PATIENT INFORMATION
OXBRYTA®(ox brye ta)
(voxelotor) tablets

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.

Do not take OXBRYTA if you have had an allergic reaction to voxelotor or any of the ingredients in OXBRYTA.
See the end of this 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.
Keep a list of all your medicines and show it to your healthcare provider.

How should I take OXBRYTA?

- Take OXBRYTA exactly as your healthcare provider tells you.
- Do not change your dose or stop taking OXBRYTA unless your healthcare provider tells you to.
- Take OXBRYTA 1 time each day. Swallow each OXBRYTA tablet whole. Do not cut, crush or chew the tablets.
  - Your healthcare provider may change your dose if needed.
- Your healthcare provider may also prescribe hydroxyurea during treatment with OXBRYTA.
- Take OXBRYTA with or without food.
- If you forget to take a dose of OXBRYTA, skip that dose and return to your normal dosing schedule the next day.

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 the 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, Inc. at 1-833-428-4968 (1-833-GBT-4YOU).

How should I store OXBRYTA?

- Store OXBRYTA at or below 86°F (30°C).
- OXBRYTA comes in a child-resistant package.
- The bottle contains a desiccant to help keep your medicine dry (protect it from moisture) and polyester coil. Do not eat.

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

General information about the safe and effective use of OXBRYTA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use OXBRYTA for a condition for which it was not prescribed. Do not give OXBRYTA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about OXBRYTA that is written for health professionals.

What are the ingredients of OXBRYTA?

Active Ingredient: voxelotor

Inactive Ingredients: colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, and sodium lauryl sulfate. The film coating contains: polyethylene glycol 3350, polyvinyl alcohol, talc, titanium dioxide, and yellow iron oxide.

Manufactured for: Global Blood Therapeutics, Inc. South San Francisco, CA 94080, USA.

This Patient Information has been approved by the U.S. Food and Drug Administration. Issued: 01/2021