

MEDICATION GUIDE

Deferasirox (dee-FER-a-sir-ox) Tablets for Oral Suspension

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

Deferasirox tablets for oral suspension can cause serious side effects, including:

Kidney problems. Deferasirox tablets for oral suspension 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 for oral suspension 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 for oral suspension.

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 for oral suspension. **Call your or your child's healthcare provider right away if:**

- **your child becomes sick with fever, vomiting, or diarrhea and cannot drink fluids normally during treatment with deferasirox tablets for oral suspension.** Your child may be dehydrated. Your child's healthcare provider may need to temporarily stop treatment with deferasirox tablets for oral suspension and treat your child for dehydration to help prevent kidney problems. Your child's 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 for oral suspension.**

Liver problems. Deferasirox tablets for oral suspension can cause liver problems, including liver failure that can sometimes cause death. Liver problems with deferasirox tablets for oral suspension 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 for oral suspension. **Call your healthcare provider right away,** if you develop any of the following signs and symptoms:

- drowsiness
- yellowing or increased yellowing of your skin or eyes
- upper right stomach-area (abdomen) pain
- 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 for oral suspension, 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 tablets for oral suspension, 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 for oral suspension along with other medicines that can cause ulcers or bleeding, such as:

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

Before you start taking deferasirox tablets for oral suspension, 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 for oral suspension.

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

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

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

What are deferasirox tablets for oral suspension?

Deferasirox tablets for oral suspension are prescription medicine that is 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

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

It is not known if deferasirox tablets for oral suspension are 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.

Do not take deferasirox tablets for oral suspension 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 for oral suspension. See the end of this leaflet for a list of the ingredients in deferasirox tablets for oral suspension.

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

Before taking deferasirox tablets for oral suspension, 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 for oral suspension 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 for oral suspension can harm your unborn baby. Hormonal forms of birth control may not be as effective if used during treatment with deferasirox tablets for oral suspension. 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 for oral suspension.
- 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 for oral suspension 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 for oral suspension works, and deferasirox tablets for oral suspension may affect how other medicines work. Also, **your risk of sudden kidney problems or severe bleeding may be increased if you take deferasirox tablets for oral suspension with certain medicines. See 'What is the most important information I should know about deferasirox tablets for oral suspension?'**

- Avoid taking the following medicines during treatment with deferasirox tablets for oral suspension:
 - 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.

How should I take deferasirox tablets for oral suspension?

- Take deferasirox tablets for oral suspension exactly as your healthcare provider tells you to.
- **Do not** change your dose of deferasirox tablets for oral suspension or stop taking it unless your healthcare provider tells you to.
- Take deferasirox tablets for oral suspension 1 time every day, preferably at the same time every day.
- Take deferasirox tablets for oral suspension on an empty stomach **at least 30 minutes before eating food.**
- **Do not** to chew deferasirox tablets for oral suspension tablets or swallow them whole.
- Place the prescribed number of deferasirox tablets for oral suspension tablets in a cup with water, orange juice, or apple juice. Stir to disperse the tablets in the liquid.
 - If your prescribed dose of deferasirox tablets for oral suspension is less than 1 gram, use 3.5 ounces of liquid to disperse the tablets.
 - If your prescribed dose of deferasirox tablets for oral suspension is 1 gram or more, use 7 ounces of liquid to disperse the tablets.
- Completely disperse the tablets until it becomes a fine suspension. Then drink the suspension right away.
- **Do not** disperse deferasirox tablets for oral suspension tablets in carbonated drinks or milk.
- After drinking the suspension, add a small amount of water, orange juice, or apple juice to the cup to disperse any remaining medicine, and then drink it.
- Do not take deferasirox tablets for oral suspension with aluminum-containing antacid products. See “Before taking deferasirox tablets for oral suspension”
- Tell your healthcare provider if you or your child gain or lose any weight. Your or your child's dose of deferasirox tablets for oral suspension may need to be adjusted.
- If you take the diabetes medicine repaglinide during treatment with deferasirox tablets for oral suspension, 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 tablets for oral suspension, and to monitor you for side effects. Your healthcare provider may change your dose, temporarily or permanently stop deferasirox tablets for oral suspension 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 tablets for oral suspension.
- If you or your child take too much deferasirox tablets for oral suspension, call your healthcare provider right away or go to the nearest hospital emergency room.

What should I avoid while taking deferasirox tablets for oral suspension?

- Deferasirox tablets for oral suspension may cause dizziness. Avoid driving or operating machinery until you know how deferasirox tablets for oral suspension affects you. Do not drive or operate machinery if deferasirox tablets for oral suspension make you dizzy.

What are the possible side effects of deferasirox tablets for oral suspension?

Deferasirox tablets for oral suspension can cause serious side effects, including:

- **See “What is the most important information I should know about deferasirox tablets for oral suspension?”**
- **Effects on your bone marrow.** Deferasirox tablets for oral suspension 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 for oral suspension 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:**
 - difficulty in breathing or swallowing
 - chest pain
 - rapid heartbeat
 - feeling faint
 - swelling of the face, lips, mouth, tongue or throat
 - severe itching of the skin with a red rash or raised bumps
 - hives

- **Skin rash and severe skin reactions.** Skin rashes are common with deferasirox tablets for oral suspension. If you get a more severe rash, your healthcare provider may temporarily stop deferasirox tablets for oral suspension.

Severe skin reactions can also happen with deferasirox tablets for oral suspension 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 skin peeling
- o blisters on your lips, or around your
- o high fever or flu-like symptoms mouth or eyes
- o mouth sores
- o enlarged lymph nodes

- **Hearing and vision problems.** Deferasirox tablets for oral suspension 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 for oral suspension if you develop hearing or vision problems.

Tell your healthcare provider if you develop any changes in your vision or hearing during treatment with deferasirox tablets for oral suspension.

The most common side effects in anyone who takes deferasirox tablets for oral suspension 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 for oral suspension.

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 for oral suspension?

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

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

General information about the safe and effective use of deferasirox tablets for oral suspension.

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

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

What are the ingredients in deferasirox tablets for oral suspension?

Active ingredient: deferasirox

Inactive ingredients: Crospovidone (NF), sodium starch glycolate (NF), croscarmellose sodium (NF), colloidal silicon dioxide (NF), sodium lauryl sulphate (NF), povidone (K-30) (USP), lactose monohydrate (NF), and magnesium stearate (NF).

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

Additional pediatric use information is approved for Novartis Pharmaceuticals Corporation's EXJADE® (deferasirox) tablets for oral suspension. However, due to Novartis Pharmaceuticals Corporation's marketing exclusivity rights, this drug product is not labeled with that pediatric information.

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

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Revised: 11/2019

20028777