Generic Name:
Voxelotor
Trade Name:
Oxbryta
Company:
Global Blood Therapeutics
Notes:

FDA granted accelerated approval to voxelotor, a hemoglobin S polymerization inhibitor for adults and children ages 12 years and older with sickle cell disease.

Efficacy was evaluated in 274 patients with sickle cell disease in HOPE, a randomized, double-blind, placebo-controlled, multicenter trial. The primary efficacy outcome measure was hemoglobin (Hb) response rate, defined as an Hb increase of > 1 g/dL from baseline to week 24. The response rate for voxelotor was 51.1% (46/90) compared with 6.5% (6/92) in the placebo group ($P < 0.0001$).

The most common adverse reactions to voxelotor are headache, diarrhea, abdominal pain, nausea, rash, fatigue, and pyrexia. Product information includes a warning for hypersensitivity and potential laboratory interference. Voxelotor may interfere with measurement of Hb subtypes (HbA, HbS, and HbF) by high-performance liquid chromatography.

The recommended voxelotor dose is 1,500 mg orally once daily with or without food. Recommended dosage for patients with severe hepatic impairment (Child Pugh C) is 1,000 mg orally once daily.

Medication Monitor Categories:
New Drug Approvals