

PATIENT INFORMATION LEAFLET

OXFET 180 mg film-coated tablets

For oral use.

- **Active ingredient:** Each film coated tablet contains 180 mg deferasirox.
- **Excipients:** Microcrystalline Cellulose 101, microcrystalline Cellulose 102, povidone K30, crospovidone XL 10, poloxamer 188, colloidal silicon dioxide, magnesium stearate, hydroxypropyl methylcellulose, titanium dioxide, macrogol, talc, FD&C Blue # 2/indigo carmine aluminum lacquer

▼ 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 PATIENT INFORMATION LEAFLET carefully before you start taking this medicine, because it contains important information for you.

- *Keep this leaflet because you may need to read it again.*
- *If you have any further questions or are not sure about anything, please ask your doctor or your pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others as it may harm them, even if their symptoms are the same as yours.*
- *Tell your doctor or pharmacist that you use this medicine if you visit your doctor or go to the hospital*
- *Strictly follow these instructions. Do not take **lower or higher** doses than the recommended dose*

What is in this leaflet

- 1. What OXFET is and what it is used for**
- 2. What you need to know before you take OXFET**
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- 4. Possible side effects**
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are found.

1- What OXFET is and what it is used for

OXFET is blue coloured, biconvex, ovaloid film coated tablets. Each film coated tablet contains 180 mg deferasirox.

OXFET is available 30 or 90 film-coated tablets in the blisters.

Iron overload due to blood transfusion (patients receiving regular transfusions):

OXFET is used in the treatment of iron overload caused by blood transfusion.

It can be used in the treatment of adults, teenagers and children 6 years and older. This film coated tablets should not be preferred for 2-5 years old patients, if dispersible tablet and parenterally iron chelating agents can be used.

OXFET is an iron-binding drug (iron chelator) that removes excess iron (also called iron overload) in the body. OXFET binds iron and ensures that it is largely excreted through the faeces.

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.

Non-transfusion-dependent thalassemia syndromes (thalassemia patients not receiving regular blood transfusions)

OXFET, used for the treatment of patients that have iron overload associated with thalassemia syndromes but not receiving blood transfusions. Can be used in adults, adolescents and children over 10 years and older with this condition. At patients with thalassemia syndromes not due to transfusion may develop iron overload over time, primarily due to increased absorption of dietary iron in response to low blood cell counts. High iron levels in thalassemia patients who do not receive regular blood transfusions are observed in patients usually only for those aged 10 years or older.

Over time, excess iron can damage important organs such as the liver and heart.

As an iron chelator called drugs are used to remove excess iron and reduce the risk of organ damage.

OXFET is used in the treatment of chronic iron overload caused by frequent blood transfusions in beta Thalassemia patients aged 6 years and older.

OXFET is also used to treat patients 10 years of age and older associated with thalassemia syndromes for whom deferoxamine therapy is contraindicated or inadequate.

If you have questions about how OXFET works or why this medicine has been prescribed for you, consult your doctor.

2- What you need to know before you take OXFET

DO NOT TAKE OXFET in the following situations

- if you are allergic or have hypersensitivity to deferasirox or any of the other ingredients of OXFET.
- if you have moderate or severe kidney disease.
- if you are currently taking any other iron chelator medicines.

If you think you may be allergic, consult your doctor

OXFET is NOT RECOMMENDED in the following situations

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

USE OXFET® CAREFULLY in the following situations

- If you have any liver or kidney problems,
- If you have a heart problem due to excessive iron accumulation,
- If you notice a significant decrease in the amount of urine (sign of kidney disease),
- If you notice a severe rash or difficulty breathing and dizziness or swelling, usually of the face and throat (signs of a severe allergic reaction),
- If you are using or have recently used painkillers, anti-inflammatory (anti-inflammatory) drugs or oral bisphosphonate group (medication used for the prevention and treatment of osteoporosis) (see “Use with other drugs”),
- Post-marketing reports of metabolic acidosis occurring during treatment with OXFET have been received. The vast majority of these patients have disorders of the kidneys, disorders of the kidney ducts (Fanconi syndrome), or disorders for which diarrhea (diarrhea) or disturbance of acid-base balance is a known consequence. The acid-base balance in your body should be

monitored as clinically appropriate. Interruption of OXFET treatment should be considered if your body develops kidney-induced acidosis (a severe disease caused by an excess of acid substances in the blood).

- If you are taking or have recently used drugs that prevent blood clotting (anticoagulant) (see “Use with other drugs”),
- If you have a low platelet (blood cells responsible for clotting, platelet) or white blood cell count in your blood test,
- If you vomit blood and/or your stools are black,
- If you experience frequent heartburn or abdominal pain (ulcer), especially after eating or using OXFET,
- If you notice a significant decrease in the amount of urine (sign of kidney disease),
- If you notice a severe rash or difficulty breathing and dizziness or swelling, usually of the face and throat (signs of a severe allergic reaction),
- If you experience rash, redness of the skin, blisters on the lips, eyes or mouth, peeling of the skin, sore throat (signs of a severe skin reaction),
- If you experience blurred vision, vomiting or diarrhoea,
- If you experience some of the symptoms of dizziness, pain in the upper right part of the abdomen, jaundice or increased jaundice of the skin and eyes, and darkening of the urine color (signs of liver disease),
- If you see any of these symptoms, inform your doctor immediately.
- If these warnings apply to you, even at any time in the past, please consult your doctor.

