

MEDICATION GUIDE

Deferasirox (dee-FER-a-sir-ox) Tablets

What is the most important information I should know about deferasirox tablets?

Deferasirox tablets can cause serious side effects, including:

Kidney problems: Deferasirox tablets can cause sudden (acute) kidney problems, including kidney failure that may require treatment with dialysis, and may cause death. Deaths have happened mostly in people who also have other health problems and had a blood disorder that was in an advanced stage. Adults and children who already have kidney problems and are taking certain medicines with deferasirox tablets may also have an increased risk of sudden kidney problems. Be sure to tell your healthcare provider about all the medicines you take during treatment with deferasirox tablets.

Your healthcare provider should do blood and urine tests to check your or your child's kidney function before and during treatment with deferasirox tablets.

Call your healthcare provider right away if:

- **your child becomes sick with fever, vomiting, or diarrhea and cannot drink fluids normally during treatment with deferasirox tablets.** Your child may be dehydrated. Your healthcare provider may need to temporarily stop treatment with deferasirox tablets and treat your child for dehydration to help prevent kidney problems. Your healthcare provider may monitor your child's kidney function more closely.
- **you notice that you or your child are passing less urine than usual during treatment with deferasirox tablets.**

Liver problems. Deferasirox tablets can cause liver problems, including liver failure that can sometimes cause death. Liver problems with deferasirox tablets may be more common in people who are over 55 years of age but can also happen in children. Liver failure has happened more often in people with cirrhosis of the liver and failure of other organs. Liver failure has also happened along with kidney problems in certain children who become dehydrated.

See "Kidney problems" above.

Your healthcare provider should do blood tests to check your liver function before you start and regularly during treatment with deferasirox tablets. **Call your healthcare provider right away**, if you develop any of the following signs and symptoms:

- drowsiness
- upper right stomach-area (abdomen) pain
- yellowing or increased yellowing of your skin or eyes
- dark urine

Bleeding, ulcers and tears of the stomach or intestine. Severe stomach and intestine bleeding (hemorrhage) that have caused death have happened in some people treated with deferasirox tablets, especially in elderly people who have advanced blood cancers or low platelet counts. Some people have also had ulcers of the stomach or intestine, sometimes with tears (perforation) that have caused death. In some people who have taken deferasirox, including children and adolescents, irritation of the upper gastrointestinal tract, ulcers, and bleeding have happened, but did not cause death.

Your risk of severe bleeding (hemorrhage) may be increased if you take deferasirox tablets along with other medicines that can cause ulcers or bleeding, such as:

- nonsteroidal anti-inflammatory drugs (NSAIDs)
- corticosteroids
- certain osteoporosis medicines called oral bisphosphonates
- blood thinner medicines

Before you start taking deferasirox tablets, tell your healthcare provider if you are taking one of these medicines. Ask your healthcare provider if you are not sure. If you develop an ulcer of the stomach or intestine, or severe bleeding, your healthcare provider may stop deferasirox tablets.

Elderly people may be at a higher risk of developing serious side effects and death due to serious side effects with deferasirox tablets. Your healthcare provider may need to monitor you more closely during treatment with deferasirox tablets.

- Tell your healthcare provider if you get heartburn during treatment with deferasirox tablets.
- **Get emergency medical help right away if you vomit blood or pass black or bloody stools, or if you have severe stomach-area (abdomen) pain during treatment with deferasirox tablets.**

See "What are possible side effects of deferasirox tablets?" for more information about side effects.

What are deferasirox tablets?

Deferasirox tablets are prescription medicines that are used to treat:

- people 2 years of age and older who have an increased amount of iron in their blood for a long period of time (chronic), caused by repeated blood transfusions
- certain people 10 years of age or older with thalassemia who have an increased amount of iron in their blood but who are not receiving regular blood transfusions

It is not known if deferasirox tablet is safe and effective when used with other medicines to treat an increased amount of iron in the blood.

