Package leaflet: Information for the patient

Deferiprone Lipomed 500 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.
- Provided in the folding box, you will find a patient card. You should complete and read the card carefully and carry it with you. Provide this 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 Deferiprone Lipomed is and what it is used for

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

Deferiprone Lipomed 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 Deferiprone Lipomed

Do not take Deferiprone Lipomed
- 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 Deferiprone Lipomed”);
- if you are pregnant or breast-feeding.

Warnings and precautions
The most serious side effect that may occur while taking Deferiprone Lipomed 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 trials. 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 Deferiprone Lipomed. It is very important for you to keep all of these appointments. Please refer to the patient card provided in the folding box. 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 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.

Talk to your doctor or pharmacist before taking Deferiprone Lipomed.

Other medicines and Deferiprone Lipomed
Do not take medicines known to cause neutropenia or agranulocytosis (see "Do not take Deferiprone Lipomed"). 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 Deferiprone Lipomed.

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

Pregnancy and breast-feeding
Deferiprone Lipomed may cause harm to unborn babies when used by pregnant women. Deferiprone Lipomed must not be used during pregnancy unless clearly necessary. If you are pregnant or you become pregnant during treatment with Deferiprone Lipomed, 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 Deferiprone Lipomed 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 Deferiprone Lipomed if you are breast-feeding. Please refer to the patient card provided in the folding box.

Driving and using machines
This medicine has no or negligible influence on the ability to drive and use machinery.

Deferiprone Lipomed contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet and that is to say essentially 'sodium-free'.

3. How to take Deferiprone Lipomed

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 Deferiprone Lipomed 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. Deferiprone Lipomed can be taken with or without food; however, you may find it easier to remember to take Deferiprone Lipomed if you take it with your meals.

If you take more Deferiprone Lipomed 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 Deferiprone Lipomed
Deferiprone Lipomed 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 Deferiprone Lipomed 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 trials. 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 Deferiprone Lipomed 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.

Additional side effects in children
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 discontinuation of deferiprone.

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

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

Do not store above 25 °C.

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

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 Deferiprone Lipomed contains
The active substance is deferiprone. Each film-coated tablet contains 500 mg deferiprone.

The other ingredients are:

Tablet core: hypromellose, croscarmellose sodium (see section 2 “Deferiprone Lipomed contains sodium”), silica, colloidal anhydrous, microcrystalline cellulose, magnesium stearate

Coating: hypromellose, macrogol 6 000, titanium dioxide

What Deferiprone Lipomed looks like and contents of the pack
Deferiprone Lipomed 500 mg film-coated tablets are white to off-white, glossy surface, oval film-coated tablets. The tablets are scored and breakable in half. Deferiprone Lipomed is packaged in blisters. One pack contains 100 film-coated tablets.

Marketing Authorisation Holder and Manufacturer
Lipomed GmbH
Hegenheimer Strasse 2
79576 Weil am Rhein
Germany
Phone number: +49 7621 1693 472
Fax number: +49 7621 1693 474
Electronic mail: lipomed@lipomed.com

This leaflet was last revised in May 2023.