

Jadenu[®] Sprinkle (deferasirox) – New formulation approval

- On May 18, 2017, the [FDA approved](#) Novartis' [Jadenu Sprinkle \(deferasirox\)](#) oral granules, for the treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) in patients ≥ 2 years old, and for the treatment of chronic iron overload in patients ≥ 10 years old with non-transfusion-dependent thalassemia (NTDT) syndromes and with a liver iron concentration (LIC) of at least 5 mg of iron per gram of liver dry weight (mg Fe/g dw) and a serum ferritin greater than 300 mcg/L.
 - Controlled clinical trials of Jadenu with myelodysplastic syndromes (MDS) and chronic iron overload due to blood transfusions have not been performed.
 - The safety and efficacy of Jadenu when administered with other iron chelation therapy have not been established.
- Deferasirox is also available as oral tablets under the brand name, Jadenu.
- Jadenu was evaluated in healthy subjects. There are no clinical data in patients with Jadenu. Jadenu contains the same active ingredients as [Exjade[®] \(deferasirox\)](#) tablets for oral suspension.
- Jadenu Sprinkle carries a boxed warning regarding renal failure, hepatic failure, and gastrointestinal (GI) hemorrhage.
- Jadenu Sprinkle is contraindicated in patients with serum creatinine greater than two times the age-appropriate upper limit of normal or creatinine clearance less than 40 mL/min, poor performance status, high-risk MDS, advanced malignancies, platelet counts less than $50 \times 10^9/L$, and known hypersensitivity to deferasirox or any component of Jadenu Sprinkle.
- Other warnings and precautions of Jadenu Sprinkle include bone marrow suppression; increased risk of toxicity in the elderly; hypersensitivity; severe skin reactions; skin rash; auditory and ocular abnormalities; and overchelation.
- In patients with transfusional iron overload, the most common adverse events ($> 5\%$) with deferasirox use were diarrhea, vomiting, nausea, abdominal pain, skin rashes, and increases in serum creatinine.
- In deferasirox-treated patients with NTDT syndromes, the most common adverse events ($> 5\%$) with deferasirox use were diarrhea, rash and nausea.
- For transfusional iron overload, the recommended initial dose of deferasirox is 14 mg/kg orally once daily. For NTDT syndromes, the recommended initial dose is 7 mg/kg once daily.
 - Calculate each dose to the nearest whole tablet or whole sachet content for granules.
 - Deferasirox therapy should only be considered when a patient has evidence of chronic transfusional iron overload. The evidence should include the transfusion of at least 100 mL/kg of packed red blood cells (e.g., at least 20 units of packed red blood cells for a 40 kg person or more in individuals weighing more than 40 kg), and a serum ferritin consistently greater than 1000 mcg/L.
 - Deferasirox therapy should only be considered when a patient with NTDT syndrome has an LIC of at least 5 mg Fe/g dw and a serum ferritin greater than 300 mcg/L.

- Novartis' launch plans for Jadenu Sprinkle are pending. Jadenu Sprinkle will be available as 90 mg, 180 mg, and 360 mg oral granules in sachets.



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