

Available by prescription only.
DEFERASIROX DISPERSIBLE TABLETS:
IS THE ONLY ONCE-DAILY ORAL IRON CHELATOR.

TAJ PHARMA

Generic deferasirox Taj Pharma., India

Deferasirox TABLETS

For chronic iron overload due to blood transfusion

100mg, 125mg, 250mg, 400mg & 500mg

Learn about a once-daily prescription tablet for chronic iron overload (IO).

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INDICATIONS

Treatment of Chronic Iron Overload Due to Blood Transfusions (Transfusional Iron Overload)

Deferasirox Tablets is indicated for the treatment of chronically elevated levels of iron in the blood caused by repeated blood transfusions (transfusional hemosiderosis) in patients 2 years of age and older.

In these patients, Deferasirox lowered the levels of iron in the blood (measured by serum ferritin levels) and liver (measured by liver iron concentration).

An improvement in survival or disease symptoms resulting from reduction in elevated iron levels, however, has not been proven.

Treatment of Chronic Iron Overload in Non-Transfusion-Dependent Thalassemia Syndromes

Deferasirox is indicated to treat patients ages 10 years and older who have chronic iron overload resulting from a genetic blood disorder called non-transfusion-dependent thalassemia (NTDT).

Deferasirox should be used when these patients have elevated levels of iron in the liver (measured by liver iron concentration of at least 5 milligrams of iron per gram of dry liver tissue weight) and in the blood (measured by serum ferritin levels greater than 300 mcg/L).

An improvement in survival or disease symptoms resulting from reduction in elevated iron levels, however, has not been proven.

Limitations on the Use of Deferasirox

It is not known if Deferasirox is safe or effective when taken with another therapy that lowers iron levels in the blood.

There are patients with a serious blood disorder known as myelodysplastic syndromes (MDS) who may take Deferasirox to treat chronically elevated levels of iron in the blood caused by repeated blood transfusions.

The iron lowering effects and safety of Deferasirox have not been studied in clinical trials specifically designed for just these patients with MDS.

Treating high levels of iron in the blood.
Deferasirox is an iron-chelating agent. It works by binding to the extra iron in the blood and removing it from the body.

IF YOU GET REGULAR BLOOD TRANSFUSIONS FOR A CHRONIC ANEMIA OR
IF YOU HAVE CHRONIC NON-TRANSFUSION-DEPENDENT THALASSEMIA,
YOU MAY BE AT RISK OF CHRONIC IRON OVERLOAD,
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To take the tablets for suspension, follow these steps:

If you are taking less than 1000 mg of deferasirox, fill a cup halfway (about 3.5 oz/100 mL) with water, apple juice, or orange juice.

If you are taking more than 1000 mg of deferasirox, fill a cup (about 7 oz/200 mL) with water, apple juice, or orange juice.

If you are not sure how much deferasirox you are to take, ask your doctor or pharmacist.

Place the number of tablets your doctor has told you to take in the cup.

Stir the liquid for 3 minutes to completely dissolve the tablets. The mixture may become thick as you stir it.

Drink the liquid immediately.

Add a small amount of liquid to the empty cup and stir. Swish the cup to dissolve any medication that is still in the glass or on the stirrer.

Drink the rest of the liquid.

Deferasirox removes extra iron from your body slowly over time. Continue to take deferasirox as long as it is prescribed by your doctor.

Do not stop taking deferasirox without talking to your doctor.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking deferasirox,

tell your doctor and pharmacist if you are allergic to deferasirox, any other medications, or any of the ingredients in deferasirox tablets.

Ask your doctor or pharmacist for a list of the ingredients.

tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products

you are taking or plan to take. Be sure to mention the medications listed in the IMPORTANT WARNING section and any of the following:

cholestyramine (Locholest, Questran, Prevalite), cyclosporine (Gengraf, Neoral, Sandimmune), hormonal contraceptives

(birth control pills, patches, rings, or injections), other medications to remove excess iron from the body, paclitaxel (Abraxane, Taxol),

phenytoin, phenobarbital, repaglinide (Prandin, in Prandimet), rifampin (Rimactane, Rifadin, in Rifater, in Rifater), ritonavir (Norvir),

and simvastatin (Zocor, in Simcor, in Vytorin). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.

if you are taking aluminum-containing antacids such as Amphogel, Alternagel, Gaviscon, Maalox, or Mylanta, take them 2 hours before

or after deferasirox.

tell your doctor if you have an infection or severe nausea, vomiting, or diarrhea, or if you think you may be dehydrated.

