Package leaflet: Information for the patient

Deferasirox Teva 125 mg dispersible tablets
Deferasirox Teva 250 mg dispersible tablets
Deferasirox Teva 500 mg dispersible tablets

deferasirox

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 only for you or your child. 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

1. What <Product name> is and what it is used for

What <Product name> is
<Product name> 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 <Product name> 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.

<Product name> is used to treat chronic iron overload caused by frequent blood transfusions in patients with beta thalassaemia major aged 6 years and older.

<Product name> 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.

<Product name> 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 <Product name>

Do NOT take <Product name>
- 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 <Product name>**. 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.

<Product name> 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 <Product name>
- 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 <Product name>,
- 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 <Product name> 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 <Product name> 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 <Product name> most suitable for you and will also use these tests to decide when you should stop taking <Product name>.

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

Other medicines and <Product name>
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 <Product name>,
- antacids (medicines used to treat heartburn) containing aluminium, which should NOT be taken at the same time of day as<Product name>,
- 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)
<Product name> 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
<Product name> 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.

<Product name> 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.

<Product name> is NOT recommended during pregnancy unless clearly necessary.

If you are currently using a hormonal contraceptive to prevent pregnancy, you should use an additional or different type of contraception (e.g. condom), as <Product name> may reduce the effectiveness of hormonal contraceptives.

Breast-feeding is NOT recommended during treatment with <Product name>.

Driving and using machines
If you feel dizzy after taking <Product name>, do not drive or operate any tools or machines until you are feeling normal again.

<Product name> contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

<Product name> contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take <Product name>

Treatment with <Product name> 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 <Product name> to take
The dose of <Product name> 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 <Product name> 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 <Product name> 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 <Product name> 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 and granules. If you are switching from the film-coated tablets or granules to these dispersible tablets, your dose will change. Your doctor will calculate the dose you need and tell you how many dispersible tablets to take each day.

When to take <Product name>

- Take <Product name> once a day, every day, at about the same time each day.
- Take the <Product name> dispersible tablets on an empty stomach.
- Then wait at least 30 minutes before eating any food.

Taking <Product name> at the same time each day will also help you remember when to take your tablets.

How to take <Product name>: • **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. Do NOT chew, break or crush the tablets. Do NOT swallow the tablets whole.	  

How long to take <Product name>
Continue taking <Product name> 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 <Product name> treatment").

If you have questions about how long to take <Product name>, talk to your doctor.

If you take more <Product name> than you should
If you have taken too much <Product name>, or if someone else accidentally takes your tablets, contact your doctor or hospital for advice straight away. Show the doctor the pack of tablets. Urgent medical treatment may be necessary. You may experience effects such as abdominal pain, diarrhoea, nausea and vomiting and kidney or liver problems that can be serious.

If you forget to take <Product name>
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 <Product name>
Do NOT stop taking <Product name> 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 <Product name>").

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 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 reactions),
- 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 experience difficulty thinking, remembering information, or solving problems, beingless 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 and lead to a change in your brain function),
- If you vomit blood and/or have black stools,
- If you experience frequent abdominal pain, particularly after eating or taking <Product name>,
- 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.

Frequency not known *(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

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 <Product name>

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 <Product name> contains

- The active substance is deferasirox
  <Product name 125mg>: Each dispersible tablet contains 125 mg deferasirox.
  <Product name 250mg>: Each dispersible tablet contains 250 mg deferasirox.
  <Product name 500mg>: Each dispersible tablet contains 500 mg deferasirox.
- The other ingredients are lactose monohydrate, microcrystalline cellulose, crospovidone type A, povidone K30, sodium laurilsulfate, colloidal anhydrous silica and magnesium stearate.

What <Product name> looks like and contents of the pack

<Product name> 125 mg dispersible tablets are white to off-white, round, flat tablets with bevelled edges and debossing 77 on one side and 438 on the other side. Diameter of each tablet is approx. 12 mm
<Product name> 250 mg dispersible tablets are white to off-white, round, flat tablets with bevelled edges and debossing 77 on one side and 439 on the other side. Diameter of each tablet is approx. 15 mm
<Product name> 500 mg dispersible tablets are white to off-white, round, flat tablets with bevelled edges and debossing 77 on one side and 440 on the other side. Diameter of each tablet is approx. 20 mm

<Product name> 125 mg and 250 mg dispersible tablets are available in blister packs of 28, 28x1, 30, 30x1, 84, 84x1, 98 and 98x1 dispersible tablets.
<Product name> 500 mg dispersible tablets are available in blister packs of 28, 28x1, 30, 30x1, 84, 84x1, 98, 98x1 and in multipacks comprising 3 cartons, each containing 98 dispersible tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicine is authorised in the Member States of the European Economic Area under the following names:

[To be completed nationally]

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