HOW TO TAKE OXBRYTA® (voxelotor) 500 MG TABLETS



FOR PATIENTS AGES 12 YEARS AND UP, AS WELL AS PATIENTS AGES 4 TO LESS THAN 12 YEARS WHO WEIGH 88 LBS (40 KG) OR MORE

DIMA ··· Mother, author, and actual Oxbryta patient

WHAT YOU'LL NEED





- The prescribed number of Oxbryta 500 mg Tablets (film-coated, light yellow, oval shaped, and marked with "GBT 500" on one side)
 - For information on Dosage and Administration, see the **Patient Information** on **Oxbryta.com**.

HOW TO TAKE YOUR MEDICINE

- Swallow each Oxbryta tablet whole
- **Do not** cut, crush, or chew the tablets

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.

OXBRYTA is approved under accelerated approval based on an increase in hemoglobin. Continued approval may depend on verification of clinical benefits in ongoing trials.

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.

IMPORTANT INFORMATION

- 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. Your healthcare provider may change your dose if needed
- Take your prescribed dose of Oxbryta 1 time each day
- Take Oxbryta with or without food
- Swallow each Oxbryta tablet whole. Do not cut, crush, or chew the tablets
- Check to make sure you receive the correct dosage form of Oxbryta each time your prescription is filled to avoid taking the wrong medicine. Contact your pharmacist or healthcare provider if you did not receive the correct medication
- Your healthcare provider may also prescribe a medicine called hydroxyurea during treatment with Oxbryta
- If you or your child miss a dose or do not take the entire dose of Oxbryta, skip that dose and return to your normal dosing schedule the next day
- Do not take St. John's wort during treatment with Oxbryta

HOW TO STORE OXBRYTA

- Store Oxbryta at 68°F to 86°F (20°C to 30°C)
- Oxbryta comes in a child-resistant package
- The bottle contains a desiccant canister to help keep your medicine dry (protect it from moisture) and polyester coil. Do not eat the desiccant or polyester coil

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

Please see additional <u>Important Safety Information</u> on page 2 and <u>Patient Information</u> on <u>Oxbryta.com</u>.



IMPORTANT SAFETY INFORMATION (CONTINUED)

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:

- Severe skin rash and serious allergic reactions. Treatment with OXBRYTA may cause severe skin reactions and serious allergic reactions. The organs in your body may also be affected, such as your liver, kidneys or lungs, and your blood cells.
- Stop taking OXBRYTA, and tell your healthcare provider or get emergency medical help right away if you develop any of the following signs or symptoms during treatment:
- o rash
- hives
- high temperature (fever)
- swollen glands (lymph nodes)
- trouble swallowing
- shortness of breath (difficult breathing)
- swelling of your face, around your eyes, lips, or tongue
- lack of energy and tiredness (fatigue)
- muscle or joint aches

The most common side effects of OXBRYTA include:

- headache
- nausea or vomiting
- fever

- stomach-area (abdominal) pain
- diarrhea
- rash or hives

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 Pfizer Inc. at 1-800-438-1985.

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