Oxbryta® (voxelotor) 500mg tablets

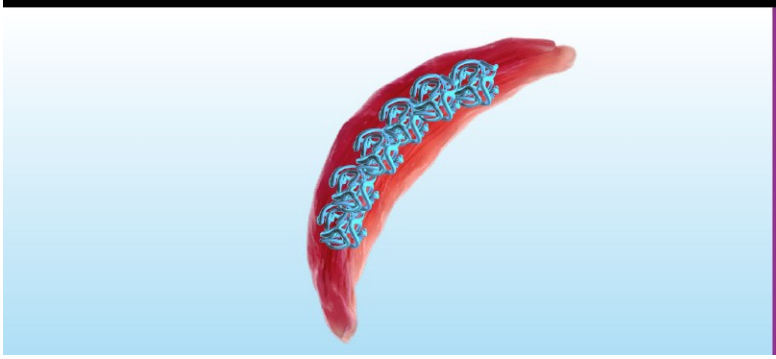
INDICATIONS AND USAGE

Oxbryta is indicated for the treatment of sickle cell disease (SCD) in adults and pediatric patients 12 years of age and older.

This indication is approved under accelerated approval based on increase in hemoglobin (Hb). Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Please see Important Safety Information below

Virtual **Speaker Series**



The First and Only Hemoglobin S (Hbs) Polymerization Inhibitor[1]

Presented by

ALAN ANDERSON, MD

Director, Comprehensive Sickle Cell Disease Program
Prisma Health-Upstate

Thursday, September 17, 2020 06:30 PM CDT

Planning on attending?

Please let us know by calling or texting your Sickle Cell Therapeutic Specialist, Blaine Matray, at (405) 317-5678 or emailing bmatray@gbt.com.

Enter the following link into your web browser:
https://tallenevents.webex.com/tallenevents/onstage/g.php?MTID=e3eb097b7573cadfb71ff039e2e4bac20

This presentation uses Webex web conferencing software. You may use your desktop or mobile device to view the presentation. You may be prompted to download the Webex software or mobile app. You'll be listening through your computer's speakers or a phone. To test Webex on your device prior to the presentation, go to webex.com/test-meeting.html.

Sponsored by Global Blood Therapeutics, Inc.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Oxbryta is contraindicated in patients with a history of serious drug hypersensitivity reaction to voxelotor or excipients.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Serious hypersensitivity reactions after administration of Oxbryta have occurred in <1% of patients treated. Clinical manifestations may include generalized rash, urticaria, mild shortness of breath, mild facial swelling, and eosinophilia.

CONTINUED ON NEXT PAGE

IMPORTANT SAFETY INFORMATION (continued)

If hypersensitivity reactions occur, discontinue Oxbryta and administer appropriate medical therapy. Do not reinitiate Oxbryta in patients who experience these symptoms with previous use.

Laboratory Test Interference

Oxbryta administration may interfere with measurement of Hb subtypes by (HbA, HbS, and HbF) HPLC. If precise quantitation of Hb species is required, chromatography should be performed when the patient is not receiving Oxbryta therapy.

ADVERSE REACTIONS

Clinical Trials Experience

Serious adverse reactions occurred in 3% (3/88) of patients receiving OXBRYTA 1,500 mg, which included headache, drug hypersensitivity, and pulmonary embolism occurring in 1 patient each.

Adverse Reactions (≥10%) in patients receiving Oxbryta with a difference of >3% compared to placebo: Headache (26% vs. 22%), Diarrhea (20% vs. 10%), Abdominal Pain (19% vs. 13%), Nausea (17% vs. 10%), Fatigue (14% vs. 10%), Rash (14% vs. 10%), and Pyrexia (12% vs. 7%).

DRUG INTERACTIONS

Sensitive CYP3A4 Substrates

Voxelotor increased the systemic exposure of midazolam (a sensitive CYP3A4 substrate). Avoid co-administration with sensitive CYP3A4 substrates with a narrow therapeutic index. If unavoidable, consider dose reduction of the CYP3A4 substrate(s).

Strong CYP3A4 Inhibitors or Fluconazole

Co-administration of strong CYP3A4 inhibitors or fluconazole may increase voxelotor plasma concentrations and may lead to increased toxicity. Avoid co-administration of strong CYP3A4 inhibitors or fluconazole. Decrease Oxbryta dosage if unavoidable.

Strong or Moderate CYP3A4 Inducers

Co-administration of strong or moderate CYP3A4 inducers may decrease voxelotor plasma concentrations and may lead to reduced efficacy. Avoid co-administration of strong or moderate CYP3A4 inducers. Increase the Oxbryta dosage if unavoidable.

USE IN SPECIFIC POPULATIONS

Lactation

Because of the potential for serious adverse reactions in the breastfed child, including changes in the hematopoietic system, advise patients not to breastfeed while taking Oxbryta and for at least 2 weeks after the last dose.

Recommended Dosage for Hepatic Impairment

Severe hepatic impairment increases voxelotor exposures. Reduce dose to 1,000 mg orally once daily for severe hepatic (Child Pugh C) impairment.

For additional information about Oxbryta, please see Full Prescribing Information accompanying this piece.

Reference

1. Oxbryta Full Prescribing Information. South San Francisco, CA: Global Blood Therapeutics, Inc.; 11/2019.

P-VOX-US-00551 v1