Chiesi TOTAL care℠

Dosing and Administration Guide

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)

Dosing and administration designed with patients in mind[1]

Recommended dosing for IV infusions every 2 weeks

Recommended Dose:
1 mg/kg (actual body weight)

Initial 4-6 Infusions:
No less than 3 hours

Maintenance Infusions:
As short as **1.5 hours**

Sample infusion schedule

Please see the accompanying Full Prescribing Information (Table 1) for specific infusion volumes and rates.

- Maintenance infusion duration may decrease by 30 minutes every third infusion, based on patient tolerance and your recommendation. The minimum recommended duration of a maintenance infusion is 1.5 hours

Decreasing need for premedication over time[1]*

In ERT-experienced patients, consider continuing pretreatment for the initial Elfabrio infusions. **After 4-6 Elfabrio infusions, a decrease or discontinuation of premedications may be considered**.

*Premedications may include antihistamines, fever reducers, or corticosteroids.
ERT, enzyme replacement therapy; IV, intravenous.

Consider offering your patients home infusion[1]

Treatment in the comfort of their home:

- The initial 4-6 infusions must be administered in a medical facility
- After maintenance infusions have been established, infusions at home or in the clinic are available at your discretion†
  - The dosage should remain constant for home administration and should only be changed under the supervision of a healthcare professional

Chiesi Total Care℠ is here to help

Chiesi TOTAL Care℠

- The Chiesi Total Care Team will work with patients and their insurance for **home infusion coverage**†
- If home infusion is approved by a patient's insurance, **Chiesi Total Care may provide a certified infusion nurse and work with the patient's schedule to begin home infusions**
- Chiesi Total Care may assist with the coordination of infusions for patients whose insurance requires using infusion nurses other than those provided by Chiesi

†Patients receiving treatment or residing in MA or RI are not eligible for infusion assistance. To receive home infusion support, patients must be referred to home infusion by their prescribing physician. Please refer to the accompanying full Terms and Conditions for additional eligibility requirements.

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.

- 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.

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

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

For more information, visit elfabrio.com.
Chiesi Total Care℠ is offered through EVERSANA® Life Science Services Specialty Pharmacy.

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