FOR PATIENTS AS YOUNG AS 4 YEARS OLD

# FREQUENTLY ASKED QUESTIONS ABOUT OXBRYTA



#### **COMMON QUESTIONS YOU MAY HAVE ABOUT TAKING YOUR MEDICINE**

#### How do I take Oxbryta?

Take Oxbryta once a day, 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. Your healthcare provider will decide which dosage form you take based on your age, weight, and ability to swallow tablets.

If you take Oxbryta 500 mg Tablets: Swallow each tablet whole. **Do not** cut, crush, or chew the tablets.

If you take Oxbryta 300 mg Tablets: Swallow each tablet whole. Do not cut, crush, or chew the tablets.

If you take Oxbryta 300 mg Tablets for Oral Suspension: You must first mix the tablets in a room temperature clear drink such as drinking water, clear soda, apple juice, clear electrolyte drinks, clear flavored drinks, or clear sports drinks, and then take by mouth. **Do not** swallow whole, cut, crush, or chew the tablets for oral suspension.

Please see the <u>Patient Information</u> and <u>Instructions for Use</u> for specific instructions on dosage and administration.

#### Can I take Oxbryta with other medicines for sickle cell disease?

Tell your healthcare provider about all the medicines you or your child take. Your healthcare provider may also prescribe a medicine called hydroxyurea during treatment with Oxbryta.

#### **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.

#### **SELECTED 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.



300mg tablets for oral suspension

## How is Oxbryta 300 mg Tablets for Oral Suspension different from Oxbryta 300 mg Tablets and Oxbryta 500 mg Tablets?

	OXBRYTA 300 MG TABLETS FOR ORAL SUSPENSION	OXBRYTA 300 MG TABLETS	OXBRYTA 500 MG TABLETS
Patient Population	Pediatric patients 4 to less than 12 years, based on weight and ability to swallow tablets	Pediatric patients 4 to less than 12 years, based on weight and ability to swallow tablets	<ul> <li>Adults and pediatric patients 12 years or older*</li> <li>Pediatric patients 4 to less than 12 years who weigh 88 lbs (40 kg) or more*</li> </ul>
Dose	300 mg	300 mg	500 mg
Shape	Round	Oval	Oval
Imprinting	300 D	G 300	GBT 500
Color	Light yellow to yellow	Light purple to purple	Light yellow to yellow
Flavor	Grape Flavor	No flavor added	No flavor added
Administration	Mixed in room temperature clear drink before it is taken/given	Swallowed whole	Swallowed whole

<sup>\*</sup> Based on their ability to swallow tablets.

#### What does "tablet for oral suspension" mean? Is it a tablet (pill) or is it a liquid?

The Oxbryta 300 mg Tablets for Oral Suspension are a type of pill that must be placed in a clear drink so that it fully mixes before it is taken/given.

#### How is the number of tablets a child needs determined?

Your child's healthcare provider will determine the correct number of tablets for your child.

#### Can Oxbryta be taken with food?

**Yes.** Oxbryta can be taken with or without food.

#### What is a clear drink?

A clear drink is a drink you can see through. Examples of clear drinks that can be used are drinking water, clear soda, apple juice, clear electrolyte drinks, clear flavored drinks, or clear sports drinks. You must first mix the tablets in a room temperature clear drink and then take by mouth. Please see <u>Instructions For</u> Use for more information.

#### **SELECTED SAFETY INFORMATION**

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.

Oxbryta (voxelotor) 300mg · 500mg tablets 300mg tablets for oral suspension

Please see additional <u>Important Safety Information</u> on page 4 and <u>Patient Information</u> and <u>Instructions for Use</u> on <u>Oxbryta.com</u>.

### Can I mix Oxbryta 300 mg Tablets for Oral Suspension with yogurt, applesauce, or other type of food?

**No.** Oxbryta 300 mg Tablets for Oral Suspension will not fully mix in yogurt or other semisolid foods. Only clear drinks should be used for mixing with the Oxbryta 300 mg Tablets for Oral Suspension.

#### Can I crush or cut the Oxbryta 300 mg Tablets for Oral Suspension before I mix it in liquid?

**Do not** cut, crush, chew, or swallow the tablets for oral suspension whole.

The Oxbryta 300 mg Tablets for Oral Suspension will mix in a room temperature clear drink.

## My child has no trouble taking tablets. Can they swallow the Oxbryta 300 mg Tablets for Oral Suspension?

Oxbryta 300 mg Tablets for Oral Suspension must first be mixed in a room temperature clear drink and then taken.

**Do not** swallow Oxbryta 300 mg Tablets for Oral Suspension whole.

#### My child has no trouble taking pills. Can they take the 300 mg or 500 mg Tablet?

Your child's healthcare provider can select the appropriate dosage form based on your child's weight and ability to swallow tablets. Please consult their healthcare provider for the correct dosage form for your child.

If Oxbryta 300 mg or 500 mg Tablets are prescribed, your child should swallow each tablet whole. **Do not** cut, crush, or chew the tablets.

If Oxbryta 300 mg Tablets for Oral Suspension are prescribed, they should be mixed in a room temperature clear drink and then taken by mouth. **Do not** swallow whole, cut, crush, or chew the tablets for oral suspension.

#### What do I do if I miss / my child misses a dose?

Oxbryta should be dosed once per day.

**If you miss a dose** of Oxbryta or if the entire dose is not taken, skip that dose and return to your normal dosing schedule the next day.

#### What do I do if my child spits up or vomits some or all of the dose?

Oxbryta should be dosed once per day.

If your child does not take the entire dose of Oxbryta, skip that dose and return to your normal dosing schedule the next day.

To learn more about Oxbryta, talk to your healthcare provider or visit Oxbryta.com.



#### INDICATION AND IMPORTANT SAFETY INFORMATION

#### **INDICATION**

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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.

## 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:
  - 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.

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

To learn more about Oxbryta, talk to your healthcare provider or visit Oxbryta.com.

Please see <u>Patient Information</u> and <u>Instructions for Use</u> on <u>Oxbryta.com</u>.



