



## News Articles, FDA Update, Pharmacology

### Pediatric safety labeling updated for iron chelation drug

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The Food and Drug Administration (FDA) added new safety information to the product labeling for deferasirox (Exjade, Jadenu and Jadenu Sprinkle) due to post-marketing reports of serious toxicity, including fatal acute kidney injury (AKI) and liver failure in pediatric patients treated with deferasirox.

Deferasirox is indicated for chelation in certain iron overload conditions (see below).

FDA analyses of cases of toxicity found the AKI risk to be dose-related, greater in patients younger than 6 years of age and more prevalent in the presence of excess chelation as measured by low serum ferritin concentration. Overchelation also increased the risk of hepatic, ocular and auditory toxicity.

The FDA identified that small decreases in glomerular function can increase deferasirox exposure, particularly in young patients. This increased exposure can lead to a cycle of worsening renal function and further increases in deferasirox exposure unless the dose is reduced or interrupted.

Pediatric patients with pre-existing renal disease, declining renal function or a recent AKI episode might be more susceptible to kidney injury. Acute illnesses associated with volume depletion may increase the risk of AKI.

Key measures to mitigate deferasirox toxicity include interrupting deferasirox in pediatric patients who have acute illness that can cause volume depletion, such as vomiting, diarrhea or prolonged decreased oral intake. Renal and hepatic function should be monitored closely. Renal function should be evaluated by estimating glomerular filtration with a serum creatinine-based equation validated in pediatrics.

#### Deferasirox indications

Deferasirox (Exjade, Jadenu and Jadenu sprinkle) is approved for treatment of chronic iron overload in patients:

- 2 years of age and older due to blood transfusions and
- 10 years of age and older with non-transfusion dependent thalassemia syndromes\* who have liver iron concentration (LIC) of at least 5 milligrams (mg) iron (Fe) per gram of dry weight (Fe/g dw) and a serum ferritin greater than 300 micrograms/liter.

\*This indication is based on achievement of an LIC less than 5 mg Fe/g dw. An improvement in survival or disease-related symptoms has not been established.

#### Resources

- [For more information about the FDA's safety analyses, see Bird ST, et al. Lancet Child Adolesc Health. 2019;3:15-22.](#)
- [Prescribing information for the deferasirox products](#)
- [Additional FDA Update columns](#)