Package leaflet: Information for the user

Deferiprone DOC 500 mg film-coated tablets
Deferiprone DOC 1000 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 this leaflet. 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 Deferiprone DOC is and what it is used for
2. What you need to know before you take Deferiprone DOC
3. How to take Deferiprone DOC
4. Possible side effects
5. How to store Deferiprone DOC
6. Contents of the pack and other information

1. What Deferiprone DOC is and what it is used for

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

Deferiprone DOC 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 DOC

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

Warnings and precautions
- the most serious side effect that may occur while taking Deferiprone DOC 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 Deferiprone DOC. It is very important for you to keep all of these appointments. Please refer to the patient card attached to this leaflet. 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 Deferiprone DOC
Do not take medicines known to cause neutropenia or agranulocytosis (see "Do not take Deferiprone DOC"). 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 taking Deferiprone DOC.

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

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

Driving and using machines
Not relevant.

3. How to take Deferiprone DOC

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

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

If you forget to take Deferiprone DOC
Deferiprone DOC 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 DOC 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 DOC 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 Deferiprone DOC with some food. Discolored 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.

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 deferiprone 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 the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Deferiprone DOC

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 blister after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 DOC contains

- The active substance is deferiprone.

Deferiprone DOC 500 mg: Each tablet contains 500 mg deferiprone
Deferiprone DOC 1000 mg: Each tablet contains 1000 mg deferiprone

- The other ingredients are:

Tablet core: (maize) starch pregelatinised, magnesium stearate
Coating: hypromellose, hydroxypropylcellulose, titanium dioxide, macrogol

What Deferiprone DOC looks like and contents of the pack

Deferiprone DOC 500 mg: white to off-white film coated tablets, debossed with 'DL 500' with score line on one side and plain on the other and with dimensions of 14.2 mm x 8.2 mm. Tablets can be divided to equal halves.

Deferiprone DOC 1000 mg: white to off-white film coated tablets, debossed with 'DH 1000' with a score line on one side and plain on the other and with dimensions of 19.2 mm x 9.2 mm. Tablets can be divided to equal halves.

Deferiprone DOC 500 mg tablets are supplied in:
- blister packs of 100 tablets

Deferiprone DOC 1000 mg tablets are supplied in:
- blister packs of 50 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

{Name of the Member State} {Name of the medicinal product}

[To be completed nationally]

This leaflet was last revised in: 2023-12-14

PATIENT CARD

((Front Cover)) **PATIENT CARD** **Important Safety Reminders for Patients taking Deferiprone DOC (deferiprone)** **Prescribing doctor: _____** **Phone No: _____**	((Back Cover)) **PREGNANCY, FERTILITY, LACTATION** Do not take Deferiprone DOC if you are pregnant, trying to become pregnant, or are breastfeeding. Deferiprone DOC may seriously harm the baby. If you are pregnant or breastfeeding during treatment with Deferiprone DOC, tell your doctor and get medical advice immediately. Women of childbearing potential are recommended to use effective contraception during the treatment with Deferiprone DOC 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. Ask your doctor which method is best for you.
((Inside 1)) **MONITORING YOUR WHITE BLOOD CELL COUNT WITH Deferiprone DOC** There is a small chance that you may develop agranulocytosis (very low white blood cell count) while taking Deferiprone DOC, 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 for the first one year of treatment with Deferiprone DOC and as regularly as your doctor recommends thereafter. 2. 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.