



# Information for patients



## Reporting of side effects

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See below for how to report side effects.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet.

You can help by reporting any side effects you may get. See <https://yellowcard.mhra.gov.uk> for how to report side effects.

By reporting side effects, you can help provide more information on the safety of this medicine.

Oxbryta® (voxelotor) is indicated for the treatment of haemolytic anaemia due to sickle cell disease (SCD) in adults and paediatric patients 12 years of age and older as monotherapy or in combination with hydroxycarbamide.

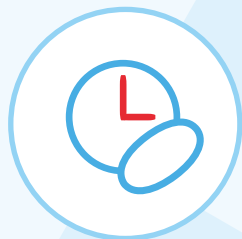


# How to take your medicine

## What is Oxbryta®?

**It is important that you understand how to take your medicine. This leaflet provides practical information about taking Oxbryta® and tips on how to live with sickle cell disease.**

You have been prescribed Oxbryta® because you have sickle cell disease. Oxbryta® helps to stop your red blood cells from changing into the sickle shape. This improves their function and prolongs their lifespan which can help to alleviate the symptoms of sickle cell disease.



### Before taking Oxbryta®

Always read the Patient Information Leaflet that came with your medicine. Ask your healthcare professional if you have any questions about Oxbryta®.

It is important to tell your doctor if you are taking any other medicines, including prescription and over-the-counter medications, vitamins and herbal supplements, as some of these may affect how Oxbryta® works or may make side effects more likely. Please speak with your healthcare professional or consult the Patient Information Leaflet for more information.

Talk to your doctor if you have severe kidney or liver problems, or if you are pregnant, think you may be pregnant or are planning to have a baby. Do not breastfeed if you are taking Oxbryta®.

**DO NOT TAKE OXBRYTA®** if you are allergic to voxelotor or any of the ingredients in Oxbryta®. See the end of this leaflet for a list of the ingredients.



### Warnings and precautions

Talk to your doctor if you have severe kidney or liver problems.

If you get any symptoms of allergic reactions, stop taking Oxbryta® and talk to your doctor or get emergency medical help immediately. For a list of possible symptoms of an allergic reaction, please see page 5 of this leaflet.

Serious skin reactions, such as drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with Oxbryta® treatment. Stop using Oxbryta® and seek medical attention immediately if you notice any of the symptoms related to this serious skin reaction, which are listed on page 4 of this leaflet.



### Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Your doctor will help you to decide whether you should stop taking Oxbryta® during pregnancy.

Do not breastfeed while taking Oxbryta® because it is not known if voxelotor passes into breast milk and could affect the baby.



### How much Oxbryta® should I take?

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. The recommended dose of Oxbryta® for adults and children from 12 years is **three 500 mg tablets once daily** by mouth. If you have been told you have severe hepatic impairment (liver disease), you should only take two 500 mg tablets once daily by mouth.



Swallow the tablets whole with one glass of water, with or without food.



Do not cut, crush, or chew the tablets because of the bad taste.



The medicine does not require any special storage conditions but do keep this medicine out of sight and reach of children.



### What do I do if I forget to take my tablets?

Continue with your normal dosing schedule on the next day. Do not take a double dose to make up for a forgotten dose.



**It is important to take Oxbryta® every day.**

**Do not stop taking Oxbryta® without your doctor's advice.**

If you are having trouble with your dosing schedule, talk to your doctor.



## What do I do if I have side effects?

Like all medicines, Oxbryta® could cause side effects, although not everybody gets them.

It's important to talk to your healthcare professional about them so you can come up with a management plan to help you live with sickle cell disease and your Oxbryta® treatment.

### Side effects associated with Oxbryta®

Side effect	Frequency*
<b>Headache</b>	Very common
<b>Diarrhoea</b>	Very common
<b>Abdominal (belly) pain</b>	Very common
<b>Nausea</b>	Very common
<b>Rash</b>	Very common
<b>Allergic reactions</b>	Uncommon
<b>Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome)</b>	Not known

\*Very common = may affect more than 1 in 10 people; uncommon = may affect up to 1 in 100 people; not known = frequency cannot be estimated from the available data.



**If you get any side effects, talk to your doctor. This includes any possible side effects not listed here. Try keeping a log or diary of your side effects to show your doctor. You can use the **Notes for my doctor** page of this leaflet.**

## Signs and symptoms of an allergic reaction

Some side effects of Oxbryta® are serious and could mean you are having an allergic reaction to your medicine. **Stop taking Oxbryta® and inform your doctor or get emergency medical help immediately if you experience any of the following serious side effects:**



**Rash and/or hives**



**Swelling**



**Shortness of breath**

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You can help by reporting any side effects you may get. See <https://yellowcard.mhra.gov.uk> for how to report side effects.

By reporting side effects, you can help provide more information on the safety of this medicine.





