2D Data Matrix to be printed with serial number on each leaflet. The number should not be repeated

Deferasirox Tablets

013-2023-11

2102740

Dummy

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use DEFERASIROX TABLETS safely and effectively. See full prescribing information for DEFERASIROX TABLETS.

DEFERASIROX tablets, for oral use

Initial U.S. Approval: 2005

WARNING: RENAL FAILURE, HEPATIC FAILURE, and GASTROINTESTINAL HEMORRHAGE

See full prescribing information for complete boxed warning.

Deferasirox may cause serious and fatal:

- **acute kidney injury, including acute renal failure requiring dialysis and renal tubular toxicity including Fanconi syndrome (5.1)**
- **hepatic toxicity, including failure (5.2)**
- **gastrointestinal hemorrhage (5.3)**

Deferasirox therapy requires close patient monitoring, including laboratory tests of renal and hepatic function. (5)

INDICATIONS AND USAGE

Deferasirox tablets are an iron chelator indicated for the treatment of chronic iron overload due to blood transfusions in patients 2 years of age and older. (1.1)

Deferasirox tablets are indicated for the treatment of chronic iron overload in patients 10 years of age and older with non-transfusion-dependent thalassemia (NTDT) syndromes, and with a liver iron (Fe) concentration (LIC) of at least 5 mg Fe per gram of dry weight (Fe/g dw) and a serum ferritin greater than 300 mcg/L. (1.2)

Limitations of Use:

The safety and efficacy of deferasirox tablets when administered with other iron chelation therapy have not been established. (1.3)

DOSAGE AND ADMINISTRATION

- Transfusional Iron Overload: Initial dose for patients with estimated glomerular filtration rate (eGFR) greater than 60 mL/min/1.73 m^2 is 14 mg per kg (calculated to nearest whole tablet) once daily. (2.1)
- NTDT Syndromes: Initial dose for patients with eGFR greater than 60 mL/min/1.73 m^2 is 7 mg per kg (calculated to nearest whole tablet) once daily. (2.2)
- See full prescribing information for information regarding monitoring, administration, and dose-reductions for organ impairment. (2.1, 2.2, 2.3, 2.4)

DOSAGE FORMS AND STRENGTHS

Tablets: 90 mg, 180 mg, 360 mg. (3)

CONTRAINDICATIONS

- Estimated GFR less than 40 mL/min/1.73 m^2. (4)
- Patients with poor performance status. (4)
- Patients with high-risk myelodysplastic syndrome (MDS). (4)
- Patients with advanced malignancies. (4)
- Patients with platelet counts less than 50 x 10^9/L. (4)
- Known hypersensitivity to deferasirox or any component of deferasirox tablets. (4)

WARNINGS AND PRECAUTIONS

- Acute Kidney Injury: Measure serum creatinine in duplicate before starting therapy. Monitor renal function during deferasirox therapy and reduce dose or interrupt therapy for toxicity. (2.1, 2.4, 5.1)
- Hepatic Toxicity: Monitor hepatic function. Reduce dose or interrupt therapy for toxicity. (5.2)
- Fatal and Nonfatal Gastrointestinal (GI) Bleeding, Ulceration, and Irritation: Risk may be greater in patients who are taking deferasirox in combination with drugs that have known ulcerogenic or hemorrhagic potential. (5.3)
- Bone Marrow Suppression: Neutropenia, agranulocytosis, worsening anemia, and thrombocytopenia, including fatal events; monitor blood counts during deferasirox therapy. Interrupt therapy for toxicity. (5.4)
- Age-related Risk of Toxicity: Monitor elderly and pediatric patients closely for toxicity. (5.5)
- Hypersensitivity Reactions: Discontinue deferasirox for severe reactions and institute medical intervention. (5.7)
- Severe Skin Reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS): Discontinue deferasirox. (5.8)

