FACT SHEET

Oxbryta (voxelotor) 500mg tablets

Oxbryta is approved by the U.S. Food and Drug Administration (FDA)
for the treatment of sickle cell disease in adults and children 12 years of age and older.

What is Oxbryta?

Oxbryta (ox brye ta) is a sickle hemoglobin polymerization inhibitor taken orally once daily to treat sickle cell disease in adults and children 12 years of age and older.

It was approved by the U.S. Food and Drug Administration (FDA) in November 2019 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).

What is Sickle Cell Disease?

Sickle cell disease is an inherited blood disorder that affects an estimated 100,000 people in the United States and millions of people throughout the world, particularly of African, Hispanic, South Asian, Southern European, and Middle Eastern ancestry.

Hemoglobin is the part of the red blood cell that carries oxygen to all parts of the body. When a person has sickle cell disease, the hemoglobin causes the red blood cells to change shape from round cells into curved sickle shapes, like the shape of a crescent moon. The sickled red blood cells break down by a process called hemolysis faster than the body can make new ones, which can lead to a condition called anemia, impairing oxygen delivery. Anemia and hemolysis are serious consequences of sickle cell disease because they can cause other problems.

Important Safety Information

The Prescribing Information for Oxbryta includes Warnings and Precautions for hypersensitivity reactions.

Please see additional Important Safety Information on page two and the Full Prescribing Information for Oxbryta at Oxbryta.com

How Does Oxbryta Work?

Oxbryta inhibits hemoglobin polymerization, the process that causes red blood cells to deform and become sickle shaped. Oxbryta may slow the breakdown of red blood cells and improve anemia, which helps increase the amount of hemoglobin in your blood. Having more hemoglobin may help reduce the ongoing complications of sickle cell disease.

What Data Support the Use of Oxbryta?

The efficacy of Oxbryta in sickle cell disease was evaluated in the Phase 3 HOPE (Hemoglobin Oxygen Affinity Modulation to Inhibit HbS PolymErization) Study. In this study, 274 patients were randomized to receive Oxbryta 1500 mg or 900 mg, or placebo. The results showed that the study met its primary endpoint of an improvement in hemoglobin greater than >1 g/dL at 24 weeks with Oxbryta 1500 mg compared with placebo ($p<0.001$). Additionally Oxbryta demonstrated an improvement in markers of hemolysis.

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IMPORTANT SAFETY INFORMATION

Oxbryta™ (voxelotor) 500mg tablets

INDICATION

What is OXBRYTA?

OXBRYTA is a prescription medicine used for the treatment of sickle cell disease in adults and children 12 years of age and older.

It is not known if OXBRYTA is safe and effective in children below 12 years of age.

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).

IMPORTANT SAFETY INFORMATION

Do not take OXBRYTA if you have had an allergic reaction to voxelotor or any of the ingredients in OXBRYTA. See the end of the patient leaflet for a list of the ingredients in OXBRYTA.

If you are receiving exchange transfusions, talk to your healthcare provider about possible difficulties with the interpretation of certain blood tests when taking OXBRYTA.

Before taking OXBRYTA, tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems
- are pregnant or plan to become pregnant. It is not known if OXBRYTA can harm your unborn baby
- are breastfeeding or plan to breastfeed. It is not known if OXBRYTA can pass into your breastmilk and if it can harm your baby. Do not breastfeed during treatment with OXBRYTA and for at least 2 weeks after the last dose

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines may affect how OXBRYTA works. OXBRYTA may also affect how other medicines work.

What are the possible side effects of OXBRYTA?
OXBRYTA can cause serious side effects, including:
Serious allergic reactions. Tell your healthcare provider or get emergency medical help right away if you get:

- rash
- hives
- shortness of breath
- swelling of face

The most common side effects of OXBRYTA include:

- headache
- diarrhea
- stomach (abdominal) pain
- nausea
- tiredness
- rash
- fever

These are not all the possible side effects of OXBRYTA.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.
You may also report side effects to Global Blood Therapeutics at 1-833-428-4968 (1-833-GBT-4YOU).

Keep OXBRYTA and all medicines out of the reach of children.

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To learn more about Oxbryta, visit Oxbryta.com.

P-VOX-US-00261 v1