Monitoring your OXFET 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 OXFET 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 for you and will also use these tests to decide when you should stop taking OXFET.

Using OXFET with food and drink

OXFET should be taken on an empty stomach or with very little food, preferably at the same time each day.

Pregnancy

Consult your doctor or pharmacist before using this medication.

OXFET is not recommended for use during pregnancy unless clearly necessary. If you are pregnant or think you may be pregnant, inform your doctor. Your doctor will advise you whether you can use OXFET during pregnancy.

The effects of OXFET on fertility in humans are unknown. OXFET may reduce the effect of hormonal contraceptives. Therefore, you should use an additional or different method of birth control (such as a condom).

If you realize that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Breast-feeding

Consult your doctor or pharmacist before using this medication.

It is not recommended to breastfeed your baby while on OXFET therapy. Inform your doctor if you are breastfeeding.

Driving and using machines

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

Concomitant use with other drugs

Medicines used in the treatment of heartburn (aluminium-containing antacids) should not be used at the same time of day as OXFET.

Do not use OXFET together with other iron chelator drugs.

Tell your doctor and pharmacist if you are using any of the following medicines:

- Cyclosporine (used in organ transplants to prevent rejection of transplanted tissue (graft) and other conditions such as rheumatoid arthritis or atopic dermatitis, an allergic skin disease)
- Simvastatin (used to lower cholesterol)
- Birth control drugs (hormonal contraceptive agents)
- Some pain relievers and anti-inflammatory drugs (eg aspirin, ibuprofen, corticosteroids)
- Oral (oral) bisphosphonates (used in the treatment of osteoporosis)
- Medicines that prevent blood clotting (anticoagulant)
- Repaglinide (used to treat diabetes)
- Rifampicin (used to treat tuberculosis)
- Phenytoin, phenobarbital, carbamazepine (used in the treatment of epilepsy)
- Ritonavir (used to treat HIV infection (AIDS disease))
- Paclitaxel (used in cancer treatment)
- Theophylline (used in the treatment of respiratory diseases such as asthma)
- Bepridil (used to treat cardiac (heart) chest pain), ergotamine (used to treat migraine-type headache)
- Clozapine (used to treat psychiatric disorders such as schizophrenia)
- Tizanidine (used as a muscle relaxant)
- Cholestyramine (used when blood cholesterol levels are low)
- Busulfan (used as a pre-transplant treatment to destroy the original bone marrow before transplant)

Your doctor may need to test the level of some of these medicines in your blood. Your doctor will consider these tests when determining the most appropriate dose of these drugs for you.

If you are currently using or have recently used any prescription or non-prescription drugs, please inform your doctor or pharmacist about them.

3- How to take OXFET

Instructions for proper use and dose/frequency of administration:

Always use OXFET exactly as your doctor has told you. If there is anything you are not sure about, consult your doctor or pharmacist.

The dose of OXFET is calculated based on the patient's body weight. Your doctor will calculate the dose you need and will tell you how many tablets you should take per day.

- The daily dose at the start of treatment is usually 14 mg per kilogram of body weight for patients receiving regular blood transfusions. Depending on individual treatment needs, your

doctor may recommend a lower or higher starting dose.

- The daily dose at the start of treatment is usually 7 mg per kilogram of body weight for patients not receiving regular blood transfusions.
- Depending on your response to treatment, your doctor may adjust a lower or higher dose.
- The highest dose of film-coated tablets that can be taken in a day;
- 28 mg per kilogram of body weight for patients receiving regular blood transfusions,
- 14 mg per kilogram of body weight for adult patients who do not receive regular blood transfusions,
- For pediatric patients and adolescents not receiving regular blood transfusions, it is 7 mg per kilogram of body weight.

Deferasirox is also available in a dispersible tablet form. If you are changing from a dispersible tablet to a film-coated tablet, you will need a dose adjustment.

Route of and method administration:

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

Taking OXFET 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, OXFET 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.

Continue taking OXFET 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.

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

Different age groups:

Use in children:

OXFET can be used in children and adolescents aged 6 years and older who receive regular blood transfusions, and in children and adolescents aged 10 years and older who do not receive regular blood transfusions. The doctor will adjust the dose as the patient grows.

If this film-coated tablet is in the 2-5 age group; It should not be preferred in patients where water-dispersible tablets and parenteral iron chelators can be used.

In children younger than 23 months:

The efficacy and safety of OXFET in children younger than 23 months has not been established. No data available.

