

Pharmacode

Package leaflet: Information for the user

Deferasirox 90 mg film-coated tablets

Deferasirox 180 mg film-coated tablets

Deferasirox 360 mg film-coated tablets

Deferasirox

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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.

- These products are referred to as Deferasirox tablets in this leaflet.

What is in this leaflet

1. What Deferasirox tablets are and what it is used for

2. What you need to know before you take Deferasirox tablets

3. How to take Deferasirox tablets

4. Possible side effects

5. How to store Deferasirox tablets

6. Contents of the pack and other information

1. What Deferasirox tablets are and what it is used for

What Deferasirox tablets are

Deferasirox tablets contain an active substance called deferasirox. It is an iron chelator which is a medicine used to remove the excess iron from the body (also called iron overload). It traps and removes excess iron which is then excreted mainly in the stools.

What Deferasirox tablets are used for

Repeated blood transfusions may be necessary in patients with various types of anaemia (for example thalassaemia, sickle cell disease or myelodysplastic syndromes (MDS)). However, repeated blood transfusions can cause a build-up of excess iron. This is because blood contains iron and your body does not have a natural way to remove the excess iron you get with your blood transfusions. In patients with non-transfusion-dependent thalassaemia syndromes, iron overload may also develop over time, mainly due to increased absorption of dietary iron in response to low blood cell counts. Over time, the excess iron can damage important organs such as the liver and heart. Medicines called iron chelators are used to remove the excess iron and reduce the risk of it causing organ damage.

Deferasirox tablets are used to treat chronic iron overload caused by frequent blood transfusions in patients with beta thalassaemia major aged 6 years and older.

Deferasirox tablets are also used to treat chronic iron overload when deferoxamine therapy is contraindicated or inadequate in patients with beta thalassaemia major with iron overload caused by infrequent blood transfusions, in patients with other types of anaemias, and in children aged 2 to 5 years.

Deferasirox tablets are also used when deferoxamine therapy is contraindicated or inadequate to treat patients aged 10 years or older who have iron overload associated with their thalassaemia syndromes, but who are not transfusion dependent.

2. What you need to know before you take Deferasirox tablets

Do not take Deferasirox tablets

- if you are allergic to deferasirox or any of the other ingredients of this medicine (listed in section 6). If this applies to you, **tell your doctor before taking Deferasirox tablets**. If you think you may be allergic, ask your doctor for advice.

- if you have moderate or severe kidney disease.

- if you are currently taking any other iron chelator medicines.

Deferasirox tablets are not recommended

- if you are at an advanced stage of myelodysplastic syndrome (MDS; decreased production of blood cells by the bone marrow) or have advanced cancer.

Warnings and precautions

Talk to your doctor or pharmacist before taking Deferasirox tablets:

- if you have a kidney or liver problem.

- if you have a cardiac problem due to iron overload.

- if you notice a marked decrease in your urine output (sign of kidney problem).

- if you develop a severe rash, or difficulty breathing and dizziness or swelling mainly of the face and throat (signs of severe allergic reaction, see also section 4 “Possible side effects”).

- if you experience a combination of any of the following symptoms: rash, red skin, blistering of the lips, eyes or mouth, skin peeling, high fever, flu-like symptoms, enlarged lymph nodes (signs of severe skin reaction, see also section 4 “Possible side effects”).

- if you experience a combination of drowsiness, upper right abdominal pain, yellowing or increased yellowing of your skin or eyes and dark urine (signs of liver problems).

- if you experience difficulty thinking, remembering information, or solving problems, being less alert or aware or feeling very sleepy with low energy (signs of a high level of ammonia in your blood, which may be associated with liver or renal problems, see also section 4 “Possible side effects”).

- if you vomit blood and/or have black stools.

- if you experience frequent abdominal pain, particularly after eating or taking Deferasirox tablets.

- if you experience frequent heartburn.

- if you have a low level of platelets or white blood cells in your blood test.

- if you have blurred vision

- if you have diarrhoea or vomiting.

If any of these apply to you, tell your doctor straight away.