# Coping with the side effects of treatment

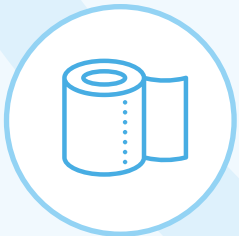
Side effects won't affect everyone who takes a medicine. But if you do experience a side effect, there are steps you can take to help you get on with your day.

**Here are some practical tips to help you manage some common side effects. Don't stop taking Oxbryta<sup>®</sup> without talking to your doctor first**



## Headache

- Dehydration can cause headaches or make them worse. Drink plenty of water to stay hydrated through the day
- Try to relax – stress could make a headache worse
- Don't skip meals, sleep more than usual or look at screens for too long
- Speak to your pharmacist or doctor about medications to reduce your headaches
- **Seek urgent medical help if your headache is extreme**



## Diarrhoea

- Diarrhoea usually clears up within a few days to a week without needing special treatment. If it doesn't, speak with your doctor
- Drink plenty of fluids to avoid dehydration – drink small sips of water often, but avoid fruit juice or fizzy drinks as they could make diarrhoea worse
- Eat solid foods as soon as you feel able to – try foods like white bread, pasta and rice in place of wholegrain options. Choose fluid-rich foods such as soup, vegetables and potatoes as water in food also contributes towards replenishing fluid levels
- Speak to your pharmacist or doctor about medications to reduce your diarrhoea



### Abdominal (belly) pain

- A dull ache in the abdomen does not usually last long. If you are worried about your abdominal pain or it does not go away, consult with your doctor immediately
- Speak to your pharmacist or doctor about treatments that might help



### Nausea

- If you are worried about your nausea or it does not go away, speak with your doctor
- Go outside and breathe fresh air
- Distract yourself with something you enjoy, like music or a movie
- Take regular sips of a cold drink
- Eat smaller, more frequent meals – avoid hot, fried or greasy food. Try foods containing ginger, like ginger biscuits or ginger tea. Peppermint tea can also help



### Rash

- Dermatological creams are available, but you must consult with your doctor, nurse, or pharmacist first. Speak with your doctor or nurse if a rash does not improve or clear up over time

## Consider the time at which you take your medication, as this might help with symptoms

Be sure to speak with your doctor or nurse if you're unsure or worried or if a side effect does not improve over time.



**Sometimes the symptoms of illness and the side effects of medication might be difficult to tell apart. Talk to your doctor or nurse if anything is worrying you so you can discuss how to improve things.**

**Always seek medical help if you experience sudden or severe symptoms that are different to your usual symptoms.**



# Living with sickle cell disease

Living with the symptoms associated with sickle cell disease may be unsettling, but understanding them is the first step to being proactive with your health and taking action.

## Living with sickle cell disease means building a foundation of healthy habits and learning what works for you



### Pain

**You may find that you could get relief from pain with options in addition to – or even instead of – painkillers.**

- **Try different approaches to managing pain:** drink plenty of fluids, avoid extreme temperatures, avoid strenuous exercise and practise relaxation techniques such as breathing exercises
- **Talk with your healthcare professional:** discuss your symptoms and make a plan



### Fatigue

**Sickle cell disease could cause fatigue because not enough oxygen reaches your muscles and other tissues. Also, the pain that comes with sickle cell disease could make it hard to sleep.**

#### Diet and exercise

##### DO:

- Have a healthy diet and exercise regularly (strenuous exercise should be avoided. People with sickle cell disease should be active, but intense activities that cause you to become seriously out of breath are best avoided)

##### DON'T:

- Drink too much alcohol
- Have caffeine or exercise in the couple of hours before sleep

#### Good sleep habits

##### DO:

- Try to stick to the same sleep times
- Aim for 6–9 hours of sleep a night
- Try to relax a couple of hours before your sleep time (read, or listen to music or a podcast)
- Have a relaxing sleep area (not too bright, noisy, or warm)

##### DON'T

- Use smartphones or screens in the hour before sleep

**Talk to your healthcare professional if your tiredness affects your daily life.**





## Mental health

The daily emotional strain of living with sickle cell disease could build up over time, leading to more serious mental health conditions.

### Connect with other people

#### DO:

- If possible, take time each day to spend time with other people
- Arrange a day out with friends you have not seen for a while
- Try switching off the TV to talk or play a game with your children, friends or family
- Make the most of technology to stay in touch with friends and family. Video-chat apps are useful, especially if you live far apart

#### DON'T:

- Rely on technology or social media alone; it's easy to get into the habit of only ever texting, messaging, or emailing people

### Learn new skills

#### DO:

- Try learning to cook something new
- Try taking on new responsibilities at work
- Work on a DIY project
- Consider signing up to a course at a local college
- Try new hobbies that challenge you

#### DON'T

- Feel you have to learn new qualifications or sit exams if this does not interest you

### Be physically active

#### DO:

- Read more about aerobic, strength and flexibility exercises to get you moving and help improve your fitness

#### DON'T

- Feel you have to spend hours in the gym – find activities you enjoy and make them part of your life



**Listen to your body. Contact your doctor if you notice new symptoms or if existing symptoms or side effects of treatment get worse.**



## Exercise

Being physically active can help with maintaining overall good physical and mental health.

