PATIENT PACKAGE INSERT IN ACCORDANCE WITH
THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed with a doctor's prescription only

FERRIPROX® TABLETS 500/1000 mg
Film-coated tablets

Composition:
Each film-coated tablet contains:

Ferriprox tablets 500 mg

Deferiprone 500 mg

Ferriprox tablets 1000 mg

Deferiprone 1000 mg

Inactive ingredients:
Kindly refer to section 6, Additional Information.

Read the leaflet carefully in its entirety before using the medicine.

This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

This medicine is not to be used in children under 6 years old.

1. WHAT IS THE MEDICINE INTENDED FOR?

Ferriprox is a medicine for the treatment of iron overload in patients over 6 years old who suffer from thalassemia major when deferoxamine therapy is contraindicated or inadequate.

Therapeutic group: Iron-binding agents **(chelators)**

2. BEFORE USING THE MEDICINE:

Do not use this medicine if:

You are pregnant and/or breastfeeding. Children under the age of 6. You suffer from hypersensitivity to deferiprone or to any of this medicine's ingredients (see section 6). You suffer, or have suffered in the past, from neutropenia (low white blood cell (neutrophil) count). You suffer, or have suffered in the past, from agranulocytosis (very low white blood cell (neutrophil) count). You are currently being treated with medicines known to cause neutropenia or agranulocytosis.

Special warnings regarding the use of the medicine:

The most serious side effect that may occur as a result of taking Ferriprox is a very low white blood cell (neutrophil) count. This condition, known as severe neutropenia or agranulocytosis, has occurred in 1 to 2 out of 100 people who have taken Ferriprox in clinical studies. Because white blood cells help to fight infection, a low neutrophil count may place the patient at risk of developing a serious and potentially life-threatening infection. To monitor for neutropenia, your doctor will ask you to have a blood test (to check your white blood cell count) performed regularly, as frequently as every week, for as long as you are being treated with Ferriprox. It is very important for you to undergo all of these tests. If you get any symptoms of infection such as fever, sore throat or flu-like symptoms, immediately seek medical attention. Your white blood cell count must be checked within 24 hours in order to detect potential agranulocytosis.

If you are HIV positive or if your liver or kidney function is impaired, your doctor may recommend additional tests.
Before starting treatment with Ferriprox, tell the doctor if:

You suffer, or have suffered in the past, from impaired function of: the liver, kidneys, blood system (low white blood cell count).

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking or intend to take:

- Preparations containing vitamin C.

Do not take medicines for the treatment of heartburn (antacids containing aluminium) while using Ferriprox.
Do not take medicines known to cause neutropenia or agranulocytosis (see “Do not use this medicine if:”).

Pregnancy and breastfeeding
Do not use this medicine if you are pregnant or are planning to become pregnant. This medicine could seriously harm your baby. Use effective contraception for as long as you are being treated with Ferriprox. Ask the doctor which method is best for you. If you become pregnant while taking Ferriprox, stop taking the medicine immediately and tell the doctor.

Do not use Ferriprox if you are breastfeeding.

Driving and use of machinery
No studies have been performed regarding the effect of the medicine on driving and use of machinery.

3. HOW TO USE FERRIPROX?

Always use this medicine as instructed by the doctor. If you are unsure, ask the doctor or pharmacist.
The amount of Ferriprox that you take will depend on your weight. The usual dose is 25 mg/kg, 3 times per day, for a total daily dose of 75 mg/kg. The total daily dose should not exceed 100 mg/kg.

Take the first dose in the morning; the second dose midday and the third dose in the evening. Ferriprox can be taken with or without food; however, you may find it easier to remember to take Ferriprox if you take it with your meals.

Do not exceed the recommended dose.

Directions for use:
Do not chew the medicine! Swallow the medicine with a small amount of water. If necessary, the film-coated tablet may be halved. If you suffer from nausea or vomiting due to use of the medicine, taking it with food may improve how you feel.

Tests and follow-up: The doctor will ask you to come to the clinic for tests to monitor body iron load. In addition, he/she may ask you to undergo liver biopsies.

If you accidentally took more Ferriprox than you should
There are no reports of severe overdose with Ferriprox. If you have accidentally taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

If you forget to take Ferriprox
Ferriprox is highly effective if no doses of the medicine are missed. If you do miss a dose, take the medicine as soon as possible and take the next dose at its regularly scheduled time. If you miss more than one dose, do not take a double dose to make up for missed doses; go back to your normal schedule. Do not change the daily dose without first consulting the doctor.

How can you contribute to the success of the treatment?

Complete the full course of treatment as instructed by your doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.

