PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Ferriprox Oral Solution 100 mg/ml

Composition: Each ml of solution contains Deferiprone 100 mg

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.

1. WHAT IS THE MEDICINE INTENDED FOR?

Ferriprox Oral Solution 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 the medicine if:

- You are pregnant or breastfeeding.
- In 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 due to 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) regularly, as frequently as every week, for as long as you are being treated with Ferriprox. It is very important to perform all these tests. If any symptoms of infection appear, such as fever, sore throat or flu-like symptoms, seek medical help immediately. White blood cell count test should be performed 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, the kidneys, blood system (low white blood cell count).

Additional tests for which you may be referred: Tests to determine your body's iron load, and possibly even liver biopsies.

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking:

- Preparations containing vitamin C
- Do not take medicines for the treatment of heartburn (antacids containing aluminium) while using Ferriprox.
- Do not take medicines that are known to cause neutropenia or agranulocytosis (see "Do not use the medicine if:").

Use of the medicine and food:
The medicine can be taken with/without food.
In order to prevent cases of nausea / vomiting, the medicine may be taken with a small amount of food.

Pregnancy and breastfeeding:
Do not take this medicine if you are pregnant or trying to become pregnant. The medicine could seriously affect your baby. Use effective methods of contraception during the period of treatment with Ferriprox. Consult the doctor regarding the suitable method. If you became pregnant during treatment with Ferriprox Oral Solution, stop treatment with the medicine immediately and consult a doctor.

Do not use this medicine if you are breastfeeding.

Children:
This medicine is not intended for use in children under the age of 6 years.

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

Important information regarding some of the ingredients of the medicine:
Ferriprox Oral Solution contains the coloring agent FD&C Yellow, which may cause an allergic reaction.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use this preparation as instructed by the doctor. Check with the doctor or pharmacist if you are unsure about the dosage or the treatment regimen.
The dosage and treatment regimen will be determined by the doctor only. The amount of Ferriprox that you take will depend on your body weight. The usual dose is 25 mg/kg, three times a day, for a total daily dose of 75 mg/kg. The total daily dose should not exceed 100 mg/kg.
Use the measuring cup to measure the volume prescribed by your doctor.
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 at mealtimes.

Do not exceed the recommended dose.
Use a measuring cup intended for measuring the correct amount of medicine. If a cup or any other measuring utensil was not provided with the package, consult the pharmacist. Do not use a household teaspoon to measure the amount of medicine. Household teaspoons vary in their sizes and you may not receive the correct amount of medicine.

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

If you forget to take Ferriprox
Ferriprox is highly effective if no doses of the medicine are missed. If you forget to take this medicine at the specified time, take a dose as soon as you remember and then continue taking Ferriprox at the regular times. If you missed taking more than one dose, do not take a double

dose; rather, continue taking the medicine according to the regular time schedule. Do not change the daily dosage without consulting the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor or pharmacist.

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 regarding use of 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 when reading the list of side effects. You may not experience any of them.

Effects requiring special attention:
The most severe side effect that may occur while taking Ferriprox Oral Solution is a very low white blood cell (neutrophils) count. This condition, known as severe neutropenia or agranulocytosis, occurred at an incidence of 1-2 patients out of 100 people who have taken Ferriprox in clinical studies. A low white blood cell count can be accompanied by serious infection that may be life-threatening. Inform your doctor immediately of any symptom 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
- Brown-reddish-colored urine

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

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

Side effects whose frequency is not known (frequency cannot be estimated from the available data):
- Allergic reactions, including skin rash or urticaria.

Cases of joint pain and swelling range from moderate pain in one or more joints to severe physical disability. In most cases, the pain disappears with continued Ferriprox Oral Solution treatment.

From post-marketing Ferriprox Oral Solution data, neurological disorders (such as tremors, walking disorders, double vision, involuntary muscle contractions, problems with coordination of body movements) have been reported in children who had been treated with more than double the maximum recommended dose of 100 mg per kg per day for several years, and have also been observed in children who received a standard dose of deferiprone. After discontinuing use of Ferriprox, these symptoms gradually disappeared.

If any of the side effects worsen, or if you suffer from any side effect not mentioned in the leaflet, consult with the doctor.

Reporting 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 kept in a closed place out of the reach of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Storage conditions:

- Store at a temperature below 30˚C.
- Store in the original package to protect from light.
- Use the preparation within 35 days of opening.

6. ADDITIONAL INFORMATION

In addition to the active ingredient, the medicine also contains:

Hydroxyethylcellulose, Glycerol, Hydrochloric acid (concentrated), Artificial cherry flavor, Peppermint oil, FD&C Yellow, Sucralose (E955) & Purified water.

What the medicine looks like and contents of the package:

A clear, reddish-orange-colored solution.

Manufacturer: Apotex Inc., Ontario, Canada.

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

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
147 69 33222 00

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