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In Brief: *Jadenu* – A New Formulation of Deferasirox for Iron Overload online only

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IN BRIEF

Jadenu – A New Formulation of Deferasirox for Iron Overload

The FDA has approved an oral tablet formulation of deferasirox (*Jadenu* [jade' new] – Novartis) for once-daily treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) in patients ≥ 2 years old or chronic iron overload in patients ≥ 10 years old with non-transfusion-dependent thalassemia syndromes. A once-daily, oral tablet for suspension formulation of deferasirox (*Exjade*) was approved in 2005 for the same indications.¹ *Jadenu* and *Exjade* are the only once-daily oral formulations for iron chelation available in the US.

Table 1. Deferasirox Products

Drug	Available Formulations	Usual Dosage ¹	Cost ²
<i>Exjade</i> (Novartis)	125, 250, 500 mg tabs for oral suspension	20-40 mg/kg PO once/d ³⁻⁵	\$10,902.30
<i>Jadenu</i> (Novartis)	90, 180, 360 mg tabs	14-28 mg/kg PO once/d ^{3,4,6}	10,902.30

1. Dosage for transfusional iron overload. Dosage adjustments are recommended for hepatic or renal impairment.
2. Approximate WAC for 30 days' treatment at the lowest usual dosage for a 70-kg patient. WAC = wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource® Monthly. April 5, 2016. Reprinted with permission by First Databank, Inc. All rights reserved. ©2016. www.fdbhealth.com/policies/drug-pricing-policy.
3. *Jadenu* dosages of 14, 21, and 28 mg/kg/day are equivalent to *Exjade* dosages of 20, 30, and 40 mg/kg/day, respectively.
4. Recommended dosage for patients ≥ 2 years old.
5. Take on an empty stomach at least 30 minutes before food. Must be dispersed in liquid before administration.
6. Can be taken on an empty stomach or with a low-fat meal. For patients who have difficulty swallowing tablets, it can be crushed and sprinkled on soft food, such as yogurt or applesauce.

No new clinical trials were required for approval of *Jadenu*, which was based on earlier clinical trials with *Exjade*. The most common adverse effects reported with use of deferasirox in clinical trials were diarrhea, vomiting, nausea, abdominal pain, rash, neutropenia, and increases in serum creatinine. Severe skin reactions, including Stevens-Johnson syndrome and erythema multiforme, have been reported rarely. Hearing loss and ocular disturbances, including cataracts, have been reported with deferasirox; patients taking the drug should have annual auditory and ophthalmic exams. Gastrointestinal ulceration and hemorrhage and renal and hepatic toxicity have also occurred.

1. Deferasirox (*Exjade*): a new iron chelator. *Med Lett Drugs Ther* 2006; 48:35.

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