

Deferasirox:
**Important information about your
treatment and possible side effects**

NAME

DATE

Please keep this document safe for future reference. This booklet is only intended for patients that have been prescribed deferasirox. It contains important information, including how to take deferasirox the right way, why monitoring your treatment is important, and which medicines you can take while on deferasirox.

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My background information

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

General Information

First name _____

Last name _____

Date of birth _____

Diagnosis _____

Have I been given transfusions? If so, 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 Deferasirox

You can start tracking your progress once your doctor decides on your goal blood level of ferritin (FAIR-it-in), or ferritin level, and dose of deferasirox. Work with your doctor to fill in your treatment goals and other information, below.

Date: _____

My current ferritin level: _____

My treatment goal is to:

Reduce my ferritin level to

My deferasirox dosing regimen

•What is my dose?

My weight:

•How many tablets will I take each day?

•When will I take my medication each day?

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

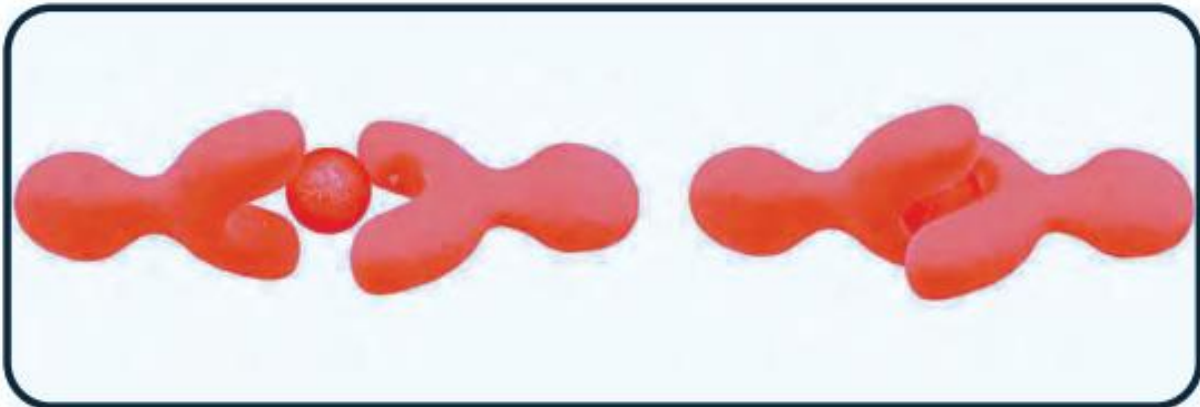
What is Deferasirox?

Deferasirox is an iron chelator (or a “chelating” agent), which is a medicine used to help remove excess iron in the body.

How does this medicine work?

Deferasirox works by a process called “chelation” (key-lay-shun).

After you have taken deferasirox, it enters your blood and “captures” extra iron it finds.



Why was I prescribed this medicine?

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

- Beta thalassaemia major - an inherited blood disorder in which patients do not have enough normal haemoglobin in the blood

- Other anaemias (low levels of haemoglobin in the blood)

If you have one of these conditions, you've probably been given a few 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. This causes extra iron in your body, 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 do I take deferasirox film coated tablets?

It is important to take your medicine as directed by your physician.

What dose will I take?

Your prescribed dose of deferasirox is based on your weight, current iron level, liver and kidney function, and how often you get transfusions.

If you are changing from deferoxamine infusions to deferasirox, your doctor may choose your deferasirox dose based on how much deferoxamine you have been taking.

Which tablet(s) will I take?

Deferasirox 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.

Film-coated tablets: 90 mg and 360 mg

When will I take deferasirox?

Deferasirox film-coated tablets should be taken once a day, preferably at the same time each day, and may be taken on an empty stomach or with a light meal.

How to take deferasirox?

Deferasirox should be swallowed whole with some water.

What if I forget to take my dose?

If you miss taking a dose of 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 deferasirox tablets than I should?

If you take more deferasirox tablets than you should, inform your doctor immediately or contact emergency services, as medical treatment may be necessary.

How will my treatment be monitored?

While taking 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 deferasirox	Every month	Once per year
Iron Amount of iron in your body (blood level of ferritin)	√	√	
Kidney function Blood level of creatinine	√ You will take this test twice before starting deferasirox	√ For the first month and in the first month after any changes in dose (including switch of formulation), you will be tested once per week; then once per month	
Creatinine clearance (to see how well your kidneys are working)	√	√ For the first month and in the first month after any changes in dose (including switch of formulation), you will be tested once per week; then once per month	
Protein in urine	√	√	
Liver function Blood levels of transaminases, bilirubin, alkaline phosphatase	√	√ For the first month, you will be tested every 2 weeks; then once per month	
Hearing and vision	√		√
Body weight and height	√		√
Paediatric patients: Assess body development (e.g. 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 significant kidney damage

Does deferasirox have side effects?

Like all medicines, deferasirox 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 with deferasirox

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

Your kidney and liver function will be tested before you start deferasirox 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, red 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 deferasirox
- Severe upper stomach pain (pancreatitis)
- Frequent heartburn

- Partial vision loss
- Decreased hearing

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.

What about other medicines that I may be taking?

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)
- 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)
- Cholestyramine (used to lower cholesterol levels in the blood)
- Midazolam (used as a sedative and to treat anxiety and amnesia)

My progress with deferasirox

My treatment goal

The goal of 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 goal based on the results of a blood ferritin test. This test gives your current ferritin level and tells your doctor how much iron is in your body. Your doctor will want to either lower your ferritin level or keep it where it is.

My deferasirox dose

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

After taking 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 dose

Glossary

Beta thalassaemia major

An inherited blood disorder in which patients do not have enough normal haemoglobin in the blood.

Biopsy

A medical procedure that involves taking a small sample of body tissue so that it can be examined.

Creatinine

A chemical waste product produced by the muscles. Healthy kidneys filter creatinine and other waste products from the blood and these are excreted, in the form of urine.

Ferritin

Your blood level of ferritin indicates the amount of iron in your blood.

MRI

A magnetic resonance imaging scan is a test for examining organs of the body; it may be used to determine the amount of iron in your liver.

Other anaemias

Low levels of haemoglobin in the blood.