Also tell your doctor if you have or have ever had hearing, ear, or vision problems.

tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking deferasirox, call your doctor.

you should know that deferasirox may make you dizzy. Do not drive a car or operate machinery until you know how this medication affects you.

tell your doctor if you develop diarrhea or vomiting during your treatment. If you have these symptoms,

it is important to drink plenty of fluid so you will not become dehydrated.

What special dietary instructions should I follow? Unless your doctor tells you otherwise, continue your normal diet.

IMPORTANT WARNING:

Deferasirox may cause serious or life-threatening damage to the kidneys or liver or severe bleeding in the stomach or intestines.

The risk that you will develop these conditions is greater if you are elderly or if you have any of the following conditions: high risk myelodysplastic syndrome (a severe problem with the bone marrow that has a high risk of developing into cancer), a low level of platelets (a type of blood cell that is needed to control bleeding), or kidney or liver disease. The risk that you will develop severe bleeding in the stomach or intestines may be greater if you are taking any of the following medications: anticoagulants (blood thinners) such as warfarin (Coumadin); aspirin or other nonsteroidal anti-inflammatory medications (NSAIDs); certain medications to strengthen the bones including alendronate (Fosamax), etidronate (Didronel), ibandronate (Boniva), risedronate (Actonel), and tiludronate (Skelid); or oral steroids such as dexamethasone, methylprednisolone (Medrol), or prednisone.

If you experience any of the following symptoms, call your doctor immediately: decreased urination, swelling in the ankles, legs, or feet, excessive tiredness, shortness of breath, confusion, yellowing of the skin or eyes, flu-like symptoms, lack of energy, loss of appetite, pain in the upper right part of the stomach, unusual bruising or bleeding, vomit that is bright red or looks like coffee grounds, bright red blood in stools, or black, tarry stools.

Keep all appointments with your doctor and the laboratory. Your doctor will order laboratory tests before and during your treatment to be sure it is safe for you to take deferasirox and to see if you are developing these serious side effects.

Deferasirox 100 mg dispersible tablets

Each dispersible tablet contains 100 mg deferasirox.

Excipient with known effect:

Deferasirox 125 mg dispersible tablets

Each dispersible tablet contains 125 mg deferasirox.

Excipient with known effect:

Each dispersible tablet contains 136 mg lactose.

Deferasirox 250 mg dispersible tablets

Each dispersible tablet contains 250 mg deferasirox.

Excipient with known effect:

Each dispersible tablet contains 272 mg lactose.

Deferasirox 400 mg dispersible tablets

Each dispersible tablet contains 500 mg deferasirox.

Deferasirox 500 mg dispersible tablets

Each dispersible tablet contains 500 mg deferasirox.

Excipient with known effect:

Each dispersible tablet contains 544 mg lactos

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Deferasirox TABLETS

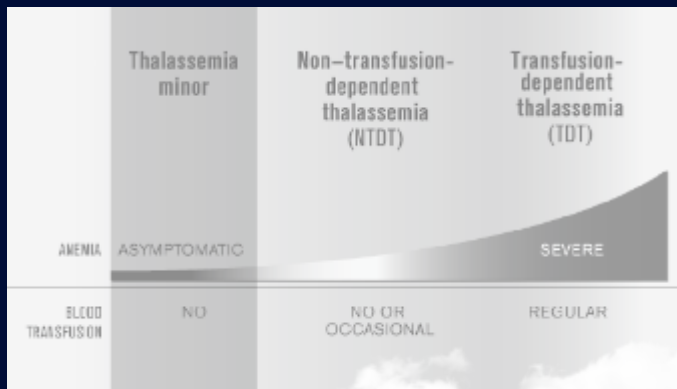
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Take Deferasirox the right way every day

Please see additional Important Safety Information throughout, and accompanying full Prescribing Information.

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Therapeutic indications

Deferasirox is indicated for the treatment of chronic iron overload due to frequent blood transfusions (≥ 7 ml/kg/month of packed red blood cells) in patients with beta thalassaemia major aged 6 years and older.