If you have additional questions on using the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS:

As with any medicine, use of Ferriprox may cause side effects in some users. Do not be alarmed to read the list of side effects. You may not experience any of them.

The most serious side effect that may occur as a result of taking Ferriprox is a very low white blood cell (neutrophil) count. This condition, known as severe neutropenia or agranulocytosis, has occurred in 1 to 2 out of 100 people who have taken Ferriprox in clinical studies. A low white blood cell count could cause a serious and potentially life-threatening infection. Report immediately to your doctor any symptoms of infection such as fever, sore throat or flu-like symptoms.

Very common side effects (may affect more than 1 in 10 people):
- Abdominal pain
- Nausea
- Vomiting

- Reddish/brown discoloration of urine

If you suffer from nausea or vomiting, it may help to take Ferriprox with food.
Discolored urine is a very common effect and is not harmful.

Common side effects (may affect up to 1 in 10 people):
- Low white blood cell count (agranulocytosis and neutropenia)
- Headache
- Diarrhea
- Increase in liver enzymes
- Fatigue
- Increase in appetite

Side effects with unknown frequency (frequency cannot be estimated from the available data):
- Allergic reactions including skin rash or hives

Events of joint pain and swelling have been reported, ranging from mild pain in one or more joints to severe disability. In most cases, the pain disappeared while the patient continued taking Ferriprox.

Data from monitoring the use of Ferriprox after its approval for marketing indicate neurological disorders (such as tremors, walking disorders, double vision, involuntary muscle contractions, problems with movement coordination), which were reported in children who as part of a clinical trial received a dosage that was more than double the maximum recommended dose of 100 mg/kg/day for a period of several years, and were also observed in children who received a standard dose of deferiprone. The children recovered from these symptoms after treatment with Ferriprox was stopped.

Reporting of side effects

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, should be stored in a safe place out of the reach of children and/or infants, to prevent poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
Do not use the medicine after the expiry date (EXP.) that appears on the carton and the label. The expiry date refers to the last day of that month.

Ferriprox tablets 500 mg
Store in a cool place, under 30°C.
After first opening the bottle, the medicine may be used within 100 days of the date of opening.

Ferriprox tablets 1000 mg
Store in a cool place, under 30°C. Make sure that the bottle is tightly closed in order to protect the medicine from moisture.

After first opening the bottle, the medicine may be used within 50 days of the date of opening.

Do not dispose of any medicines down a drain or in household trash. Ask your pharmacist how to dispose of medicines no longer in use. These measures are intended to protect the environment.

6. ADDITIONAL INFORMATION:

Ferriprox contains

Ferriprox tablets 500 mg

Deferiprone as active ingredient. Each tablet contains 500 mg of deferiprone.

In addition to the active ingredient, the medicine also contains:
Tablet core: Microcrystalline cellulose, Magnesium stearate, Colloidal silicon dioxide

Coating: Hydroxypropyl methylcellulose, Polyethylene Glycol, Titanium dioxide, Purified water

Ferriprox tablets 1000 mg

Deferiprone as active ingredient. Each tablet contains 1000 mg of deferiprone.

Tablet core: Methylcellulose A15LV, Crospovidone, Magnesium stearate vegetable source

Coating: Hydroxypropyl methylcellulose 2910E5, Hydroxypropyl cellulose (LF), Polyethylene Glycol 8000, Titanium Dioxide, Purified water

What the medicine looks like and contents of the pack:

Ferriprox tablets 500 mg

Ferriprox tablets are white to off-white, capsule-shaped, film-coated tablets imprinted on one side with “APO”, beneath which is a score line and then “500”; the other side is plain. The tablets are scored and can be broken in half.
Ferriprox is packaged in a plastic bottle containing 100 tablets.

Ferriprox tablets 1000 mg

Ferriprox tablets are white to off-white, capsule-shaped, film-coated tablets imprinted on one side with “APO”, beneath which is a score line and then “1000”; the other side is plain. The tablets are scored and can be broken in half.
Ferriprox is packaged in a plastic bottle containing 50 tablets and a desiccant.

License Holder and address: Lapidot Medical Import and Marketing Ltd.,
8 Hashita St., Caesarea Industrial Park, 3088900.

Manufacturer and address:
Apotex Inc. Canada, 50 Steinway Boulevard, Etobicoke, Ontario M9W 6Y3, Canada

Medicine Registration No. in the National Drug Registry of the Ministry of Health:

Ferriprox tablets 500 mg - 139 68 31585 00

Ferriprox tablets 1000 mg - 163 83 35170 00

Revised on April 2020