

INDICATION

What is OXBRYTA?

OXBRYTA is a prescription medicine used for the treatment of sickle cell disease in adults and children 4 years of age and older.

It is not known if OXBRYTA is safe and effective in children with sickle cell disease below 4 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 or your child 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.

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

- 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 or your child 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 and may affect the results of certain blood tests. Keep a list of all your medicines and show it to your healthcare provider.

What should I avoid while taking OXBRYTA?

Do not take St. John's wort during treatment with OXBRYTA.

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 (difficult breathing)
- swelling of the face

The most common side effects of OXBRYTA include:

- headache
- diarrhea
- stomach-area (abdominal) pain
- nausea
- rash or hives
- fever

The most common side effects of OXBRYTA in children ages 4 to less than 12 years of age include:

- fever
- vomiting
- rash
- stomach-area (abdominal) pain
- diarrhea
- headache

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.

Please see Patient Prescribing Information for more information.