIVITY REACTIONS INCLUDING ANAPHYLAXIS

Patients treated with Elfabrio have experienced hypersensitivity reactions, including anaphylaxis. Appropriate medical support measures, including cardiopulmonary resuscitation equipment, should be readily available during Elfabrio administration. If a severe hypersensitivity reaction (eg, anaphylaxis) occurs, discontinue Elfabrio immediately and initiate appropriate medical treatment. In patients with severe hypersensitivity reaction, a desensitization procedure to Elfabrio may be considered.

Prior to Elfabrio administration, consider pretreating with antihistamines, antipyretics, and/or corticosteroids. Inform patients and caregivers of the signs and symptoms of hypersensitivity reactions and infusion-associated reactions (IARs), and instruct them to seek medical care immediately if such symptoms occur.

- If a severe hypersensitivity reaction (including anaphylaxis) or severe IAR occurs, immediately discontinue Elfabrio administration and initiate appropriate medical treatment.
- If a mild to moderate hypersensitivity reaction or IAR occurs, consider slowing the infusion rate or temporarily withholding the dose.

In clinical trials, 20 (14%) Elfabrio-treated patients experienced hypersensitivity reactions. Four Elfabrio-treated patients (3%) experienced anaphylaxis reactions that occurred within 5 to 40 minutes of the start of the initial infusion. The signs and symptoms of hypersensitivity reactions and anaphylaxis included headache, nausea, vomiting, throat tightness, facial and oral edema, truncal rash, tachycardia, hypotension, rigors, urticaria, intense pruritus, moderate upper airway obstructions, macroglossia, and mild lip edema.

In clinical trials, 41 (29%) Elfabrio-treated patients experienced one or more infusion-associated reactions, including hypersensitivity, nausea, chills, pruritus, rash, chest pain, dizziness, vomiting, asthenia, pain, sneezing, dyspnea, nasal congestion, throat irritation, abdominal pain, erythema, diarrhea, burning sensation, neuralgia, headache, paresthesia, tremor, agitation, increased body temperature, flushing, bradycardia, myalgia, hypertension, and hypotension.

A case of membranoproliferative glomerulonephritis with immune depositions in the kidney was reported during clinical trials. Monitor serum creatinine and urinary protein-to-creatinine ratio. If glomerulonephritis is suspected, discontinue treatment until a diagnostic evaluation can be conducted.

When switching to Elfabrio from a prior enzyme replacement therapy, the risk of hypersensitivity reactions and infusion-associated reactions may be increased in certain patients with pre-existing anti-drug antibodies (ADAs). Consider monitoring IgG and IgE ADAs and clinical or pharmacodynamic response (eg, plasma lyso-Gb3 levels).

The most common adverse reactions (≥15%) were infusion-associated reactions, nasopharyngitis, headache, diarrhea, fatigue, nausea, back pain, pain in extremity, and sinusitis.

Please see Full Prescribing Information for Elfabrio.