



Getting Started Guide

Steps for starting a patient on
Elfabrio® (pegunigalsidase alfa-iwxj)

Visit chiesitotalcare.com or call
1-833-656-1056—we're ready to help!

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.


Please see additional Important Safety Information throughout and accompanying [Full Prescribing Information](#), including Boxed Warning, in pocket.




ELFABRIO[®]
(pegunigalsidase alfa-iwxj)

Step 1:

Fill out the Physician Order/Prescription Form



**Physician Order/Prescription &
Statement of Medical Necessity**



1. First prescription for the patient: Fax completed form to 1-636-355-3610
2. Subsequent prescription: May be e-script via EVERSANA® Life Science Services Specialty Pharmacy in your EMR/HMR system. Contact Chiesi Total Care™ at 1-833-656-1056 if you have questions regarding this form

PATIENT INFORMATION		
Patient Name (Last, First) _____		
Social Security # _____ - _____ - _____	Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female	Date of Birth ____/____/____ (mm/dd/yyyy)
Address _____ City _____ State _____ ZIP _____		
Primary Phone (Required) _____ Cell Phone _____ Language: <input type="checkbox"/> English <input type="checkbox"/> Other _____		
INSURANCE INFORMATION		
<input type="checkbox"/> No Insurance		
Primary Prescription Insurance	Primary Medical Insurance	Secondary Medical Insurance
Policy Holder _____	Policy Holder _____	Policy Holder _____
Policy ID # _____	Policy ID # _____	Policy ID # _____
Group # _____	Group # _____	Group # _____
Phone _____	Phone _____	Phone _____
<i>Please attach copies of patient insurance and prescription cards—front and back.</i>		
MEDICAL INFORMATION		
Diagnosis: <input type="checkbox"/> Fabry (-Anderson) Disease ICD-10-CM E75.21		
Height _____ inches or _____ cm	Weight _____ lb or _____ kg	Allergies: <input type="checkbox"/> None <input type="checkbox"/> Specify _____
Methods of Diagnosis (check all that apply):		
<input type="checkbox"/> Enzyme Assay <input type="checkbox"/> Genetic Testing <input type="checkbox"/> Tissue Biopsy <input type="checkbox"/> Other _____		
Prior treatment and dose: _____ Last date of prior treatment and dose: _____		
<i>Please attach copies of medical history/physical summary, most recent alpha-galactosidase A (alpha-Gal A), genotype, plasma globotriaosylsphingosine (lyso-Gb3), current medications, and allergies.</i>		
ELFABRIO® (PEGUNIGALSIDASE ALFA-IWXJ) 20 mg/10 mL PRESCRIPTION		
Dosage — Elfabrio (pegunigalsidase alfa-iwxj) 20 mg/10 mL vial		
Total Dose (mg*) _____	Route of Administration IV _____	Frequency* _____
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.		
*Quantity sufficient for a 28-day supply.		
Please list any additional treatment information, including follow-up evaluations: _____		

SITE OF SERVICE		
Preferred Acquisitions Channel:		
<input type="checkbox"/> Buy and Bill <input type="checkbox"/> Specialty Pharmacy to Bill		
Preferred Site of Infusion:		
<input type="checkbox"/> Prescribing Physician's Site-of-Care Office (if this option is selected, please proceed to the next section)		
<input type="checkbox"/> Alternate Site of Care <input type="checkbox"/> Hospital Outpatient <input type="checkbox"/> Other _____		
Name of Institution/Practice Name _____		Physician or Infusion Provider Name _____
Provider's Specialty _____		NPI # _____
Address _____ City _____ State _____ ZIP _____		
Office Contact _____		Email _____
Office Phone (and Extension) _____		Office Fax _____ Site Tax ID _____
<i>(Please continue on other side—signature required) — Please see Important Safety Information for Elfabrio, including Boxed Warning, on the back of this form and accompanying Full Prescribing Information.</i>		

A

Specify appropriate ICD-10 diagnosis code and medical information

ICD-10 Diagnosis Code

Fabry (-Anderson) Disease ICD-10-CM: E75.21

Please attach copies of medical history/physical summary, most recent alpha-galactosidase A (alpha-Gal A), genotype, plasma globotriaosylsphingosine (lyso-Gb3), current medications, and allergies.

Intended as a reference for coding and billing for product and associated services. Not intended to be a directive, nor does the use of the recommended code guarantee reimbursement. Providers are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.

ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification.

B

Specify prescription information¹

Example of completed form:

Actual Dose (mg*) 75 Frequency* Every 2 weeks Number of Refills 26

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

C

Specify site-of-service information

Preferred Acquisitions Channel

- Check the box for "Buy and Bill" if your practice will be purchasing the medication and billing the patient's insurance
- Check the box for "Specialty Pharmacy to Bill" if a specialty pharmacy is fulfilling the order and billing the patient's insurance

Preferred Site of Infusion

- Check the box for "Prescribing Physician's Site-of-Care Office" if the patient will receive infusions at your practice. If this option is selected, skip to the PHYSICIAN/OFFICE INFORMATION section
- If the patient will receive infusions at another location, check the box for either "Alternate Site of Care," "Hospital Outpatient," or "Other" and specify the facility. Then fill out the remaining areas in this section with the infusion facility's information

A

B

C

Important Safety Information (continued)

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.

Please see additional Important Safety Information throughout and accompanying Full Prescribing Information, including Boxed Warning, in pocket.

Important Safety Information (continued)

- 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.



Step 2:

Once you have completed the form:

1. Attach copies of the patient's insurance and prescription cards—front and back.
2. **First prescription for the patient:**
THE FIRST COPY OF THE FORM MUST BE FAXED FOR EACH PATIENT. Fax the completed form to Chiesi Total CareSM at 1-636-355-3610. Please complete one form per patient.
3. **Subsequent prescriptions:**
If you wish to send subsequent forms via e-script, please search for "Eversana Life Science Services Specialty Pharmacy" in your EMR/HMR's e-prescribing software.

A fillable PDF of the form can be downloaded and saved for future use. Scan the QR code to download a copy.



Important Safety Information (continued)

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 ($\geq 15\%$) were infusion-associated reactions, nasopharyngitis, headache, diarrhea, fatigue, nausea, back pain, pain in extremity, and sinusitis.

Please see additional Important Safety Information throughout and accompanying [Full Prescribing Information](#), including Boxed Warning, in pocket.

EMR, electronic medical record; HMR, home medicines review.

Reference: 1. Elfabrio. Prescribing Information. Chiesi Farmaceutici S.p.A.; 2023.

**For more information, visit elfabrio.com.
Chiesi Total CareSM is offered through EVERSANA[®] Life Science Services Specialty Pharmacy.**

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