



Ferriprox[®]

deferiprone

1000 mg Tablets

500 mg Tablets

Medication Guide

Medication Guide
FERRIPROX® (Feh' ri prox)
(deferiprone) **tablets**

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. 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. Your healthcare provider may temporarily stop treatment with FERRIPROX if you develop neutropenia or infection.

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

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 about all of your medical conditions, including if you:

- have liver problems
- are pregnant or plan to become pregnant. FERRIPROX can harm your unborn baby. You should avoid becoming pregnant during treatment with FERRIPROX. Tell your healthcare provider right away if you become pregnant during treatment with FERRIPROX.

Females who are able to become pregnant:

- Your healthcare provider should do a pregnancy test before you start treatment with FERRIPROX.
- You should use effective birth control during treatment with FERRIPROX and for at least 6 months after the last dose.

Males with female partners who are able to become pregnant:

- You should use effective birth control during treatment with FERRIPROX and for at least 3 months after the last dose.
- are breastfeeding or plan to breastfeed. It is not known if FERRIPROX passes into your breast milk. Do not breastfeed during treatment with FERRIPROX and for 2 weeks after the last dose.

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

How should I take FERRIPROX?

- Take FERRIPROX exactly as your healthcare provider tells you.
- Your healthcare provider will prescribe FERRIPROX based on your body weight.
- Your healthcare provider will check your body iron level during treatment with FERRIPROX and may change your dose if needed. Your healthcare provider may also change your dose of FERRIPROX if you have certain side effects. Do not change your dose of FERRIPROX unless your healthcare provider tells you to.
- Take FERRIPROX 3 times each day. Take your first dose in the morning, the second dose at midday, and the third dose in the evening.
- 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 tests to check your liver function during treatment with FERRIPROX.
- **Decreased levels of zinc in your blood.** Your healthcare provider will do blood tests to check your zinc levels during treatment with FERRIPROX and may prescribe a zinc supplement for you if your zinc levels are low.

The most common side effects of FERRIPROX include:

- nausea
- vomiting
- stomach-area (abdominal) pain
- joint pain

FERRIPROX may cause a change in urine color to reddish-brown. This is not harmful and is expected during treatment with 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 tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Store FERRIPROX tablets in the original bottle and tightly closed to protect from moisture.

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:

Tablet core: methylcellulose, crospovidone, and magnesium stearate.

Coating: hypromellose, hydroxypropyl cellulose, macrogol, and titanium dioxide.

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.

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Please see enclosed Full Prescribing Information, including **boxed WARNING**.

