

My IROREST® (deferasirox)

Handbook Patient handbook

Name:

Date:

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Objective

This educational material is essential to ensure the safe and effective use of the product and appropriate management of the important selected risks.

What is deferasirox (IROREST®)?

IROREST® (deferasirox) helps to remove excess iron in the body. Because of this, it is known as an “iron chelator” or “chelation agent.” Read this material carefully before prescribing/dispensing/administering the produce.

Why was I prescribed IROREST® (deferasirox) ?

Many kinds of conditions need blood transfusions. Some of these are:

- β -thalassemia major.
- Sickle cell disease, or SCD.
- Lower-risk myelodysplastic syndromes, or MDS.
- Other anemias.

If you have one of these conditions, you’ve probably received several blood transfusions. Transfusions have the healthy red blood cells your body needs and can help you feel better. Every transfusion you are given contains iron. Iron is important because red blood cells use it to carry oxygen around your body. However, the body does not have its own way of removing extra iron. The amount of iron builds up with each transfusion, and this extra iron in your body, may lead to a condition called chronic iron overload. Too much iron can be harmful and damage organs like your heart and liver. It is important to remove this extra iron to keep your iron at a safe, healthy level.

How does IROREST® (deferasirox) work?

IROREST® (deferasirox) works by a process called “chelation” (key-lay-shun).

After you swallow **IROREST®** (deferasirox) , **IROREST®** (deferasirox) enters your blood and “captures” extra iron available.

What is IROREST® (deferasirox) used for?

IROREST® (deferasirox) is used to treat chronic iron overload caused by frequent blood transfusions in patients aged 6 years and older with a blood disorder called beta-thalassemia major. IROREST® (deferasirox) is also used to treat chronic iron overload when a medication called deferoxamine should not be used or did not improve outcomes in patients with beta-thalassemia major and iron overload caused by infrequent blood transfusions, in patients with other types of blood disorders called anemias, and in children aged 2 to 5 years. IROREST® (deferasirox) is also used when deferoxamine should not be used or did not improve outcomes in patients aged 10 years or older who have iron overload associated with their thalassemia syndromes, but who are not transfusion dependent.

How do I take IROREST® (deferasirox) film-coated tablet?

What dose will I take?

Your prescribed dose of IROREST® (deferasirox) film-coated tablets is based on your weight, current iron level, liver and kidney function, and how often you get transfusions.

IROREST® (deferasirox) film-coated tablets comes in different tablet sizes, and you may need to take more than one. Your doctor will tell you how many tablets and which size(s) you should take each day.

How and when to take IROREST® (deferasirox) film-coated tablets

IROREST® (deferasirox) film-coated tablets should be swallowed whole with some water. If you're unable to swallow whole tablets, you can crush the IROREST® (deferasirox) film-coated tablets and sprinkle the full dose onto a small amount of soft food, such as yogurt or applesauce (puréed apple). You should immediately and completely consume the entire dose and not store any for future use. IROREST® (deferasirox) film-coated tablets should be taken once a day. You should ideally take your IROREST® (deferasirox) at the same time each day. IROREST® (deferasirox) film-coated tablets may be taken on an empty stomach or with a light meal.

What if I forget to take my dose?

If you miss taking a dose of IROREST® (deferasirox) , you should still take it when you remember, even if it is later in the 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).

What if I take more IROREST® (deferasirox) tablets than I should?

If you have taken too much IROREST® (deferasirox) , 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.

How will my treatment be monitored?

While taking IROREST® (deferasirox), you will have regular laboratory tests. These tests will monitor how you are responding to treatment.

Your dose may have to be adjusted up or down based on these tests.

Test	Before starting IROREST	Every month	Once per year
Iron Serum ferritin	✓	✓	
Kidneys Serum creatinine	✓ You will take this test twice before starting IROREST®	✓ For the first month and in the first month after any changes in dose, you will be tested once per week; then once per month	
Creatinine clearance	✓	✓ For the first month and in the first month after any changes in dose, you will be tested once per week; then once per month	
Liver (Serum transaminases, bilirubin, alkaline phosphatase)	✓	✓ For the first month, you will be tested every 2 weeks; then once per month	
Urine (Protein in urine)	✓	✓	
Hearing and vision	✓		✓
Pediatric patients: Assess body development (eg, your weight, sexual development, and how much you grow per year)	✓		✓

Your doctor may also

- Use a test called magnetic resonance imaging, or **MRI**, to check iron levels in your heart or liver.
- Perform a **biopsy** of your kidneys if he/she suspects important kidney damage.

Does IROREST® have side effects?

Like all medicines, IROREST® can have side effects, though not all patients experience them. The most frequent side effects are mild to moderate and will generally disappear once you get used to treatment. This can take a few days or weeks.

