

Deferasirox Accord

(deferasirox):

Important information for patients 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.

For full safety guidance, please refer to the Patient Information Leaflet

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Your Deferasirox Booklet

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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.

It is used to assess how well your kidneys are functioning.

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.

Myelodysplastic syndrome (MDS)

A blood disorder that causes a drop in the number of healthy blood cells.

Other anaemias

Low levels of haemoglobin in the blood.

Sickle cell disease – a group of inherited conditions that affect red blood cells

People with sickle cell disease produce unusually shaped red blood cells that can cause problems because they don't live as long as healthy blood cells and they can become stuck in blood vessels.

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

Have I been given blood 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 target blood level of ferritin (FAIR-it-in) 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 weight: _____

My deferasirox dosing regimen

- What is my dose?

- How many tablets will I take each day?

- When will I take my medication each day?

Please note: If you have non-transfusion-dependent thalassaemia (NTDT), liver iron concentration (LIC) is the preferred method to measure the amount of iron you have.

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

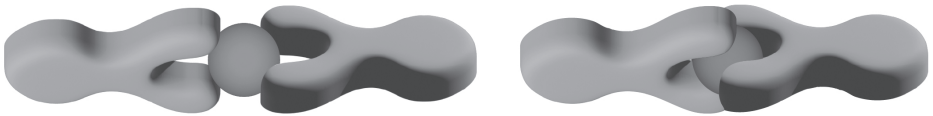
What is deferasirox?

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 condition need transfusions. Some of these include:

- Beta thalassaemia major – an inherited blood disorder in which patients do not have enough normal haemoglobin in the blood
- Sickle cell disease – a group of inherited conditions that affect red blood cells. People with sickle cell disease produce unusually shaped red blood cells that can cause problems because they don't live as long as healthy blood cells and they can become stuck in blood vessels
- Myelodysplastic syndrome (MDS) – a blood disorder that causes a drop in the number of healthy blood cells
- 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?

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

Are there different deferasirox products available?

Different deferasirox products might be available commercially, with different formulations e.g. dispersible tablets, granules, film-coated tablets. Deferasirox Accord is available as film coated tablets.

What do I need to know if my doctor changes the formulation of deferasirox I am taking?

You will need an adjustment of the dose if your doctor switches you from deferasirox dispersible tablets/granules to deferasirox film-coated formulation, along with changing the way you take deferasirox.

To avoid dosage related errors, **you must follow the details from the prescription regarding the dose and the pharmaceutical form as specified by your doctor.** For more details, please read patient information leaflet.

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 Accord 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.

When will I take deferasirox?

Deferasirox Accord 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 Accord should be swallowed whole with some water. For patients who are unable to swallow whole tablets, the deferasirox tablets may be crushed and administered by sprinkling the full dose onto a small amount of soft food, such as yoghurt or apple sauce (pureed apple). The dose should be immediately and completely consumed, and not stored for future use.

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. 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 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 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 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, height and sexual development	✓		✓ Annually in paediatric patients

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
- Test for other markers of renal tubular function (such as glycosuria in non-diabetics and low levels of serum potassium, phosphate, magnesium or urate, phosphaturia, aminoaciduria) will be performed as needed. A renal biopsy should be considered if significant renal abnormalities occur.

Does this medicine 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 include: nausea, vomiting, diarrhoea, pain in the abdomen, bloating, constipation, indigestion, skin rash, headache, and itching.

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.)

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?

Deferasirox must not be taken with other iron chelators.

Antacids (medicines used to treat heartburn) containing aluminium should not be taken at the same time of day as deferasirox.

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.

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

How to report a side effect

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the national reporting system.

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

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Malta Medicines Authority ADR reporting form available online at <http://medicinesauthority.gov.mt/adrportal> and sent to Pharmacovigilance Section at Post-Licensing Directorate, Malta Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN or sent by email to: postlicensing.medicinesauthority@gov.mt

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