

INDICATIONS

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

EXJADE® (deferasirox) 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, EXJADE® 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

EXJADE 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).

- EXJADE 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 EXJADE

- It is not known if EXJADE 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 EXJADE to treat chronically elevated levels of iron in the blood caused by repeated blood transfusions. The iron lowering effects and safety of EXJADE have not been studied in clinical trials specifically designed for just these patients with MDS

IMPORTANT SAFETY INFORMATION for EXJADE® (deferasirox)

What is the most important safety information to know about EXJADE?

EXJADE may cause serious kidney problems, liver problems, and bleeding in the stomach or intestines. In some cases, these problems were fatal. Kidney problems occurred particularly in patients with multiple medical conditions and those who were very ill because of their disease. Bleeding in the stomach or intestines occurred more often in elderly patients. Liver problems were more likely to happen in patients older than 55 years.

Your doctor should check your kidneys with a blood test called serum creatinine and/or creatinine clearance:

- **Before taking EXJADE**
- **Monthly during treatment**

If you already have a history of kidney problems or are at risk for kidney problems, your doctor should check your kidneys:

- **Every week for the first month**
- **Monthly during treatment**

Your doctor should check your liver with blood tests called serum transaminases and bilirubin:

- **Before taking EXJADE**
- **Every other week for the first month after starting EXJADE**
- **Monthly during treatment**

You should not take EXJADE if you have:

- Certain kinds of kidney problems
- Pre-existing severe liver problems
- High-risk myelodysplastic syndromes (MDS)
- Advanced cancer
- Low blood counts (low platelets)
- An allergy to EXJADE or any ingredient of EXJADE

Kidneys

- If you have a pre-existing kidney condition, are elderly, have multiple medical conditions, or are taking medicine that affects your kidneys, you are at increased

risk of complications. Your doctor will give you a blood test (called serum creatinine and/or creatinine clearance) every week for the first month you are taking EXJADE or if your dose has changed, and then every month after that. Your doctor may adjust your dose based on the results of these tests

- Your doctor may also collect urine samples monthly
- Some patients developed severe kidney problems while taking EXJADE, in some cases fatal, and in some cases requiring dialysis. Most of the fatalities occurred in patients who were very ill because of their disease

Liver

- If you have a pre-existing severe liver problem, you should not use EXJADE
- If you have mild or moderate liver problems, your doctor will give you blood tests called serum transaminases and bilirubin before starting treatment, every 2 weeks during the first month of treatment, and then monthly. Your doctor may adjust your dose based on the results of these tests
- Some patients developed severe liver problems, in some cases fatal, while taking EXJADE. Many of these patients were older than 55 years of age and/or had multiple medical conditions already affecting their liver

Bleeding in the Stomach or Intestines

- Some patients developed stomach irritation or bleeds while taking EXJADE. In some cases, stomach bleeds were fatal, usually in patients who were elderly and had pre-existing blood cancers and/or low blood counts (low platelets)
- Talk to your doctor if you are taking other drugs that can also irritate your stomach or cause a stomach bleed (eg, pain relievers/anti-inflammatory drugs, corticosteroids, oral bisphosphonates, blood thinners)

Blood Disorders

- Some patients developed severe blood disorders, in some cases fatal, while on EXJADE therapy. Having a pre-existing blood disorder may increase the risk
- Your doctor will give you a blood test to check your blood counts

Increased Risks When Used in Elderly Patients

- Since EXJADE has been on the market, there have been reports of serious reactions, sometimes leading to death. These serious reactions and deaths have happened most often when EXJADE was taken by elderly patients

Allergic Reactions

- Serious allergic reactions (which include swelling of the throat) have been reported in patients taking EXJADE, usually within the first month of treatment
- If you develop swelling of the throat, a severe rash, hearing problems, or vision disturbances, stop taking EXJADE and contact your doctor immediately

Serious Skin Reactions

- Severe skin disorders that result in a very serious rash, called Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and erythema multiforme, have been reported during treatment with EXJADE. Other skin reactions, including DRESS (drug reaction with eosinophilia and systemic symptoms), can also occur. If you develop a severe rash, stop taking EXJADE and contact your doctor immediately
- Mild to moderate skin rashes may occur during treatment with EXJADE. Let your doctor know if the rash doesn't go away on its own or gets worse. Your doctor may need to change your dose of EXJADE

Hearing and Vision Changes

- Changes to hearing and vision have been reported in patients taking EXJADE. If you notice changes in your hearing or eyesight, contact your doctor immediately
- You may also receive a hearing or vision test prior to receiving EXJADE and yearly thereafter. Your doctor may change your dose based on the results of these tests

Common Side Effects

- The most commonly reported side effects related to EXJADE in clinical trials were mainly nausea, vomiting, diarrhea, stomach pain, increases in kidney laboratory values, and skin rash
- Let your doctor know if you are experiencing any side effects. Your doctor may need to change your dose
- If you experience diarrhea or vomiting, you must continue to drink fluids
- You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088

Taking Other Medicines and EXJADE

- If you are taking other medicines, such as birth control pills, diabetes drugs, seizure drugs, cholesterol-lowering drugs, or medicine for serious illnesses, talk to your doctor. EXJADE may affect how these drugs work

Talk to your doctor to determine if prescription EXJADE therapy is right for you.

Please see full Prescribing Information, including Boxed WARNING, for EXJADE