

Medication Guide

FERRIPROX[®] (Feh' ri prox) (deferiprone) Tablets

Read this Medication Guide before you start taking FERRIPROX and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

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 patients. 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 tablets for oral use are 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.

What should I tell my healthcare provider before taking FERRIPROX?

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

- have liver problems
- have kidney problems
- have any heart problems, especially a heart rhythm problem called QT prolongation or long-QT syndrome
- have been told that you have low levels of potassium or magnesium in your blood
- 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. It is not known whether 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 non-prescription 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.

Ask your doctor or pharmacist if your medicine is one that is listed above.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take FERRIPROX?

- Take FERRIPROX exactly as prescribed by your healthcare provider. Do not change your dose of FERRIPROX unless your healthcare provider tells you to.
- Your healthcare provider will tell you how many FERRIPROX tablets to take.
- FERRIPROX is taken 3 times each day. Take your first dose in the morning, the second dose at mid-day, and third dose in the evening.
- You can take FERRIPROX with or without food.
- Taking FERRIPROX with meals may help reduce nausea. If you take too much FERRIPROX, call your healthcare provider.

- If you do 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?”

Your doctor should tell you about symptoms and signs of an irregular heart rhythm (arrhythmia). It is not clear if FERRIPROX causes arrhythmia, but it is important that you get medical help right away if you have any of the following symptoms:

- irregular or fast heart beat
- dizziness
- lightheadedness or fainting
- seizure

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of FERRIPROX. For more information, ask your healthcare provider or pharmacist.

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 68°F and 77°F (20°C to 25°C).

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 condition.

This Medication Guide summarizes the most important information about FERRIPROX. If you would like more information, talk to your doctor. You can ask your doctor or pharmacist for information about FERRIPROX that is written for healthcare professionals.

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

What are the ingredients in FERRIPROX?

Active ingredients: deferiprone

Inactive ingredients:

Tablet core: microcrystalline cellulose, magnesium stearate, colloidal silicon dioxide.

Coating: hydroxypropyl methyl cellulose, polyethylene glycol, titanium dioxide.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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