Package leaflet: Information for the patient

Deferasirox 90 mg film-coated tablets
Deferasirox 180 mg film-coated tablets
Deferasirox 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 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

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.
- if you have moderate or severe kidney disease.
- if you 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.
- 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.
- 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 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)
- 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 (aged 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.

Do not give this medicine to 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 a hormonal contraceptive to prevent pregnancy, you should use an additional or different type of contraception (e.g. condom), as Deferasirox may reduce the effectiveness of hormonal 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 sodium
This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially ‘sodium-free’.

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 recommended daily dose for Deferasirox 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 recommended daily dose for Deferasirox 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 Deferasirox 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 may also be available as “dispersible” tablets as generic alternatives. If you are switching from the dispersible tablets to these film-coated 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 with some water.
- Take Deferasirox film-coated tablets either on an empty stomach or with a light meal.

Taking Deferasirox at the same time each day will also help you remember when to take your film-coated tablets.

Deferasirox is for oral use.
For patients who are unable to swallow whole tablets, Deferasirox 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 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").

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 film-coated tablets, contact your doctor or hospital for advice straight away. Show the doctor the pack of film-coated 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 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 to make up for a forgotten dose.

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").

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

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 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

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 Yellow Card Scheme (Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store). By reporting side effects you can help provide more information on the safety of this medicine.

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 carton and the blister 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 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 Deferasirox contains
- The active substance is deferasirox.
  Each film-coated tablet of Deferasirox 90 mg contains 90 mg deferasirox.
  Each film-coated tablet of Deferasirox 180 mg contains 180 mg deferasirox.
  Each film-coated tablet of Deferasirox 360 mg contains 360 mg deferasirox.
- The other ingredients are:
  Tablet core: polysorbate 80, povidone, crospovidone, microcrystalline cellulose, colloidal anhydrous silica, talc, sodium stearyl fumarate, magnesium stearate
  Tablet coating: hypromellose, titanium dioxide (E171), polydextrose, talc, maltodextrin, medium chain triglycerides, indigo carmine aluminium lake (E132)

What Deferasirox looks like and contents of the pack
Deferasirox is supplied as film-coated tablets.
The film-coated tablets are oval and biconvex.
Deferasirox 90 mg film-coated tablets are light blue, engraved with "90" on one, with the following dimensions: length 11.0±0.1 mm, width 4.4±0.1 mm and thickness 3.5±0.2 mm.

Deferasirox 180 mg film-coated tablets are medium blue, engraved with "180" on one side, with the following dimensions: length 14.2±0.2 mm, width 5.6±0.2 mm and thickness 4.2±0.3 mm.

Deferasirox 360 mg film-coated tablets are dark blue, engraved with "360" on one side, with the following dimensions: length 17.3±0.2 mm, width 6.9±0.2 mm and thickness 5.4±0.3 mm.

Deferasirox is packaged in a cardboard box containing transparent PVC/PVDC/Aluminium blisters.

Deferasirox 90 mg and 180 mg are available in unit packs containing 30 or 90 film-coated tablets.

Deferasirox 360 mg is available in unit packs containing 30 or 90 film-coated tablets and in multipacks comprising 10 cartons, each containing 30 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Pharmathen SA,
6 Dervenakion str.,
15351 Pallini Attiki,
Greece

Manufacturer:
Pharmathen International S.A
Industrial Park Sapes, Rodopi Prefecture, Block No 5,
Rodopi 69300,
Greece

Or

Pharmathen SA,
Dervenakion 6, Pallini 15351,
Attiki,
Greece

Or

PHARMADOX HEALTHCARE LTD
KW20A Kordin Industrial Park,
Paola PLA3000,
Malta

Distributor:
Northumbria Pharma Ltd.
NETPark
Thomas Wright Way
Sedgefield
Stockton-on-Tees
TS21 3FD
UK

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:

DK/H/3112/001-003/DC

Denmark	Deferasirox Pharmathen
Germany	Deferasirox / Pharmathen 90mg, 180mg and 360mg Filmtabletten
France	Deferasirox Pharmathen 90mg, 180mg and 360mg comprimé pelliculé
Belgium	Deferasirox Pharmathen 90 mg, 180 mg and 360 mg comprimés pelliculés/filmomhulde tabletten/ Filmtabletten
Austria	Deferasirox G.L. 90 mg-Filmtabletten Deferasirox G.L. 180 mg-Filmtabletten Deferasirox G.L. 360 mg-Filmtabletten
Greece	Deferasirox / Pharmathen 90mg, 180mg and 360mg επικαλυμμένα με λεπτό υμένιο δισκία
Cyprus	Deferasirox Pharmathen 90mg, 180mg and 360mg επικαλυμμένα με λεπτό υμένιο δισκία
Italy	Deferasirox Pharmathen
Spain	Deferasirox / Pharmathen 90mg, 180mg and 360mg comprimidos recubiertos con película
Ireland	Deferasirox Pharmathen 90mg, 180mg and 360mg film coated tablets
Portugal	Deferasirox / Pharmathen 90mg, 180mg and 360mg comprimidos revestidos por película
United Kingdom (Northern Ireland)	Deferasirox / Pharmathen 90mg, 180mg and 360mg film coated tablets

DK/H/3113/001-003/DC

Denmark	Deferasirox Medical Valley
Netherlands	Deferasirox Xiromed 90 mg, 180 mg, 360 mg filmomhulde tabletten
Germany	Deferasirox AXiromed 90 mg, 180 mg, 360 mg, Filmtabletten
Sweden	Deferasirox Medical Valley
Norway	Deferasirox Medical Valley
Iceland	Deferasirox Medical Valley 90mg, 180mg, 360mg filmuhúðaðar töflur

DK/H/3114/001-003/DC

Denmark	Defloxol
Bulgaria	Defloxol
Romania	Defloxol

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