

Dispense with Medication Guide available at: [www.epic-pharma.com/medguide/Deferasirox-Oral-Granules.pdf](http://www.epic-pharma.com/medguide/Deferasirox-Oral-Granules.pdf).

#### MEDICATION GUIDE

### Deferasirox (dee-fer'a-si-rox) Oral Granules

**What is the most important information I should know about deferasirox oral granules?**

**Deferasirox oral granules can cause serious side effects, including:**

**Kidney problems:** Deferasirox oral granules 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 oral granules 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 oral granules.

Your healthcare provider should do blood and urine tests to check your or your child's kidney function before and during treatment with deferasirox oral granules. **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 oral granules.** Your child may be dehydrated. Your healthcare provider may need to temporarily stop treatment with deferasirox oral granules 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 oral granules.**

**Liver problems.** Deferasirox oral granules can cause liver problems, including liver failure that can sometimes cause death. Liver problems with deferasirox oral granules 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 oral granules. **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 oral granules, 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 oral granules, 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 oral granules 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 oral granules, 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 oral granules.

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

- Tell your healthcare provider if you get heartburn during treatment with deferasirox oral granules.
- **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 oral granules.**

**See "What are the possible side effects of deferasirox oral granules?" for more information about side effects.**

**What are deferasirox oral granules?**

Deferasirox oral granules 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 oral granules 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 oral granules 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 oral granules 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 oral granules 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 oral granules. See the end of this medication guide for a list of the ingredients in deferasirox oral granules.

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

**Before taking deferasirox oral granules 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 oral granules 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 oral granules can harm your unborn baby. Hormonal forms of birth control may not be as effective if used during treatment with deferasirox oral granules. 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 oral granules.
- are breastfeeding or plan to breastfeed. It is not known if deferasirox oral granules passes into your breast milk and can harm your baby. You and your healthcare provider should decide if you will take deferasirox oral granules 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 oral granules works, and deferasirox oral granules may affect how other medicines work. Also, **your risk of sudden kidney problems or severe bleeding may be increased if you take deferasirox oral granules with certain medicines.** **See "What is the most important information I should know about deferasirox oral granules?"**

- Avoid taking the following medicines during treatment with deferasirox oral granules:
  - antacid products (medicines used to treat heartburn) that contain aluminum
  - theophylline
  - 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.

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| <p><b>How should I take deferasirox oral granules?</b></p> <ul style="list-style-type: none"> <li>Take deferasirox oral granules exactly as your healthcare provider tells you.</li> <li><b>Do not</b> change your dose of deferasirox oral granules or stop taking unless your healthcare provider tells you to.</li> <li>Deferasirox oral granules comes as granules. <ul style="list-style-type: none"> <li>You may take deferasirox oral granules on an empty stomach or with a light meal. Examples of a light meal include: <ul style="list-style-type: none"> <li>1 whole wheat English muffin, 1 packet of jelly (0.5 ounce), and skim milk (8 fluid ounces), or</li> <li>A turkey sandwich (2 ounces of turkey on whole wheat bread with lettuce, tomato, and 1 packet of mustard)</li> </ul> </li> </ul> </li> </ul> <p><b>Taking deferasirox oral granules:</b></p> <ul style="list-style-type: none"> <li>Sprinkle the prescribed dose of granules onto soft food such as yogurt or applesauce right before taking your dose.</li> <li>Take the granules and soft food by mouth.</li> <li>Do not take deferasirox oral granules with aluminum-containing antacid products. See <b>“Before taking deferasirox oral granules.”</b></li> <li>Tell your healthcare provider if you or your child gain or lose any weight. Your or your child’s dose of deferasirox oral granules may need to be adjusted.</li> <li>If you take the diabetes medicine repaglinide during treatment with deferasirox oral granules, 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.</li> <li>Your healthcare provider should do blood and urine tests before, and during treatment to check how you respond to deferasirox oral granules, and to monitor you for side effects. Your healthcare provider may change your dose, temporarily or permanently stop deferasirox oral granules if you have certain side effects.</li> <li>In people who have thalassemia, your healthcare provider will check the amount of iron in your liver before and during treatment with deferasirox oral granules.</li> <li>If you or your child take too much deferasirox oral granules, call your healthcare provider right away or go to the nearest hospital emergency room. Symptoms that can happen if you take too much deferasirox oral granules include: stomach-area (abdominal) pain, diarrhea, nausea and vomiting.</li> </ul> <p><b>What should I avoid while taking deferasirox oral granules?</b></p> <ul style="list-style-type: none"> <li>Deferasirox oral granules may cause dizziness. Avoid driving or operating machinery until you know how deferasirox oral granules affects you. Do not drive or operate machinery if deferasirox oral granules makes you dizzy.</li> </ul> <p><b>What are the possible side effects of deferasirox oral granules? Deferasirox oral granules can cause serious side effects, including:</b></p> <ul style="list-style-type: none"> <li>See <b>“What is the most important information I should know about deferasirox oral granules?”</b></li> <li><b>Effects on your bone marrow.</b> Deferasirox oral granules 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.</li> <li><b>Serious allergic reactions.</b> Deferasirox oral granules may cause serious allergic reactions, which usually start within the first month of treatment. <b>Get medical help right away if you develop any of the following symptoms of a serious allergic reaction including:</b> <ul style="list-style-type: none"> <li>difficulty in breathing or swallowing</li> <li>chest pain</li> <li>rapid heartbeat</li> <li>feeling faint</li> <li>swelling of the face, lips, mouth, tongue or throat</li> <li>severe itching of the skin with a red rash or raised bumps</li> <li>hives</li> </ul> </li> <li><b>Skin rash and severe skin reactions.</b> Skin rashes are common with deferasirox oral granules. If you get a more severe rash, your healthcare provider may temporarily stop deferasirox oral granules.</li> </ul> |
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| <ul style="list-style-type: none"> <li><b>Severe skin reactions can also happen with deferasirox oral granules 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:</b> <ul style="list-style-type: none"> <li>rash or red skin</li> <li>blisters on your lips, or around your mouth or</li> <li>mouth sores</li> <li>skin peeling</li> <li>high fever or flu-like symptoms eyes</li> <li>enlarged lymph nodes</li> </ul> </li> <li><b>Hearing and vision problems.</b> Deferasirox oral granules 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 oral granules if you develop hearing or vision problems.</li> </ul> <p>The most common side effects in anyone who takes deferasirox oral granules include: diarrhea and nausea.</p> <p>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.</p> <p>These are not all the possible side effects of deferasirox oral granules. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.</p> <p><b>How should I store deferasirox oral granules?</b></p> <ul style="list-style-type: none"> <li>Store deferasirox oral granules at room temperature between 68°F to 77°F (20°C to 25°C).</li> <li>Keep the bottle closed tightly and away from moisture.</li> </ul> <p><b>Keep deferasirox oral granules and all medicines out of the reach of children.</b></p> <p><b>General information about the safe and effective use of deferasirox oral granules</b></p> <p>Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use deferasirox oral granules 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 oral granules.</p> <p><b>What are the ingredients in deferasirox oral granules?</b></p> <p><b>Active ingredient:</b> deferasirox</p> <p><b>Inactive ingredients:</b> crospovidone; magnesium stearate, microcrystalline cellulose, poloxamer, povidone, and silicon dioxide.</p> <p>Distributed by:<br/>Epic Pharma, LLC<br/>Laurelton, NY 11413</p> |
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This Medication Guide has been approved by the U.S. Food and Drug Administration.  
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