It is not known if deferasirox tablet is safe and effective for treating children under 2 years of age who have an increased amount of iron in their blood for a long period of time (chronic) caused by repeated blood transfusions.

It is not known if deferasirox tablet is safe and effective for treating children under 10 years of age with thalassemia who have an increased amount of iron in their blood, but who are not receiving regular blood transfusions.

Do not take deferasirox tablet if you:

- have certain kidney problems
- have high-risk myelodysplastic syndrome (MDS)
- have advanced cancer

- have a low platelet count
- are allergic to deferasirox or any of the ingredients in deferasirox tablets. See the end of this leaflet for a list of the ingredients in deferasirox tablets.

Ask your healthcare provider if you are not sure if you have any of the medical conditions listed above.

Before taking deferasirox tablets tell your healthcare provider about all of your medical conditions, including if you:

- have kidney problems
- have liver problems
- have advanced cancer. See “Do not take deferasirox tablets if you?”
- have a blood disorder that may increase your risk for bleeding
- are pregnant or plan to become pregnant. It is not known if deferasirox tablets can harm your unborn baby. Hormonal forms of birth control may not be as effective if used during treatment with deferasirox tablets. You could become pregnant. Talk to your healthcare provider about other birth control options that you can use during this time. Tell your healthcare provider right away if you become pregnant during treatment with deferasirox tablets.
- are breastfeeding or plan to breastfeed. It is not known if deferasirox passes into your breast milk and can harm your baby. You and your healthcare provider should decide if you will take deferasirox tablets or breastfeed. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription medicines, over-the-counter medicines, vitamins, and herbal supplements. Some medicines may affect how deferasirox tablets works, and deferasirox tablets may affect how other medicines work. Also, **your risk of sudden kidney problems or severe bleeding may be increased if you take deferasirox tablets with certain medicines. See “What is the most important information I should know about deferasirox tablets?”**

- Avoid taking the following medicines during treatment with deferasirox tablets:
 - o antacid products (medicines used to treat heartburn) that contain aluminum
 - o theophylline
 - o certain medicines to lower your cholesterol, called bile acid sequestrants

Ask your healthcare provider if you are not sure if you take one of these medicines.

Know the medicines you take. Keep a list of them to show your healthcare provider or pharmacist when you get a new medicine.

How should I take deferasirox tablets?

- Take deferasirox tablets exactly as your healthcare provider tells you.
- **Do not** change your dose of deferasirox tablets or stop taking unless your healthcare provider tells you to.
- Deferasirox comes as tablets.
 - o You may take deferasirox tablets on an empty stomach or with a light meal. Examples of a light meal include:
 - 1 whole wheat English muffin, 1 packet of jelly (0.5 ounce), and skim milk (8 fluid ounces), or
 - A turkey sandwich (2 ounces of turkey on whole wheat bread with lettuce, tomato, and 1 packet of mustard)

Taking deferasirox tablets:

- o Take deferasirox tablets by mouth with water or other liquids 1 time every day, preferably at the same time every day.
- o If you have trouble swallowing the tablets whole, you may crush deferasirox tablets and mix them with soft foods such as yogurt or apple sauce right before taking your dose.
- o Take the dose right away. Do not save any of the deferasirox and soft food mixture for later use.
- o **Do not** use store-bought pill crushers with serrated surfaces for crushing deferasirox 90 mg tablets.
- Do not take deferasirox tablets with aluminum-containing antacid products. See “Before taking deferasirox tablets”
- Tell your healthcare provider if you or your child gain or lose any weight. Your or your child’s dose of deferasirox tablets may need to be adjusted.
- If you take the diabetes medicine repaglinide during treatment with deferasirox you may need to test your blood sugar (glucose) levels more often. Follow your healthcare provider’s instructions about how often to test your blood sugar during this time.
- Your healthcare provider should do blood and urine tests before, and during treatment to check how you respond to deferasirox, and to monitor you for side effects. Your healthcare provider may change your dose, temporarily or permanently stop deferasirox if you have certain side effects.
- In people who have thalassemia, your healthcare provider will check the amount of iron in your liver before and during treatment with deferasirox.
- If you or your child take too much deferasirox tablets, call your healthcare provider right away or go to the nearest hospital emergency room.