- **Prepare for exercise:** keep hydrated, take breaks and set your own pace
- **Listen to your body:** if you are experiencing excessive fatigue, you should not be over-exerting yourself
- **Tell your doctor:** always talk to your doctor before starting any exercise programme



## Notes for my doctor

Use this page to keep a personal record of what is happening to you, including a log of pain triggers and any side effects and symptoms you experience. You can also write down any treatment goals you have or any questions you have about sickle cell disease and your Oxbryta<sup>®</sup> treatment.

You can fill this page in yourself or ask your doctor or nurse to help.

Personal record

Personal record



# Preparing for your next appointment

Be ready to talk to your doctor about how you have been getting on with your sickle cell disease and your Oxbryta® treatment. Some topics to bring up might include:

Use this page to note any other questions or topics you want to bring up at your next appointment.



## What side effects have you been experiencing with Oxbryta®?

- If you have kept a diary or log of your side effects, have this ready to show your doctor
- Remember to tell your doctor about any side effects or problems that you have noticed, including ones not listed in this brochure



## How have you been dealing with your side effects?

- Tell your doctor about any other medicines you have been taking, including analgesics for pain or headaches
- If you have found other ways of dealing with side effects to be effective, let your doctor know



## Have you been taking your Oxbryta® every day?

- It is important to take Oxbryta® every day. Remember, do not change your dose or stop taking Oxbryta® unless your doctor tells you to
- Tell your doctor if you are having trouble with your dosing schedule

Your questions or topics here





## What Oxbryta® contains

The active substance is voxelotor. One tablet contains 500 mg voxelotor.

The other ingredients are:

- Microcrystalline cellulose (E460)
- Sodium laurilsulfate (E487)
- Magnesium stearate (E470b)
- Titanium dioxide (E171)
- Talc (E553b)
- Croscarmellose sodium (E468)
- Silica, colloidal anhydrous (E551)
- Polyvinyl alcohol (E1203)
- Polyethylene glycol (E1521)
- Iron oxide yellow (E172)

## This leaflet was developed with the following information sources:

- Oxbryta® Summary of Product Characteristics. Available at <https://www.medicines.org.uk/emc/product/14464/smpc>. Accessed November 2023.
- Oxbryta® Patient Information Leaflet. Available at <https://www.medicines.org.uk/emc/files/pil.14464.pdf>. Accessed November 2023.
- NHS. Headaches. Available at <https://www.nhs.uk/conditions/headaches/>. Accessed November 2023.
- NHS. Diarrhoea. Available at <https://www.nhsinform.scot/illnesses-and-conditions/stomach-liver-and-gastrointestinal-tract/diarrhoea>. Accessed November 2023.
- NHS. Diarrhoea and vomiting. Available at <https://www.nhs.uk/conditions/diarrhoea-and-vomiting/>. Accessed November 2023.
- NHS. Stomach ache and abdominal pain. Available at <https://www.nhsinform.scot/illnesses-and-conditions/stomach-liver-and-gastrointestinal-tract/stomach-ache-and-abdominal-pain>. Accessed November 2023.
- NHS. Stomach ache. Available at <https://www.nhs.uk/conditions/stomach-ache/>. Accessed November 2023.
- NHS. Nausea. Available at <https://www.nhs.uk/conditions/feeling-sick-nausea/>. Accessed November 2023.
- Bedfordshire Community Health Services. Food First nutrition and dietetics - Diarrhoea. Available at <https://www.cambscommunityservices.nhs.uk/docs/default-source/Beds---Food-First/resources-page/3-diarrhoea---may-2020.pdf>. Accessed November 2023.
- NHS. Living with sickle cell disease - Managing sickle cell pain. Available at <https://www.nhs.uk/conditions/sickle-cell-disease/living-with/>. Accessed November 2023.
- NHS. Tiredness and fatigue. Available at <https://www.nhs.uk/conditions/tiredness-and-fatigue/>. Accessed November 2023.
- NHS. 5 steps to mental wellbeing. Available at <https://www.nhs.uk/mental-health/self-help/guides-tools-and-activities/five-steps-to-mental-wellbeing/>. Accessed November 2023.
- CDC. Living well with sickle cell disease. Self-care toolkit. Available at [https://www.cdc.gov/ncbddd/sicklecell/documents/LivingWell-With-Sickle-Cell-Disease\\_Self-CareToolkit.pdf](https://www.cdc.gov/ncbddd/sicklecell/documents/LivingWell-With-Sickle-Cell-Disease_Self-CareToolkit.pdf). Accessed November 2023.
- CDC. Athletes: don't get sidelined by sickle cell trait! Available at <https://stacks.cdc.gov/view/cdc/33973>. Accessed November 2023.