Deferiprone

Ferriprox™
500 mg Film-Coated Tablet
Iron Chelating Agent

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicinal product has been prescribed for you personally. Never give it to anyone else. It may harm them, even if their symptoms are the same as yours.

FORMULATION:
Each tablet contains:
Deferiprone, EP ..... 500 mg

The other ingredients are:
Microcrystalline cellulose, magnesium stearate, colloidal silicon dioxide, hypromellose, macrogol, titanium dioxide.

INDICATION:
Deferiprone (Ferriprox™) is used in the treatment of iron overload in patients with thalassaemia for whom desferrioxamine is unsuitable.

CONTRAINDICATIONS:
Deferiprone (Ferriprox™) should not be taken if:
- you have a history of hypersensitivity (an allergy) to the active substance or any of the other ingredients (see above)
- you have a history of repeated episodes of neutropenia (low white blood cell count)
- you have a history of agranulocytosis (very low white blood cell count $< 0.5 \times 10^9$/L)
- you are currently taking medication known to cause neutropenia
- you are pregnant or breast-feeding

The way deferiprone causes neutropenia is not known. Patients should not take medicinal products known to be associated with neutropenia or those which can cause agranulocytosis.

WARNINGS AND PRECAUTIONS:
The most serious undesirable effect of deferiprone is the occurrence of a very low white blood cell count. This condition, known as severe neutropenia or agranulocytosis, has occurred in about 1 out of 100 patients who have taken deferiprone in clinical studies. Because white blood cells help to fight infection, a low white blood cell count may place you at risk to develop a serious infection. If an infection of this nature is not discovered and treated early, it could cause death. Your doctor will ask you to have a blood test (to check your white blood cell count) performed regularly, as frequently as every week. It is very important for you to keep all of these appointments. Report immediately to your doctor any symptoms of infection such as: fever, sore throat or flu-like symptoms. Your doctor will also ask you to come in for tests to monitor body iron load. In addition, he or she also might ask you to undergo liver biopsies.

Patients with iron overload are at increased risk of cancer. In these circumstances, the impact of deferiprone is not known.

The positive and negative effects of iron chelation can only be demonstrated after many years. Therefore, further studies are ongoing. In addition, cancer-predicting studies are underway.

Use during pregnancy and breast-feeding
Do not take this medication if you are breast-feeding, if you are pregnant, or if you are trying to become pregnant. This medication could seriously harm your baby. You must use effective contraception while you are taking deferiprone (Ferriprox™). Ask your doctor which method is best for you. If you become pregnant while taking deferiprone (Ferriprox™), stop taking the medicine immediately and tell your doctor.

Driving and using machines
There is no evidence that deferiprone (Ferriprox™) affects your ability to drive or use machinery.

Taking deferiprone (Ferriprox™) with other products
Tell your doctor about all other medications that you are taking, even ones that you can buy without a prescription. Your doctor can tell you which medications you can safely take with deferiprone (Ferriprox™).

ADVERSE REACTIONS:
Like all medicines, deferiprone can have side effects.

Some of the patients enrolled in clinical studies with deferiprone developed joint pain and swelling. In most patients, the pain disappeared while still taking deferiprone (Ferriprox™).

Some patients treated with deferiprone (Ferriprox™) have experienced some or all of the following symptoms: increase in liver enzymes, abdominal pain, nausea, vomiting and increase in appetite. Most patients find that these undesirable effects disappear after a few days to a few weeks of continued treatment. If you experience nausea or vomiting, it may help to take your deferiprone (Ferriprox™) with some food.

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Your urine may become reddish/brown in color. This is the most common undesirable effect of deferiprone and it is not harmful.

DOSAGE AND ADMINISTRATION:
Deferiprone is given as 25 mg/kg body weight, oral use, three times a day for a total daily dose of 75 mg/kg body weight, or as prescribed by the physician.

It is important to follow the directions that your doctor has given to you. The amount of deferiprone that you take will depend on your weight. Deferiprone (Ferriprox™) is usually prescribed to be taken three (3) times per day. Take your first dose in the morning. Take your second dose midday. Take your third dose in the evening. It is not necessary to take deferiprone (Ferriprox™) with food. However, you may find it easier to remember to take your medication, if you take it with your meals. Deferiprone (Ferriprox™) will be most effective if you do not miss any doses. If you do miss one dose take it as soon as you remember and take your next dose at its regularly scheduled time. If you miss more than one dose, do not take the missed tablets, just continue with your normal schedule. Do not change your daily dose without first consulting with your doctor.

There are no reports of overdose with deferiprone.

STORAGE:
Store at temperatures not exceeding 30°C.
Do not use deferiprone (Ferriprox™) after the expiry date stated on the container.

CAUTION:
Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

AVAILABILITY:
Plastic bottles of 100's

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph. Seek medical attention immediately at the first sign of adverse drug reaction.

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KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

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