210 mm

35 mm

280 mm

Package leaflet: Information for the user

Ferriprox® 1 000 mg film-coated tablets
deferiprone

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- A patient card is attached to the carton. You should detach, complete, read the patient card carefully and carry it with you. Provide this patient card to your doctor if you develop infection symptoms such as a fever, sore throat or flu-like symptoms.

What is in this leaflet:

1. What Ferriprox is and what it is used for

Ferriprox contains the active substance deferiprone. Ferriprox is an iron chelator, a type of medicine that removes excess iron from the body.

Ferriprox is used to treat iron overload caused by frequent blood transfusions in patients with thalassaemia major when current chelation therapy is contraindicated or inadequate.

2. What you need to know before you take Ferriprox

Do not take Ferriprox
- if you are allergic to deferiprone or any of the other ingredients of this medicine (listed in section 6).
- 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).
- if you are currently taking medicines known to cause neutropenia or agranulocytosis (see "Other medicines and Ferriprox").
- if you are pregnant or breast-feeding.

Warnings and precautions
- 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. Please refer to the patient card attached to the carton. 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 human immunodeficiency virus (HIV) positive or if your liver or kidney function is severely 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 might ask you to undergo liver biopsies.

Other medicines and Ferriprox
Do not take medicines known to cause neutropenia or agranulocytosis (see "Do not take Ferriprox"). Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including medicines obtained without a prescription.

Do not take aluminium-based antacids at the same time as taking Ferriprox.

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

Pregnancy and breast-feeding
Ferriprox may cause harm to unborn babies when used by pregnant women. Ferriprox must not be used during pregnancy unless clearly necessary. If you are pregnant or you become pregnant during treatment with Ferriprox, get medical advice immediately.

Both female and male patients are recommended to take special precautions in their sexual activity if there is any possibility for pregnancy to occur: Women of childbearing potential are recommended to use effective contraception during treatment with Ferriprox and for 6 months after the last dose. Men are recommended to use effective contraception during treatment and for 3 months after the last dose. This should be discussed with your doctor.

Do not use Ferriprox if you are breast-feeding. Please refer to the patient card attached to the carton.

Driving and using machines
Not relevant.

3. How to take Ferriprox

Always take this medicine exactly as your doctor has told you. 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, this medicine can cause 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 (may affect more than 1 in 10 people):
- 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 (may affect up to 1 in 10 people):
- low white blood cell count (agranulocytosis and neutropenia);
- headache;
- diarrhoea;
- increase in liver enzymes;
- fatigue;
- increase in appetite.

Not known (frequency cannot be estimated from the available data):
- allergic reactions including skin rash or 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.

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 double the maximum recommended dose of 100 mg/kg/day for several years and have also been observed in children with standard doses of deferiprone. The children recovered from these symptoms after Ferriprox discontinuation.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ferriprox

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the label after EXP. The expiry date refers to the last day of that month.

Do not store above 30 ºC. Keep the bottle tightly closed in order to protect from moisture. After first opening, use within 50 days.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ferriprox contains
The active substance is deferiprone. Each 1 000 mg tablet contains 1 000 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
White to off-white, capsule-shaped, film-coated tablet imprinted "APO" bisect "1000" on one side, plain on the other. The tablet is 7.9 mm x 19.1 mm x 7 mm and scored. The tablet can be divided into equal halves. Ferriprox is packaged in bottles of 50 tablets.

Marketing Authorisation Holder:
Ireland & United Kingdom (Northern Ireland):
Chiesi Farmaceutici S.p.A.
Via Palermo 26/A
43122 Parma
Italy

Great Britain:
Chiesi Limited
333 Styal Road
Manchester
M22 5LG

Manufacturer:
Eurofins PROXY Laboratories B.V.
Archimedesweg 25
2333 CM Leiden
Netherlands

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Ireland/United Kingdom (Northern Ireland)
Chiesi Farmaceutici S.p.A.
IT
Tel: + 39 0521 2791

Great Britain
Chiesi Ltd
Tel: + 44 (0)161 488 5555

This leaflet was last revised in 09-2022.

Other sources of information
Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

CP0072-3