HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use FERRIPROX safely and effectively. See full prescribing information for FERRIPROX.

FERRIPROX® (deferiprone) oral solution, for oral use
Initial U.S. Approval: 2011

WARNING: AGRANULOCYTOSIS AND NEUTROPENIA
See full prescribing information for complete boxed warning.

- **FERRIPROX can cause agranulocytosis that can lead to serious infections and death. Neutropenia may precede the development of agranulocytosis. (5.1)**
- **Measure the absolute neutrophil count (ANC) before starting FERRIPROX and monitor weekly while on therapy. (5.1)**
- **Interrupt FERRIPROX if infection develops and monitor the ANC more frequently. (5.1)**
- **Advise patients taking FERRIPROX to report immediately any symptoms indicative of infection. (5.1)**

----------INDICATIONS AND USAGE----------

FERRIPROX® is an iron chelator indicated for the treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate. (1)

Approval is based on a reduction in serum ferritin levels. There are no controlled trials demonstrating a direct treatment benefit, such as improvement in disease-related symptoms, functioning, or increased survival (1).

Limitations of Use

Safety and effectiveness have not been established for the treatment of transfusional iron overload in patients with other chronic anemias. (1)

----------DOSAGE AND ADMINISTRATION----------

25 mg/kg to 33 mg/kg actual body weight, orally, three times per day, for a total daily dose of 75 mg/kg to 99 mg/kg body weight. (2.1)

----------DOSAGE FORMS AND STRENGTHS----------

Oral Solution: 100 mg/mL (50 g/500 mL) (3)

----------CONTRAINDICATIONS----------

Hypersensitivity to deferiprone or to any of the excipients in the formulation. (4)

----------WARNINGS AND PRECAUTIONS----------

- Liver Enzyme Elevations: Monitor monthly and discontinue for persistent elevations. (5.2)
- Zinc Deficiency: Monitor during therapy and supplement for deficiency. (5.3)
- Embryo-Fetal Toxicity: Can cause fetal harm. (5.4)

----------ADVERSE REACTIONS----------

The most common adverse reactions are (incidence ≥ 5%) nausea, vomiting and abdominal pain, alanine aminotransferase increased, arthralgia and neutropenia. (5.1, 6)

To report SUSPECTED ADVERSE REACTIONS, contact ApoPharma at: Telephone: 1-866-949-0995 or FDA at 1-800-FDA-1088
Email: medicalsafety@apopharma.com or www.fda.gov/medwatch

----------DRUG INTERACTIONS----------

- Drugs Associated with Neutropenia or Agranulocytosis: Avoid co-administration. If co-administration is unavoidable, closely monitor the absolute neutrophil count. (7.1)
- UGT1A6 inhibitors: Avoid co-administration. (7.2)
- Polyvalent Cations: Allow at least a 4-hour interval between administration of FERRIPROX and drugs or supplements containing polyvalent cations (e.g., iron, aluminum, or zinc). (2.2, 7.2)

----------USE IN SPECIFIC POPULATIONS----------

Lactation: Advise not to breastfeed. (8.2)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

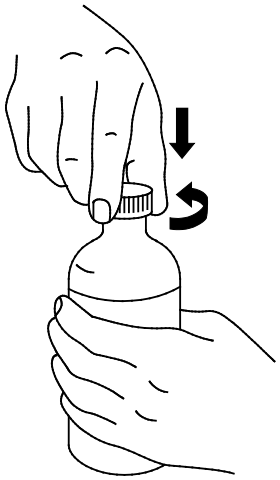
Revised: MM/YYYY

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

Step 1: To open the bottle of FERRIPROX oral solution, remove the outer plastic wrapper from the child-resistant cap. Push down on the child-resistant cap and turn the cap in the direction of the arrow **(See Figure B)**.

Figure B

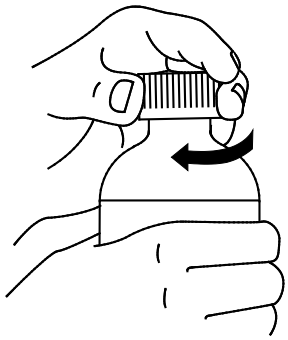


Step 2: Pour the prescribed dose of FERRIPROX oral solution into the measuring cup **(See Figure C)**.

Figure C

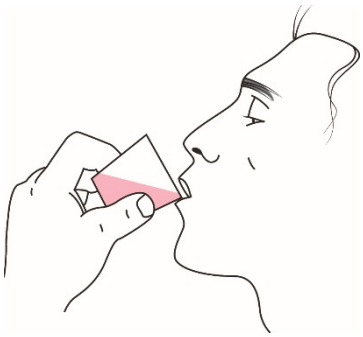
Step 3: Put the child-resistant cap back on the FERRIPROX oral solution bottle and turn it in the direction of the arrow. (**See Figure D**)

Figure D



Step 4: Swallow the prescribed dose of FERRIPROX oral solution (**See Figure E**).

Figure E



Step 5: Add about 10 to 15 mL of water to the measuring cup (**See Figure F**). Gently swirl the measuring cup to mix the water and any FERRIPROX oral solution left in the measuring cup (**See Figure G**). Drink all the mixture in the measuring cup (**See Figure H**).

Figure F

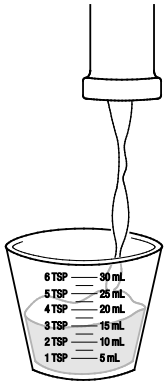


Figure G

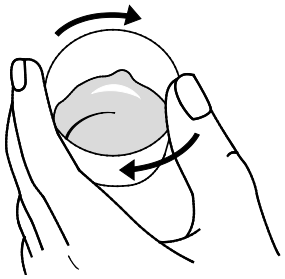
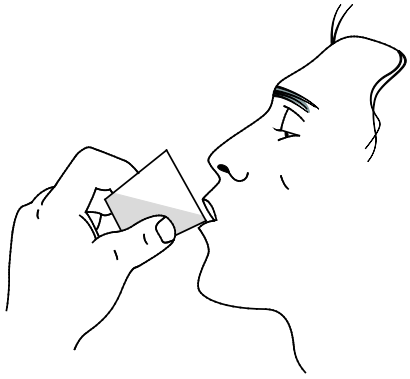


Figure H



Step 6: Hand-wash the measuring cup with water.

Step 7: Keep the measuring cup with the bottle of FERRIPROX oral solution.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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