

My Toxefro[®] (Deferasirox) Handbook

Patient handbook



Toxefro[®] 250 mg Dispersible Tablets
Toxefro[®] 500 mg Dispersible Tablets
Toxefro[®] 90mg F.C Tablets
Toxefro[®] 180mg F.C Tablets
Toxefro[®] 360mg F.C Tablets

Name:

Date:

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Toxfro[®] (Deferasirox) Handbook

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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.

This handbook contains important information about Deferasirox. You'll learn about taking Deferasirox the right way, depending on which form your doctor prescribed, as well as about monitoring your treatment, possible side effects, and taking other medicines while on Deferasirox.

What is Deferasirox?

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 Product

**Toxefro® (Deferasirox) is available in multiple forms.
Each has a specific shape and color and is taken differently**

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

1) Toxefro® (Deferasirox) film-coated tablets are blue, round-oval tablets. They may be swallowed whole on an empty stomach or with a light meal. If you are unable to swallow whole tablets, Toxefro® (Deferasirox) film-coated tablets may be crushed and sprinkled onto soft food.



2) Toxefro® (Deferasirox) dispersible tablets are white to slightly off-white, round tablets. They must be dissolved in liquid and taken on an empty stomach.



Why was I prescribed 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.

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 β -thalassemia major.

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 β -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.

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 does Deferasirox work?

Deferasirox works by a process called “chelation” (key-lay-shun). After you swallow Deferasirox, it enters your blood and “captures” extra iron available.



How do I Deferasirox film-coated tablets and dispersible tablets?

What dose will I take?

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

If you are switching from Deferasirox dispersible tablets to Deferasirox film-coated tablets, you will need a lower dose.

If you are changing from a different medication (such as deferoxamine) to Deferasirox tablets, your doctor may choose your Deferasirox dose based on how much of the previous medication you were taking.

Which tablet(s) will I take?

Deferasirox tablets come 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.

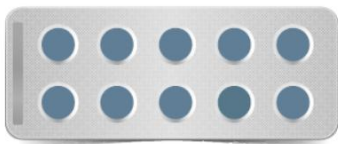
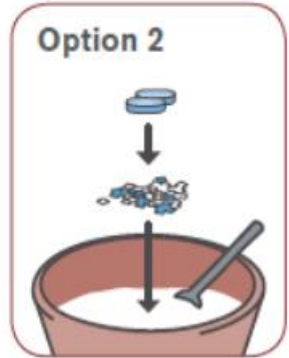
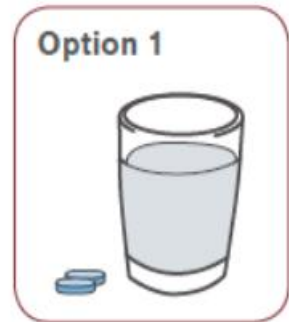
How and when to take Toxefro® (Deferasirox) film-coated tablets

Deferasirox film-coated tablets should be swallowed whole with some water. If you're unable to swallow whole tablets

You can crush the Deferasirox film-coated tablets and sprinkle the full dose onto a small amount of soft food, such as yogurt or pureed apple.

You should immediately and completely consume the entire dose and not store for future use.

Deferasirox film-coated tablets should be taken once a day. You should ideally take your Deferasirox at the same time each day. 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 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 have taken too much 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 and when do I take Toxefro® (Deferasirox) dispersible tablets?

You should take your Deferasirox dispersible tablets once a day and at the same time each day.

Taking Deferasirox at the same time each day will help you remember when you should take your tablet.

Deferasirox dispersible tablets should be taken on an empty stomach at least 30 minutes before eating.



How do I store Deferasirox?

You should store your Deferasirox tablets in their original packaging to protect against moisture.

Steps to take Deferasirox dispersible tablets



Step 1:

DROP your Deferasirox dispersible tablet(s) into a glass of orange juice, apple juice, or water. Make sure that you use the exact amount of liquid directed by your doctor.



Step 2:

STIR until the Deferasirox tablet(s) completely dissolve. The liquid in the glass will look cloudy and the consistency of the mixture may be thick.



Step 3:

DRINK all of the Deferasirox mixture immediately. Then add a little water or juice to what is left in the glass, swirl the liquid around and drink that, too.

Do not chew or swallow tablets whole. Do not break or crush the tablets.

Do not dissolve your Deferasirox dispersible tablets in fizzy drinks or milk.

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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 doctor may adjust your Deferasirox dose up or down based on these tests.

Test	Before Starting Deferasirox	Every month	Once per year
Iron Serum ferritin	✓	✓	
Kidneys Serum creatinine	✓ This blood test will be taken twice before starting Toxefro [®] (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	✓	✓ 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 magnetic resonance imaging, or **MRI**, to check iron levels in your heart or liver
- Perform a **biopsy** of your kidneys if he/she suspects kidney problems

Does Deferasirox have side effects?

Like all medicines, Deferasirox can have side effects. However, not all patients experience them. The most frequent side effects are mild to moderate and usually go away 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, skin rash, headache, and itching.

Your kidney and liver function will be tested before you start Deferasirox and will be checked 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 right 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).
- Rash, red skin, blistering of lips, eyes or mouth, skin peeling, high fever, flu-like symptoms, enlarged lymph nodes, (signs of severe skin reactions);
- Marked decrease in the amount of urine your body produces (sign of kidney problem);
- Vomiting blood and/or have black stools;
- 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 (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 Deferasirox
- Severe upper stomach pain;
- Frequent heartburn;
- Partial vision loss

Remember: Always tell your healthcare 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)
- Bepidil (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 Deferasirox may reduce the effectiveness of oral and patch contraceptives.

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 goals based on a blood test called serum Ferritin, 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 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 Toxefro[®] (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?

Call for reporting:

Additional copies of the materials can be obtained by contacting MS pharma for pharmaceuticals.

Report suspected adverse drug reactions associated with Toxefro[®] (Deferasirox) by contacting:

Pharmacovigilance Department at MS Pharma:

- Email: pharmacovigilance@mspharma.com
- Website: www.mspharma.com
- Phone No: + 966112790122 Ext. 6013

The National Pharmacovigilance Center (NPC): (Saudi food and drug authority)

- Email: npc.drug@sfd.gov.sa
- Call Center: 19999
- Website: <https://ade.sfda.gov.sa/>
- QR Code