ADVERSE REACTIONS

In patients with transfusional iron overload, the most frequently occurring (greater than 5%) adverse reactions are diarrhea, vomiting, nausea, abdominal pain, skin rashes, and increases in serum creatinine. In deferasirox-treated patients with NTDT syndromes, the most frequently occurring (greater than 5%) adverse reactions are diarrhea, rash, and nausea. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Annora Pharma Private Limited at 1-866-495-1995 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Do not take deferasirox with aluminum-containing antacid preparations. (7.1)
- Deferasirox increases the exposure of repaglinide. Consider repaglinide dose reduction and monitor blood glucose levels. (7.3)
- Avoid the use of deferasirox with theophylline as theophylline levels could be increased. (7.4)
- Deferasirox increases exposure of busulfan. Monitor plasma concentrations of busulfan when coadministered with deferasirox to allow dose adjustment of busulfan, as needed. (7.7)

USE IN SPECIFIC POPULATIONS

Lactation: Advise women not to breastfeed. (8.2)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 11/2023

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

WARNING: RENAL FAILURE, HEPATIC FAILURE, and GASTROINTESTINAL HEMORRHAGE

Renal Failure

- **Deferasirox can cause acute renal failure and death, particularly in patients with comorbidities and those who are in the advanced stages of their hematologic disorders.**
- **Evaluate baseline renal function prior to starting or increasing deferasirox dosing in all patients. Deferasirox is contraindicated in adult and pediatric patients with eGFR less than 40 mL/min/1.73 m^2. Measure serum creatinine in duplicate prior to initiation of therapy. Monitor renal function at least monthly. For patients with baseline renal impairment or increased risk of acute renal failure, monitor renal function weekly for the first month, then at least monthly. Reduce the starting dose in patients with preexisting renal disease. During therapy, increase the frequency of monitoring and modify the dose for patients with an increased risk of renal impairment, including use of concomitant nephrotoxic drugs, and pediatric patients with volume depletion or overchelation *[see Dosage and Administration (2.1, 2.4, 2.5), Warnings and Precautions (5.1), Adverse Reactions (6.1, 6.2)]*.**

Hepatic Failure

- **Deferasirox can cause hepatic injury including hepatic failure and death.**
- **Measure serum transaminases and bilirubin in all patients prior to initiating treatment, every 2 weeks during the first month, and at least monthly thereafter.**

[illegible]

Artwork information

Customer	Camber	Market	USA
Dimensions (mm)	400 x 800 mm	Non Printing Colors	Die cut
Pharma Code No.	Front-407 & Back-408		
Printing Colours (01)	Black		

Others: Pharma code position and Orientation are tentative, will be changed based on folding size.

Prepared by:		Approved by:		
PK	PK	RA	PD	QA

- **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 tablets, 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, and to monitor you for side effects. Your healthcare provider may change your dose, or temporarily or permanently stop deferasirox tablets 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.
- If you or your child take too much deferasirox tablets, call your healthcare provider right away or go to the nearest hospital emergency room. Symptoms that can happen if you take too much deferasirox tablets include: stomach-area (abdominal) pain, diarrhea, nausea and vomiting.

What should I avoid while taking deferasirox tablets?

- Deferasirox tablets may cause dizziness. Avoid driving or operating machinery until you know how deferasirox tablets affects you. Do not drive or operate machinery if deferasirox tablets 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:**
  - difficulty in breathing or swallowing
  - swelling of the face, lips, mouth, tongue, or throat
  - chest pain
  - severe itching of the skin with a red rash or raised bumps
  - rapid heartbeat
  - hives
  - feeling faint
- **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:
  - rash or red skin
  - skin peeling
  - blisters on your lips, or around your mouth or eyes
  - high fever or flu-like symptoms
  - mouth sores
  - 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 room temperature between 68°F to 77°F (20°C to 25°C).
- 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 1-866-495-1995.

What are the ingredients in deferasirox tablets?

Deferasirox tablets:

Active ingredient: deferasirox

Inactive ingredients: Colloidal silicon dioxide, crospovidone, microcrystalline cellulose, poloxamer 188, povidone, and sodium stearyl fumarate. The film coating contains hypromellose, polyethylene glycol, talc and titanium dioxide.

Medication Guide available at http://camberpharma.com/medication-guides

CAMBER®

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

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