

For the use only of a Registered Medical Practitioners or a Hospital or a Laboratory

Defratraj® * डेफ़राताज
Deferasirox



125 mg / 250 mg & 500 mg
dispersible tablets

TABLETS FOR ORAL SUSPENSION



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.

What is in this leaflet

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1. What Deferasirox is and what it is used for

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

Do not take Deferasirox 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. If you think you may be allergic, ask your doctor for advice.
• have moderate or severe kidney disease
• are currently taking any other iron chelator medicines.
Deferasirox is 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 if you:

- have a kidney or liver problem
- have a cardiac problem due to iron overload
- notice a marked decrease in your urine output (sign of kidney problem)
- 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")
- develop a rash, red skin, blistering of lips, eyes or mouth, skin peeling, fever (signs of severe skin reaction, see also section 4 "Possible side effects")
- 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)
- vomit blood and/or have black stools
- experience frequent abdominal pain, particularly after eating or taking Deferasirox
- experience frequent heartburn

• have a low level of platelets or white blood cells in your blood test
• have blurred vision
• 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 is 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 most suitable for you and will also use these tests to decide when you should stop taking Deferasirox.
Your eyesight and hearing will be tested each year during treatment as a precautionary measure.

Other medicines and Deferasirox

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
• antacids (medicines used to treat heartburn) containing aluminium, which should not be taken at the same time of day as Deferasirox
• 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).
Additional tests may be required to monitor the blood levels of some of these medicines.
Older people (age 65 years and over)
Deferasirox 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 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 is 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 is 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 may reduce the effectiveness of oral and patch contraceptives. Breast-feeding is not recommended during treatment with Deferasirox.
Driving and using machines
If you feel dizzy after taking Deferasirox, do not drive or operate any tools or machines until you are feeling normal again.

Deferasirox contains lactose monohydrate
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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 may reduce the effectiveness of oral and patch contraceptives. Breast-feeding is not recommended during treatment with Deferasirox.

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3. How to take Deferasirox

Treatment with Deferasirox 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 to take

The dose of Deferasirox 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 dispersible tablets at the start of the treatment for patients receiving regular blood transfusions is 20 mg per kilogram body weight. A higher or lower

starting dose may be recommended by your doctor based on your individual treatment needs.

- The usual daily dose for Deferasirox dispersible tablets at the start of the treatment for patients not receiving regular blood transfusions is 10 mg per kilogram body weight.
 - Depending on how you respond to treatment, your doctor may later adjust your treatment to a higher or lower dose.
 - The maximum recommended daily dose for Deferasirox dispersible tablets is 40 mg per kilogram body weight for patients receiving regular blood transfusions, 20 mg per kilogram body weight for adult patients not receiving regular blood transfusions and 10 mg per kilogram body weight for children and adolescents not receiving regular blood transfusions.
- Deferasirox also comes as "film-coated" tablets. If you are switching from the film-coated tablets to these dispersible tablets, you will need an adjustment of the dose.
When to take Deferasirox
• Take Deferasirox once a day, every day, at about the same time each day.
• Take the tablets on an empty stomach.
• Then wait at least 30 minutes before eating any food.
Taking Deferasirox at the same time each day will also help you to remember when to take your tablets.

If you have questions about how long to take Deferasirox, talk to your doctor.

If you take more Deferasirox than you should

If you have taken too much Deferasirox, or if someone else accidentally takes your tablets, contact your doctor or hospital for advice straight away. Show them the pack of tablets. Medical treatment may be necessary.

If you forget to take Deferasirox

If you miss a dose, take it as soon as you remember on that day. Take your next dose as scheduled. Do **not** take a double dose on the next day to make up for the forgotten tablet(s).

If you stop taking Deferasirox

Do **not** stop taking Deferasirox unless your doctor tells you to. If you stop taking it, the excess iron will no longer be removed from your body (see also above section "How long to take Deferasirox").

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Most of the side effects are mild to moderate and will generally disappear after a few days to a few weeks of treatment.

Some side effects could be serious and need immediate medical attention.

These side effects are uncommon (may affect up to 1 in 100 people) or rare (may affect up to 1 in 1,000 people):

- If you get a severe rash, or difficulty breathing and dizziness or swelling mainly of the face and throat (signs of severe allergic reaction)
 - If you get a severe rash, red skin, blistering of lips, eyes or mouth, skin peeling, fever (signs of severe skin reaction)
 - If you notice a marked decrease in your urine output (sign of kidney problem)
 - 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 vomit blood and/or have black stools
 - If you experience frequent abdominal pain, particularly after eating or taking Deferasirox,
 - If you experience frequent heartburn
 - If you experience partial loss of vision
 - If you experience severe upper stomach pain (pancreatitis)
- stop taking this medicine and tell your doctor straight away. Some side effects could become serious.
These side effects are uncommon:
• If you get blurred or cloudy eyesight

If you get reduced hearing tell your doctor as soon as possible.

Other side effects

- Very common: may affect more than 1 in 10 people
 - disturbance in kidney function tests.
 - Common: may affect up to 1 in 10 people
 - gastrointestinal disorders, such as nausea, vomiting, diarrhoea, pain in the abdomen, bloating, constipation, indigestion
 - rash
 - headache
 - disturbance in liver function tests
 - itching
 - disturbance in urine test (protein in the urine).
- If any of these affects you severely, tell your doctor.

Uncommon: may affect up to 1 in 100 people

- dizziness
- fever
- sore throat
- swelling of arms or legs
- change in the colour of the skin
- anxiety
- sleep disorder
- tiredness.

If any of these affects you severely, tell your doctor.

Not known: frequency cannot be estimated from the available data

- a decrease in the number of cells involved in blood clotting (thrombocytopenia), in the number of red blood cells (anaemia aggravated), in the number of white blood cells (neutropenia) or in the number of all kinds of blood cells (pancytopenia)
- hair loss
- kidney stones
- low urine output
- tear in stomach or intestine wall that can be painful and cause nausea
- severe upper stomach pain (pancreatitis)
- abnormal level of acid in blood.

5. How to store Deferasirox

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 blister and the carton after EXP. The expiry date refers to the last day of that month. This medicine does not require any special storage conditions.
Do not use any pack that is damaged or shows signs of tampering.

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 Deferasirox contains

- The active substance is deferasirox
- Deferasirox 125mg: Each dispersible tablet contains 125mg deferasirox.
Deferasirox 250mg: Each dispersible tablet contains 250mg deferasirox.
Deferasirox 500mg: Each dispersible tablet contains 500mg deferasirox.

Manufactured In India By:

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DISCLAIMER: THE INFORMATION GIVEN BELOW IS FOR THE USE OF MEDICAL SALES REP AND IS NOT FOR DOCTORS.

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist. This leaflet was last revised in December 2018.

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Not all pack sizes may be marketed.

<p>How to take Deferasirox:</p> <ul style="list-style-type: none">• Drop the tablet(s) into a glass of water, or apple or orange juice (100 to 200 ml).• Stir until the tablet(s) dissolve completely. The liquid in the glass will look cloudy.• Drink everything in the glass. Then add a little water or juice to what is left in the glass, swirl the liquid around and drink that too. Do not dissolve the tablets in fizzy drinks or milk.	
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Do not chew, break or crush the tablets. Do not swallow the tablets whole.

How long to take Deferasirox

Continue taking Deferasirox every day for as long as your doctor tells you. This is a long-term treatment, possibly lasting for months or years. Your doctor will regularly monitor your condition to check that the treatment is having the desired effect (see also section 2: "Monitoring your Deferasirox treatment").

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