Use in the elderly:

OXFET is used in the elderly at the same dose as prescribed for adults. However, people aged 65 and over may experience more side effects than younger people. These patients should be closely monitored by their physician for side effects that may require a dose adjustment.

Special conditions for use:

Renal failure:

OXFET therapy should be used with caution in patients with serum creatinine levels higher than the upper limit of normal for their age. Particular care should be exercised in patients with creatinine clearance <60 mL/min, especially when there are additional risk factors that may impair renal function, such as concomitant drug use, dehydration (water loss), or severe infections. In

these patients, monitoring of creatinine and/or creatinine clearance should be performed weekly for the first month and monthly thereafter. No dose adjustment is required at the start of treatment in patients with renal impairment. Serum creatinine levels should be monitored monthly in all patients; If necessary, daily doses can be reduced by 10 mg/kg.

Hepatic failure:

The starting dose should be reduced by approximately 50% in patients with moderate hepatic impairment, and it should not be used in patients with severe hepatic impairment.

Liver function should be monitored in all patients before initiation of therapy, every 2 weeks for the first month of therapy and monthly thereafter.

If you have the impression that the effect of OXFET is too strong or weak, talk to your doctor or pharmacist.

If you use more OXFET than you should:

If you have used more OXFET than you should, or if someone else has used your tablets by mistake, contact your doctor or hospital immediately. Show the tablet pack. Medical treatment may be necessary.

If you have used more than you should use from OXFET, talk to a doctor or pharmacist.

If you forget to use the OXFET:

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).

Effects that may occur when treatment with OXFET is terminated:

Discontinuing OXFET therapy may cause your disease to get worse. If you stop using it, the excess iron will not be eliminated from your body. Do not stop using OXFET unless instructed by your doctor.

If you have any questions about the use of OXFET, consult your doctor or pharmacist.

4- Possible side effects

Like all medicines, OXFET 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.

Side effects are categorized as follows:

Very common	: in at least 1 patient of 10.
Common	: in less than 1 of 10 patients and more than 1 of 100 patients.
Uncommon	: in less than 1 of 100 patients but, more than 1 of 1000 patients.
Rare	: in less than 1 of 1000 patients but more than 1 of 10.000 patients.
Very rare	: in less than 1 of 10.000 patients.
Not known	: Cannot be estimated based on available data

Most side effects are mild to moderate and usually disappear within a few days to a few weeks after treatment.

Don't be alarmed by the list of side effects below. You may not experience any of these.

If any of the following occur, stop using OXFET and IMMEDIATELY inform your doctor or go to the nearest hospital emergency department:

- severe rash or difficulty breathing and dizziness or swelling, usually of the face and throat (signs of a severe allergic reaction),
- If you experience rash, redness of the skin, blisters on the lips, eyes or mouth, peeling skin, sore throat (signs of a severe skin reaction).

- Significant decrease in the amount of urine (sign of kidney disease),
- Dizziness, pain in the upper right part of the abdomen, jaundice of the skin and eyes or a combination of some of the symptoms of increased yellowness of the skin and eyes and darkening of the color of the urine (signs of liver disease),
- If you vomit blood and/or your stools are black,
- If you experience frequent heartburn or abdominal pain (ulcer), especially after eating or taking the medicine,
- Partial vision loss
- Severe pain in the upper abdomen

These are all very serious side effects. If you have one of these, you may need emergency medical attention or hospitalization.

If you notice any of the following, tell your doctor immediately or go to the nearest hospital emergency department:

- Blurred vision
- Decreased hearing

All these are serious side effects. Emergency medical attention may be required.

Serious side effects are uncommon (less than 1 in 100 patients, but more than 1 in 1000 patients).

Tell your doctor if you notice any of the following:

Very common (These side effects may affect more than 1 in 10 people):

- Impairment of renal function (kidney function) tests.

Common (less than 1 in 10 patients, but more than 1 in 100 patients):

- Gastrointestinal (digestive system) disorders such as nausea, vomiting, diarrhea, abdominal pain, bloating, constipation, indigestion
- Rash
- Headache
- Disorder in liver function tests
- Itching
- Urine test disorder (protein in the urine).

Uncommon (affects less than 1 in 100 but more than 1 in 1,000 patients):

- Dizziness (drowsiness)
- Fever
- Throat ache
- Swelling in the arms and legs
- Change in skin color
- Anxiety, worry (anxiety)
- Sleeping disorder
- Tiredness

Frequency unknown:

- 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

If you experience any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

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. By reporting side effects you can help provide more information on the safety of this medicine.

5- How to store OXFET

Store OXFET in its original packaging and keep out of the reach and sight of children.

Store at room temperature, below 25°C.

Use in compliance with the expiry date.

Do not use OXFET after the expiry date which is stated on the blister and the carton after expiry date.

Do not throw away drugs that have expired or are not used! Deliver to the collection system determined by the Ministry of Environment and Urbanism.

Do not use OXFET product or any pack that is damaged or shows signs of tampering.

Marketing Authorization Holder:

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