PACKAGE LEAFLET: Information for the user

FERIPAKS

Film-coated tablets – 500 mg

(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.
- Attached to this leaflet you will find a patient / carer reminder card. You should detach, complete, read the card carefully and carry it with you.

What is in this leaflet:

1. WHAT FERIPAKS IS AND WHAT IT IS USED FOR

Feripaks contains the active substance deferiprone. Feripaks is a medicine that removes iron from the body.

Feripaks 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 FERIPAKS

Do not take Feripaks:

- if you are allergic to deferiprone or any of the excipients 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 section 2 “Other medicines and Feripaks”);
- if you are pregnant or breastfeeding.

Warnings and precautions

- The most serious side effect that may occur while taking Feripaks 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 deferiprone 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 Feripaks. It is very important for you to keep all of these appointments. Please refer to the patient/carer reminder card attached to this leaflet. 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.
Talk to your doctor or pharmacist before taking Feripaks.

Other medicines and Feripaks

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 medicines known to cause neutropenia or agranulocytosis (see "Do not take Feripaks").
Do not take aluminium-based antacids while taking Feripaks.
Please consult with your doctor or pharmacist before taking vitamin C with Feripaks.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
This medicine could seriously harm your baby. You must use effective contraception while you are taking Feripaks. Ask your doctor which method is best for you.
If you become pregnant while taking Feripaks, stop taking the medicine immediately and tell your doctor.
Do not use Feripaks if you are breastfeeding. Please refer to the patient/carer reminder card attached to this leaflet.

Driving and using machines

Not relevant.

3. HOW TO TAKE FERIPAKS

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
The amount of Feripaks 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.
Feripaks can be taken with or without food; however, you may find it easier to remember to take Feripaks if you take it with your meals.

If you take more Feripaks than you should

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

If you forget to take Feripaks

Feripaks 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 Feripaks 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 deferiprone 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 Feripaks 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 deferiprone.

In post-marketing experience with deferiprone, 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. They recovered from these symptoms after deferiprone discontinuation.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE FERIPAKS

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 package.

Do not store above 25°C.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Feripaks contains

The **active substance is** deferiprone.

Each Feripaks film-coated tablet contains 500 mg deferiprone.

The excipients are:

Tablet core: pregelatinised starch, magnesium stearate.

Film-coating: Opadry II pink (polyvinyl alcohol, titanium dioxide, macrogol, talc, red iron oxide, yellow iron oxide).

Contents of the pack

Box with 100 film-coated tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

This leaflet was last revised in October 2023.

PATIENT / CARER REMINDER CARD

((Front Cover))	((Back Cover))
Important Safety Reminders for patients taking Feripaks (deferiprone) **Prescribing doctor: _____** **Phone No:_____**	**FOR WOMEN OF CHILD BEARING AGE** Do not take Feripaks if you are pregnant or if you are trying to become pregnant. If taken during pregnancy, Feripaks may seriously harm the unborn baby. You must use effective contraception while you are taking Feripaks. Ask your doctor which method is best for you. If you become pregnant while taking Feripaks, stop taking the medicine immediately and tell your doctor. Do not take Feripaks if you are breast-feeding.
((**Inside 1**)) **MONITORING YOUR WHITE BLOOD CELL COUNT WITH FERIPAKS** There is a small chance that you may develop agranulocytosis (very low white blood cell count) while taking Feripaks, which may lead to a serious infection. Even though agranulocytosis only affects 1 to 2 out of 100 users, it is important to monitor your blood on a regular basis.	((**Inside 2))** Make sure you do the following: 1. Have your blood monitored on a weekly basis. 2. Contact your doctor immediately if you develop a fever, sore throat or flu like symptoms.