Package leaflet: Information for the user

Deferasirox Sandoz 90 mg film-coated tablets
Deferasirox Sandoz 180 mg film-coated tablets
Deferasirox Sandoz 360 mg film-coated 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 [Nationally Completed Name] is and what it is used for

What [Nationally Completed Name] is
[Nationally Completed 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 [Nationally Completed 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.

[Nationally Completed Name] is used to treat chronic iron overload caused by frequent blood transfusions in patients with beta thalassaemia major aged 6 years and older.

[Nationally Completed 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.

[Nationally Completed 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 [Nationally Completed Name]

Do not take [Nationally Completed 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 [Nationally Completed 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

[Nationally Completed 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 [Nationally Completed Name] 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”)
- 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”)
- 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)
- 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”)
- vomit blood and/or have black stools
- experience frequent abdominal pain, particularly after eating or taking [Nationally Completed Name]
- 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 [Nationally Completed 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 [Nationally Completed 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 [Nationally Completed Name] most suitable for you and will also use these tests to decide when you should stop taking [Nationally Completed Name].

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

Other medicines and [Nationally Completed 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 [Nationally Completed Name]
- antacids (medicines used to treat heartburn) containing aluminium, which should not be taken at the same time of day as [Nationally Completed 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.

Elderly (age 65 years and over)
[Nationally Completed 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

[Nationally Completed 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.

[Nationally Completed Name] is not recommended for children aged under 2 years.

Pregnancy, breast-feeding and fertility
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.

[Nationally Completed 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 [Nationally Completed Name] may reduce the effectiveness of hormonal contraceptives.

Breast-feeding is not recommended during treatment with [Nationally Completed Name].

Driving and using machines
If you feel dizzy after taking [Nationally Completed Name], do not drive or operate any tools or machines until you are feeling normal again.

3. How to take [Nationally Completed Name]

Treatment with [Nationally Completed 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 [Nationally Completed Name] to take
The dose of [Nationally Completed 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 [Nationally Completed Name] film-coated 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 may be recommended by your doctor based on your individual treatment needs.
- The usual daily dose for [Nationally Completed Name] film-coated tablets at the start of the treatment for patients not receiving regular blood transfusions is 7 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 [Nationally Completed Name] film-coated tablets is:
  - 28 mg per kilogram body weight for patients receiving regular blood transfusions,
  - 14 mg per kilogram body weight for adult patients not receiving regular blood transfusions,
  - 7 mg per kilogram body weight for children and adolescents not receiving regular blood transfusions.

Deferasirox also comes as “dispersible” tablets. If you are switching from the dispersible tablets to these film-coated tablets, you will need an adjustment of the dose. Your doctor will calculate the dose you need and tell you how many film-coated tablets to take each day.

When to take [Nationally Completed Name]

- Take [Nationally Completed Name] once a day, every day, at about the same time each day with some water.
- Take [Nationally Completed Name] film-coated tablets either on an empty stomach or with a light meal.

Taking [Nationally Completed Name] at the same time each day will also help you remember when to take your tablets.

For patients who are unable to swallow whole tablets, [Nationally Completed Name] film-coated tablets may be crushed and taken by sprinkling the full dose onto soft food such as yogurt or apple sauce (pureed apple). The food should be immediately and completely consumed. Do not store it for future use.

How long to take [Nationally Completed Name]

Continue taking [Nationally Completed 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 [Nationally Completed Name] treatment”).

If you have questions about how long to take [Nationally Completed Name], talk to your doctor.

If you take more [Nationally Completed Name] than you should

If you have taken too much [Nationally Completed 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 [Nationally Completed 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 [Nationally Completed Name]

Do not stop taking [Nationally Completed 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 [Nationally Completed 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, 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 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 [nationally completed 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 [Nationally Completed 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 carton after 'EXP'. The expiry date refers to the last day of that month.

Do not use this medicine if you notice that the pack 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 [Invented name] contains

- The active substance is deferasirox.
  {[Nationally completed name] 90 mg film-coated tablets}:
  Each tablet contains 90 mg deferasirox.
  {[Nationally completed name] 180 mg film-coated tablets}:
  Each tablet contains 180 mg deferasirox.
  {[Nationally completed name] 360 mg film-coated tablets}:

Each tablet contains 360 mg deferasirox.

The other ingredients are - in the tablet core: cellulose, microcrystalline, crospovidone, magnesium stearate, povidone, poloxamer, silica, colloidal anhydrous. In the film-coating - opadry blue: hypromellose, titanium dioxide (E171), macrogol, talc, indigo carmine aluminium lake (E132)

What [Nationally completed name] looks like and contents of the pack

{[Nationally completed name] 90 mg film-coated tablets}:
Light blue unscored ovaloid biconvex film-coated tablet with bevelled edges, debossed with 'NVR' on one side and '90' on a slight upward slope in between two debossed curved lines on the other side. Dimensions: Approx. 10.7 x 4.2 mm..

{[Nationally completed name] 180 mg film-coated tablets}:
Medium blue unscored ovaloid biconvex film-coated tablet with bevelled edges, debossed with 'NVR' on one side and '180' on a slight upward slope in between two debossed curved lines on the other side. Dimensions: Approx. 14 x 5.5 mm. side.

{[Nationally completed name] 360 mg film-coated tablets}:
Dark blue unscored ovaloid biconvex film-coated tablet with bevelled edges, debossed with 'NVR' on one side and '360' on a slight upward slope in between two debossed curved lines on the other side. Dimensions: Approx. 17 x 6.7 mm.

The tablets are packed in PVC/PVDC-aluminium blister or PA/AL/PVC-aluminium blister.

Each blister pack contains 30, 90, 100 or 300 film-coated tablets. The multipacks contain 300 (10 packs of 30) film-coated tablets.

Not all pack sizes or strengths may be marketed in your country.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicinal product is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

[To be completed nationally]

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[To be completed nationally]