Deferasirox is also indicated for the treatment of chronic iron overload due to blood transfusions when deferoxamine therapy is contraindicated or inadequate in the following patient groups:

- in paediatric patients with beta thalassaemia major with iron overload due to frequent blood transfusions (≥ 7 ml/kg/month of packed red blood cells) aged 2 to 5 years,
- in adult and paediatric patients with beta thalassaemia major with iron overload due to infrequent blood transfusions (< 7 ml/kg/month of packed red blood cells) aged 2 years and older,
- in adult and paediatric patients with other anaemias aged 2 years and older.

Deferasirox is also indicated for the treatment of chronic iron overload requiring chelation therapy when deferoxamine therapy is contraindicated or inadequate in patients with non-transfusion-dependent thalassaemia syndromes aged 10 years and older.

4.2 Posology and method of administration

Treatment with Deferasirox should be initiated and maintained by physicians experienced in the treatment of chronic iron overload.

Posology

Transfusional iron overload

It is recommended that treatment be started after the transfusion of approximately 20 units (about 100 ml/kg) of packed red blood cells (PRBC) or when there is evidence from clinical monitoring that chronic iron overload is present (e.g. serum ferritin $> 1,000$ $\mu\text{g/l}$). Doses (in mg/kg) must be calculated and rounded to the nearest whole tablet size.

The goals of iron chelation therapy are to remove the amount of iron administered in transfusions and, as required, to reduce the existing iron burden. In case of switching from film-coated tablets to dispersible tablets, the dose of dispersible tablets should be 40% higher than the dose of film-coated tablets, rounded to the nearest whole tablet.

HOW TO TAKE DEFERASIROX

DEFERASIROX SHOULD BE TAKEN ONCE DAILY ON AN EMPTY STOMACH, AT LEAST 30 MINUTES PRIOR TO FOOD, PREFERABLY AT THE SAME TIME EVERY DAY.

YOU SHOULD COMPLETELY DISPERSE THE TABLETS IN WATER, ORANGE JUICE, OR APPLE JUICE, AND DRINK THE RESULTING SUSPENSION IMMEDIATELY.

AFTER THE SUSPENSION HAS BEEN SWALLOWED, RESUSPEND ANY RESIDUE IN THE CUP WITH A SMALL AMOUNT OF THE LIQUID AND DRINK.

DEFERASIROX SHOULD NOT BE CHEWED OR SWALLOWED WHOLE, AND SHOULD NOT BE TAKEN AT THE SAME TIME AS ALUMINUM-CONTAINING ANTACIDS (FOR EXAMPLE, MAALOX®).

TALK TO YOUR DOCTOR TO DETERMINE IF PRESCRIPTION DEFERASIROX THERAPY IS RIGHT FOR YOU.

PLEASE SEE FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING, FOR DEFERASIROX TABLETS.

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- In these patients, Deferasirox lowered the levels of iron in the blood (measured by serum ferritin levels) and liver (measured by liver iron concentration).
- An improvement in survival or disease symptoms resulting from reduction in elevated iron levels, however, has not been proven.

Talk to your doctor to determine if Deferasirox therapy is right for you. The expected benefit and risks of the therapy, as well as factors such as life expectancy and other illnesses, should be considered. The safety and efficacy of Deferasirox when taken with other iron chelation therapy have not been proven. Further studies are being performed to determine the long-term benefits and risks of Deferasirox. Deferasirox is available by prescription only.



The Deferasirox Mixer cup helps ensure your Deferasirox tablet dissolves completely so you get the correct dose every time by following 3 simple steps—Set, Mix, Drink.



SET
SET the timer to 3 minutes



MIX
MIX your Deferasirox with water, orange or apple juice by holding the button down until the timer beeps.



DRINK
DRINK all of the Deferasirox mixture



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Taher AT, Porter J, Viprakasit V, et al. Deferasirox reduces iron overload significantly in nontransfusion-dependent thalassemia: 1-year results from a prospective, randomized, double-blind, placebo-controlled study. *Blood*. 2012;120(5):970-977.

Galanello R, Origa R. Beta-thalassemia. *Orphanet J Rare Dis*. 2010;5:11.

Taher AT, Musallam KM, Capellini MD, Weatherall DJ. Optimal management of β thalassemia intermedia. *Br J Haematol*. 2011;152(5):512-523.

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