Medication Guide

FERRIPROX® (Feh' ri prox)
(deferiprone)
oral solution

What is the most important information I should know about FERRIPROX?

FERRIPROX can cause serious side effects, including a very low white blood cell count in your blood. One type of white blood cell that is important for fighting infections is called a neutrophil. If your neutrophil count is low (neutropenia), you may be at risk of developing a serious infection that can lead to death. Neutropenia is common with FERRIPROX and can become severe in some people. Severe neutropenia is known as agranulocytosis. If you develop agranulocytosis, you will be at risk of developing serious infections that can lead to death.

Your healthcare provider should do a blood test before you start FERRIPROX and weekly during treatment to check your neutrophil count. If you develop neutropenia, your healthcare provider should check your blood counts every day until your white blood cell count improves.

Stop taking FERRIPROX and get medical help right away if you develop any of these symptoms of infection:

- fever
- sore throat or mouth sores
- flu-like symptoms
- chills and severe shaking

See **"What are the possible side effects of FERRIPROX?"** for more information about side effects.

What is FERRIPROX?

FERRIPROX is a prescription medicine used to treat people with thalassemia syndromes who have iron overload from blood transfusions, when current iron removal (chelation) therapy does not work well enough.

It is not known if FERRIPROX is safe and effective:

- to treat iron overload due to blood transfusions in people with any other type of anemia that is long lasting (chronic)
- in children

Who should not take FERRIPROX?

Do not take FERRIPROX if you are allergic to deferiprone or any of the ingredients in FERRIPROX. See the end of this Medication Guide for a complete list of ingredients in FERRIPROX.

Before you take FERRIPROX, tell your healthcare provider if you:

- have liver problems
- have any other medical conditions.
- are pregnant or plan to become pregnant. FERRIPROX can harm your unborn baby. You should avoid becoming pregnant while taking FERRIPROX. Tell your healthcare provider right away if you become pregnant or plan to become pregnant while taking FERRIPROX.
- are breastfeeding or plan to breastfeed. It is not known if FERRIPROX passes into your breast milk. You and your healthcare provider should decide if you will take FERRIPROX or breastfeed. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

Especially tell your healthcare provider if you take:

- other medicines that can cause a lowering of your neutrophil count
- antacids or mineral supplements that contain: iron, aluminum, and zinc. **Allow at least 4 hours between taking FERRIPROX and any of these products.**

How should I take FERRIPROX?

- Read the **Instructions for Use** for detailed instructions.
- Take FERRIPROX exactly as your healthcare provider tells you. Do not change your dose of FERRIPROX unless your healthcare provider tells you to.
- Your healthcare provider will tell you how much FERRIPROX to take.
- Use the measuring cup to measure the amount of FERRIPROX your healthcare provider tells you to take. Note that a teaspoonful (TSP) equals 5 milliliters (mL).
- Take FERRIPROX 3 times each day. Take your first dose in the morning, the second dose at mid-day, and the third dose in the evening.
- You can take FERRIPROX with or without food.
- Taking FERRIPROX with meals may help reduce nausea.
- **If you must take a medicine to treat indigestion (antacid), or mineral supplements that contain iron, aluminum, or zinc during treatment with FERRIPROX, allow at least 4 hours between taking FERRIPROX and these products.**
- If you take too much FERRIPROX, call your healthcare provider.
- If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and then continue with your regular schedule. Do not try to catch-up or take 2 doses at the same time to make up for a missed dose.

What are the possible side effects of FERRIPROX?

FERRIPROX can cause serious side effects, including:

- **See "What is the most important information I should know about FERRIPROX?"**
- **Increased liver enzyme levels in your blood.** Your healthcare provider should do monthly blood test to check your liver function during treatment with FERRIPROX.

The most common side effects of FERRIPROX include:

- reddish-brown colored urine. This is not harmful and is expected when you are taking FERRIPROX.
- nausea • vomiting • stomach-area (abdominal) pain • joint pain
- low neutrophil count. See "What is the most important information I should know about FERRIPROX?"

These are not all the possible side effects of FERRIPROX. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1 800-FDA-1088.

How should I store FERRIPROX?

- Store FERRIPROX at room temperature between 20°C to 25°C (68°F to 77°F).
- Store in the original bottle and carton to protect from light.
- After first opening, use a bottle of FERRIPROX oral solution within 35 days. After 35 days, throw away the bottle and any unused medicine that is still in the bottle.

Keep FERRIPROX and all medicines out of the reach of children.

General information about the safe and effective use of FERRIPROX.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use FERRIPROX for a condition for which it was not prescribed. Do not give FERRIPROX to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about FERRIPROX that is written for health professionals.

What are the ingredients in FERRIPROX?

Active ingredients: deferiprone

Inactive ingredients: purified water, hydroxyethylcellulose, glycerin, hydrochloric acid, artificial cherry flavor, peppermint oil, FD&C Yellow No. 6, and sucralose.

Distributed by:
ApoPharma USA, Inc., Weston, FL, United States of America, 33326.

Manufactured by:
Apotex Inc., Toronto, Ontario, Canada, M9L 1T9.

For more information, call 1-866-949-0995.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Issued: 05/2017