

PACKAGE LEAFLET: INFORMATION FOR THE USER

Ferriprox® 1000 mg film-coated tablets Deferiprone

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 any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Ferriprox is and what it is used for
2. Before you take Ferriprox
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1. WHAT FERRIPROX IS AND WHAT IT IS USED FOR

Ferriprox® contains the active substance deferiprone. Ferriprox is a medicine that removes iron from the body. Ferriprox should be prescribed by Specialist Doctors only.

Ferriprox is indicated for the treatment of patients with transfusional iron overload due to thalassaemia syndromes when current chelation therapy is inadequate.

2. BEFORE YOU TAKE FERRIPROX

Do not take Ferriprox

- if you are allergic (hypersensitive) to deferiprone or any of the other ingredients of Ferriprox.
- if you have a history of repeated episodes of neutropenia (low white blood cell (neutrophil) count).
- if you have a history of agranulocytosis (very low white blood cell (neutrophil) count $<0.5 \times 10^9/l$).
- if you are currently taking medicines known to cause neutropenia or agranulocytosis (see “Taking other medicines”).
- if you are pregnant or breastfeeding.

Take special care with Ferriprox

- the most serious side effect that may occur while 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 you 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, while you are being treated with Ferriprox. 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.
- if you are HIV positive or if your kidney or liver function is impaired, your doctor may recommend additional tests.

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.

Taking other medicines

Do not take medicines known to cause neutropenia or agranulocytosis (see “Do not take Ferriprox”). Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Do not take aluminium-based antacids while taking Ferriprox.

Please consult with your doctor or pharmacist before taking vitamin C with Ferriprox.

Pregnancy and breastfeeding

Do not take this medicine if you are pregnant or if you are trying to become pregnant. This medicine could seriously harm your baby. You must use effective contraception while you are taking Ferriprox. Ask your doctor which method is best for you. If you become pregnant while taking Ferriprox, stop taking the medicine immediately and tell your doctor.

Do not use Ferriprox if you are breast-feeding.

Driving and using machines

Not relevant.

3. HOW TO TAKE FERRIPROX

Always take Ferriprox exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. 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 your first dose in the morning. Take your second dose midday. Take your 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.

If you take more Ferriprox than you should

There are no reports of acute overdose with Ferriprox. If you have accidentally taken more than the prescribed dose, you should contact your doctor.

If you forget to take Ferriprox

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 a double dose to make up for forgotten individual doses, just continue with your normal schedule. Do not change your daily dose without first talking to your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Ferriprox can have side effects, although not everybody gets them.

The most serious side effect of 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 can be associated with 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 (affect more than 1 user in 10):

- abdominal pain
- nausea
- vomiting
- reddish/brown discolouration of urine

If you experience nausea or vomiting, it may help to take your Ferriprox with some food. Discoloured urine is a very common effect and is not harmful.

Common side effects (affect 1 to 10 users in 100):

- low white blood cell count (agranulocytosis and neutropenia)
- headache
- diarrhoea
- increase in liver enzymes
- fatigue
- increase in appetite
- rash

Frequency Not Known (cannot be estimated from the available data):

- allergic reactions including hives

Events of joint pain and swelling ranged from mild pain in one or more joints to severe disability. In most cases, the pain disappeared while patients continued taking Ferriprox.

In post-marketing experience with Ferriprox, neurological disorders (such as tremors, walking disorders, double vision, involuntary muscle contractions, problems with movement coordination) have been reported in children who had been voluntarily prescribed more than 2.5 times the maximum recommended dose of 100 mg/kg/day for up to 16 months. They recovered from these symptoms after Ferriprox discontinuation.

If you notice these or any side effects not listed in this leaflet, please tell your doctor, pharmacist or the local distributing company immediately, who will in turn communicate it to the Medical Safety Group by email: medicalsafety@apopharma.com or by calling: +1 (416) 401-7650.

5. HOW TO STORE FERRIPROX

Keep out of the reach and sight of children.

Do not use Ferriprox after the expiry date which is stated on the label after EXP.

Store below 30°C. 請存放於攝氏30°C以下

For the bottle: Keep the bottle tightly closed in order to protect from moisture.

6. FURTHER INFORMATION

What Ferriprox contains

The active substance is deferiprone.

Each 1000 mg tablet contains 1000 mg deferiprone.

The other ingredients are: Tablet core: Methylcellulose, crospovidone, magnesium stearate. Coating: Hypromellose, hydroxypropyl cellulose, macrogol, titanium dioxide.

What Ferriprox looks like and contents of the pack

Ferriprox 1000 mg tablets are white to off-white, capsule-shaped, film-coated tablets engraved “APO” bisect “1000” on one side, plain on the other. The tablets are scored and breakable in half. Ferriprox is packaged in bottles of 50 tablets.

Marketed by: Apotex Inc.
150 Signet Drive,
Toronto, Ontario,
Canada, M9L 1T9

Manufactured by: Apotex Inc. – Etobicoke Site,
50 Steinway Boulevard,
Etobicoke, Ontario,
Canada, M9W 6Y3

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