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**Medication Guide
Deferiprone (de-fer-ip-rone) Tablets**

What is the most important information I should know about deferiprone tablets?

Deferiprone tablets 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 deferiprone tablets 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 will do a blood test before you start deferiprone tablets and regularly 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 deferiprone tablets if you develop neutropenia or infection.

Stop taking deferiprone tablets and call your healthcare provider or 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

It is important for you to have your white blood cell count checked within 24 hours of developing symptoms of an infection to see if you have severe neutropenia (agranulocytosis). Do not delay getting medical care if you are unable to reach your healthcare provider.

See “**What are the possible side effects of deferiprone tablets?**” for more information about side effects.

What is deferiprone?

Deferiprone is a prescription medicine used to treat iron overload from blood transfusions in adults and children 8 years of age and older with:

- thalassemia syndromes.

It is not known if deferiprone tablets is safe and effective to treat iron overload due to blood transfusions:

- in people with myelodysplastic syndrome
- in children less than 8 years of age

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

Before taking deferiprone tablets, tell your healthcare provider about all of your medical conditions, including if you:

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

Females who are able to become pregnant:

- Your healthcare provider should do a pregnancy test before you start treatment with deferiprone tablets.
- You should use effective birth control during treatment with deferiprone tablets 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 deferiprone tablets and for at least 3 months after the last dose.
- are breastfeeding or plan to breastfeed. It is not known if deferiprone tablets passes into your breast milk. Do not breastfeed during treatment with deferiprone tablets and for at least 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 deferiprone tablets?

- Take deferiprone tablets exactly as your healthcare provider tells you.
- Your healthcare provider will prescribe deferiprone tablets based on your body weight.
- Your healthcare provider will check your body iron level during treatment with deferiprone tablets and may change your dose if needed. Your healthcare provider may also change your dose of deferiprone tablets if you have certain side effects. Do not change your dose of deferiprone tablets unless your healthcare provider tells you to.
- **Take deferiprone tablets 3 times each day.** Take your first dose in the morning, the second dose at midday, and the third dose in the evening.
- Taking deferiprone tablets with meals may help reduce nausea.
- **If you must take a medicine to treat indigestion (antacid), or supplements that contain iron, aluminum, or zinc during treatment with deferiprone tablets, allow at least 4 hours between taking deferiprone tablets and these products.**
- If you take too much deferiprone tablets, 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 deferiprone tablets?

Deferiprone tablets can cause serious side effects, including:

- See **“What is the most important information I should know about deferiprone tablets?”**
- **Increased liver enzyme levels in your blood.** Your healthcare provider should do blood tests to check your liver function before you start and then monthly during treatment with deferiprone tablets. Your healthcare provider may temporarily stop treatment with deferiprone tablets if you develop increased liver enzyme levels and they continue to be increased.
- **Decreased levels of zinc in your blood.** Your healthcare provider will do blood tests to check your zinc levels before you start and during treatment with deferiprone tablets, and may prescribe a zinc supplement for you if your zinc levels are low.

The most common side effects of deferiprone tablets in people with thalassemia include:

- nausea
- vomiting
- stomach-area (abdominal) pain
- joint pain
- abnormal liver function tests
- low white blood cells

Deferiprone tablets may cause a change in urine color to reddish-brown. This is not harmful and is expected during treatment with deferiprone tablets.

These are not all of the possible side effects of deferiprone tablets.

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 deferiprone tablets?

Deferiprone Tablets 500 mg (3 times each day)

- Store at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep the bottle tightly closed to protect from moisture.

Keep deferiprone tablets and all medicines out of the reach of children.

General information about the safe and effective use of deferiprone tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use deferiprone tablets for a condition for which it was not prescribed. Do not give deferiprone tablets 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 deferiprone tablets that is written for health professionals.

What are the ingredients in deferiprone tablets?

Deferiprone Tablets 500 mg (3 times each day)

Active ingredient: deferiprone

Inactive ingredients: *Tablet core:* colloidal silicon dioxide, magnesium stearate, and microcrystalline cellulose.

Mfd. by: Taro Pharmaceutical Industries Ltd., Haifa Bay, Israel, 2624761

Dist. by: **Taro Pharmaceuticals U.S.A., Inc.**, Hawthorne, NY, 10532

MG5200805-0822-02

For more information, call 1-866-923-4914 or visit www.taro.com.

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

Revised: 8/2022