Monitoring your Deferasirox treatment

You will have regular blood and urine tests during treatment. These will monitor the amount of iron in your body (blood level of *ferritin*) to see how well Deferasirox tablets are working. The tests will also monitor your kidney function (blood level of creatinine, presence of protein in the urine) and liver function (blood level of transaminases). Your doctor may require you to undergo a kidney biopsy, if he/she suspects significant kidney damage. You may also have MRI (magnetic resonance imaging) tests to determine the amount of iron in your liver. Your doctor will take these tests into consideration when deciding on the dose of Deferasirox tablets most suitable for you and will also use these tests to decide when you should stop taking Deferasirox tablets.

Your eyesight and hearing will be tested each year during treatment as a precautionary measure.

Other medicines and Deferasirox tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes in particular:

- other iron chelators, which must not be taken with Deferasirox tablets,

- antacids (medicines used to treat heartburn) containing aluminium, which should not be taken at the same time of day as Deferasirox tablets,

- ciclosporin (used to prevent the body rejecting a transplanted organ or for other conditions, such as rheumatoid arthritis or atopic dermatitis),

- simvastatin (used to lower cholesterol),

- certain painkillers or anti-inflammatory medicines (e.g. aspirin, ibuprofen, corticosteroids),

- oral bisphosphonates (used to treat osteoporosis),

- anticoagulant medicines (used to prevent or treat blood clotting),

- hormonal contraceptive agents (birth control medicines),

- bepridil, ergotamine (used for heart problems and migraines),

- repaglinide (used to treat diabetes),

- rifampicin (used to treat tuberculosis),

- phenytoin, phenobarbital, carbamazepine (used to treat epilepsy),

- ritonavir (used in the treatment of HIV infection),

- paclitaxel (used in cancer treatment),

- theophylline (used to treat respiratory diseases such as asthma),

- clozapine (used to treat psychiatric disorders such as schizophrenia),

- tizanidine (used as a muscle relaxant),

- cholestyramine (used to lower cholesterol levels in the blood),

- busulfan (used as a treatment prior to transplantation in order to destroy the original bone marrow before the transplant).

- midazolam (used to relieve anxiety and/or trouble sleeping).

Additional tests may be required to monitor the blood levels of some of these medicines.

Older people (age 65 years and over)

Deferasirox tablets can be used by people aged 65 years and over at the same dose as for other adults. Elderly patients may experience more side effects (in particular diarrhoea) than younger patients. They should be monitored closely by their doctor for side effects that may require a dose adjustment.

Children and adolescents

Deferasirox tablets can be used in children and adolescents receiving regular blood transfusions aged 2 years and over and in children and adolescents not receiving regular blood transfusions aged 10 years and over. As the patient grows the doctor will adjust the dose.

Deferasirox tablets are not recommended for children aged under 2 years.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Deferasirox tablets are not recommended during pregnancy unless clearly necessary.

If you are currently using an oral contraceptive or using a patch contraceptive to prevent pregnancy, you should use an additional or different type of contraception (e.g. condom), as Deferasirox tablets may reduce the effectiveness of oral and patch contraceptives.

Breast-feeding is not recommended during treatment with Deferasirox tablets.

Driving and using machines

If you feel dizzy after taking Deferasirox tablets, do not drive or operate any tools or machines until you are feeling normal again.

Deferasirox tablets contain sodium

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially ‘sodium-free’.

3. How to take Deferasirox tablets

Treatment with Deferasirox tablets will be overseen by a doctor who is experienced in the treatment of iron overload caused by blood transfusions.

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How much Deferasirox tablets to take

The dose of Deferasirox tablets is related to body weight for all patients. Your doctor will calculate the dose you need and tell you how many tablets to take each day.

The usual daily dose for Deferasirox tablets at the start of the treatment for patients receiving regular blood transfusions is 14 mg per kilogram body weight. A higher or lower starting dose

Pharmacode

150 mm
Front Side

Type: Pack Insert
Size: 150 x 600 mm

Colour : Black

LOCATION : -		COUNTRY : UK		Supersedes A/W No.:			
SIZE : 150 x 600 mm_Front Side				CODE : 8111703-7803	DATE : 18-06-2026		
REMARK :							
SUBSTRATE :							
Activities	Department	Name	Signature	Date			
Prepared By	Pkg.Dev						
Reviewed By	Pkg.Dev						
Approved By	Quality						

This colour proof is not colour binding. Follow Pantone shade reference for actual colour matching.