Common side effects include nausea, vomiting, diarrhea, pain in the abdomen, bloating, constipation, indigestion, rash, and headache.

Your kidney and liver function will be tested before you start IROREST® and you will be monitored regularly during treatment. (See table on previous page.)

Some side effects could be serious and need immediate medical attention. These side effects are uncommon or rare. Stop taking this medicine and tell your doctor straight away if you experience any of the following:

- Severe rash, or difficulty breathing and dizziness or swelling mainly of the face and throat (signs of severe allergic reaction).
- Severe rash, reddening of the skin, blistering of lips, eyes or mouth, skin peeling, sore throat (signs of severe skin reaction).
- Marked decrease in your urine output (sign of kidney problem).
- A combination of drowsiness, upper right abdominal pain, yellowing or increased yellowing of your skin or eyes and dark urine (signs of liver problems).
- Vomiting blood and/or have black stools.
- Frequent abdominal pain, particularly after eating or taking IROREST®.
- Frequent heartburn.
- Partial vision loss.
- If you experience difficulty thinking, remembering information, or solving problems, being less alert or aware or feeling very sleepy with low energy (potential 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)
- Frequent abdominal pain, particularly after eating or taking IROREST® (deferasirox) ;

Remember: Always tell your health care provider about any side effects you experience. If you have any serious side effects, STOP taking your medication and contact your doctor immediately.

For more details on side effects and serious side effects, please see the Patient Leaflet.

What about other medicines that I also need to take for my health?

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicine you take without a prescription. Your doctor may need to do laboratory tests to monitor these medicines.

Important medicines to tell your doctor about include, in particular:

- Other iron chelators, which must not be taken with Deferasirox
- Antacids (medicines used to treat heartburn) containing aluminum, which should not be taken at the same time as Deferasirox
- Cyclosporine (used to prevent the body from 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 (eg, 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 (used as a treatment for heart problems and migraines)
- Ergotamine (used as a treatment for migraine)
- 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)
- Midazolam (used as a sedative and to treat anxiety and amnesia)
- Busulfan (used as a treatment prior to transplantation in order to destroy the original bone marrow before the transplant)

Contraception

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 (eg, condom), as IROREST® (deferasirox) may reduce the effectiveness of oral and patch contraceptives.

My progress with IROREST® (deferasirox)

My treatment Goal

The goal of IROREST® (deferasirox) treatment is to have a healthy amount of iron in your body. Each month you will visit your doctor to track your progress toward your treatment goal.

Your doctor will set your treatment goals based on a blood test called serum ferritin (SEER-um FAIR-it-in), or SF, test. This test tells your doctor how much iron is in your body. Your doctor will want to either lower your SF level or keep it where it is.

My Dose

Your doctor may decide to change your dose based on your SF level, other laboratory tests, or how often you get transfusions.

After taking IROREST® (deferasirox) for 3 to 6 months, check with your doctor that you are making progress as planned. If you are not, ask your doctor about his/her plan for helping you reach your treatment goal.

Between each visit

Other important events may occur between doctor visits. You should keep a record of them and share them with your doctor. They include:

- Side effects
- Other medicines
- Any deviation from the prescribed dosage

My background information

Your background information is helpful for both you and your doctor when planning your treatment with IROREST® (deferasirox). Ask your doctor if you need help answering these questions.

<u>General Information</u>
First name:
Last name:
Date of birth:
Diagnosis:

Have I been given transfusions? If no, how many and how often?

Do I have any other health issues?

Am I taking any medicine right now for other health issues?

Do I have any allergies?

Starting IROREST®

You can start tracking your progress once your doctor decides on your goal SF level and dose of IROREST®. Work with your doctor to fill in your treatment goals and other information, below.

Date:	My Current SF level:
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My treatment goal is to:

Reduce my SF level to:

.....

My weight:

.....

My IROREST® dosing regimen

• What is my dose?

.....

• How many tablets will I take each day?

.....

• How much liquid should I mix it with?

.....

• When will I take my medication each day?

.....

Monthly testing follower:

Patient name	Test name	Date of test

Notes: Write down any notes or questions from your visit.

You can report any problem or adverse events through:

Apotex Saudi contact information:

Pharmacovigilance Department

Mobile: +966 55 111 9619

E-mail: pharmacovigilance-ksa@apotex.com

Address: 7503 Al Muhandis Masaid Al Anqari Street, Sulaimaniyah, Office B19, 2nd floor, Building B.
Riyadh, Saudi Arabia

The National Pharmacovigilance Center (NPC):

SFDA Call Center: 19999

E-mail: npc.drug@sfd.gov.sa

Website: <https://ade.sfd.gov.sa>

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



References

IROREST Patient leaflet