What should I avoid while taking deferasirox tablets?

- Deferasirox tablets may cause dizziness. Avoid driving or operating machinery until you know how deferasirox tablet affects you. Do not drive or operate machinery deferasirox tablet makes you dizzy.

What are the possible side effects of deferasirox tablets?

Deferasirox tablets can cause serious side effects, including:

- See “What is the most important information I should know about deferasirox tablets?”
- **Effects on your bone marrow.** Deferasirox tablets can affect your bone marrow and cause you to have low white blood cell count which can be serious, decreased platelets, or worsening of your anemia, and may lead to death. Your risk for effects on your bone marrow may be increased if you already have other blood disorders. Your healthcare provider will do blood tests to monitor your blood cell counts for these problems.
- **Serious allergic reactions.** Deferasirox tablets may cause serious allergic reactions, which usually start within the first month of treatment. **Get medical help right away if you develop any of the following symptoms of a serious allergic reaction including:**

- o difficulty in breathing or swallowing
 - o chest pain
 - o rapid heartbeat
 - o feeling faint
 - o swelling of the face, lips, mouth, tongue or throat
 - o severe itching of the skin with a red rash or raised bumps
 - o hives
- **Skin rash and severe skin reactions.** Skin rashes are common with deferasirox tablets. If you get a more severe rash, your healthcare provider may temporarily stop deferasirox tablets.

Severe skin reactions can also happen with deferasirox tablets and can be life-threatening or lead to death. Get medical help right away if you develop any one or more of the following signs and symptoms of a severe skin reaction, including:

- o rash or red skin
 - o blisters on your lips, or around your mouth or eyes
 - o mouth sores
 - o skin peeling
 - o high fever or flu-like symptoms
 - o enlarged lymph nodes
- **Hearing and vision problems.** Deferasirox tablets can cause decreased hearing and changes in your vision including cataracts, increased pressure in your eye, and problems with your retinas. Your healthcare provider should do hearing and vision tests before you start and then regularly during treatment. Your healthcare provider may decrease your dose or stop deferasirox tablets if you develop hearing or vision problems.

The most common side effects in anyone who takes deferasirox tablets include: diarrhea and nausea. Other common side effects in people with too much iron in their blood due to repeated blood transfusions include: vomiting, stomach-area (abdomen) pain, and an abnormal kidney function blood test.

These are not all the possible side effects of deferasirox tablets.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store deferasirox tablets?

- Store deferasirox tablets at 25°C (77°F); excursions are permitted to 15° to 30°C (59° to 86°F).
- Keep the bottle closed tightly and away from moisture.

Keep deferasirox tablets and all medicines out of the reach of children.

General information about the safe and effective use of deferasirox tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use deferasirox tablets for a condition for which it was not prescribed. Do not give it to other people, even if they have the same symptoms you have. It may harm them. You can ask your healthcare provider or pharmacist for more information about deferasirox tablets.

For more information call Alembic Pharmaceuticals Limited at 1-866-210-9797.

What are the ingredients in deferasirox tablets?

Active ingredient: deferasirox

Inactive ingredients: microcrystalline cellulose, crospovidone, colloidal silicon dioxide, povidone (K30), poloxamer (188), sodium starch glycolate, and magnesium stearate. The film coating contains hypromellose, titanium dioxide, polyethylene glycol, talc, and FD&C Blue No. 2 Aluminium Lake.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Medication Guide available at <http://www.alembicusa.com/medicationguide.aspx> or call 1-866-210-9797.

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