

Package leaflet: Information for the patient

Oxbryta 500 mg film-coated tablets voxelotor

▼ 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 the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Oxbryta is and what it is used for
2. What you need to know before you take Oxbryta
3. How to take Oxbryta
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1. What Oxbryta is and what it is used for

What Oxbryta is and how it works

Oxbryta contains the active substance voxelotor. Voxelotor works on a protein in red blood cells called haemoglobin to help it take up oxygen that red blood cells can deliver throughout the body.

Patients with the condition called sickle cell disease have an altered form of haemoglobin called sickle haemoglobin which is different from the normal haemoglobin. When the sickle haemoglobin gives up oxygen to the tissues, it sticks together to form long rods and causes red blood cells to alter their shape to that of a crescent moon making these cells rigid and sickled shape. Sickle red blood cells cannot deliver oxygen as well as healthy red blood cells and are also broken down more quickly, leading to lowered levels of red blood cells (haemolytic anaemia). By improving the way the altered haemoglobin holds onto oxygen, Oxbryta improves the function of red blood cells and prolongs their lifespan.

What Oxbryta is used for

Oxbryta, alone or together with hydroxycarbamide (also known as hydroxyurea), is used to treat **haemolytic anaemia** in adults and children from 12 years with **sickle cell disease**.

2. What you need to know before you take Oxbryta

Do not take Oxbryta

- if you are allergic to voxelotor or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor before taking Oxbryta if you have:

- severe kidney problems
- severe liver problems. Your doctor may need to adjust the dose of Oxbryta.

If you get any symptoms of allergic reactions, stop taking Oxbryta and talk to your doctor or get emergency medical help immediately. Symptoms are for example rash, including nettle rash (hives), shortness of the breath and swelling of the face.

Serious skin reaction such as drug reaction with eosinophilia and systemic symptoms (DRESS), has 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 described in section 4.

If you are receiving blood transfusions, talk to your doctor about possible difficulties with the interpretation of certain blood tests when taking this medicine.

Children under 12 years

This medicine is not recommended for children under 12 years due to lack of data in this age group.

Other medicines and Oxbryta

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Some medicines can affect how Oxbryta works or may make side effects more likely. In particular, tell your doctor if you take any of the following medicines:

- rifampicin (used to treat bacterial infections)
- phenobarbital, carbamazepine, phenytoin (used to treat epilepsy and other illnesses)
- sirolimus, tacrolimus (used to prevent organ rejection after transplantation)
- St John's wort (a herbal medicine to treat depression)
- alfentanil (a painkiller used during an operation with anaesthetics)

Tell your doctor that you are taking Oxbryta if you are having a medical procedure or surgery.

Pregnancy and breast-feeding

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

- **Pregnancy**
Your doctor will help you to decide whether you should stop taking Oxbryta during pregnancy.
- **Breast-feeding**
Do not breast-feed while taking Oxbryta because it is not known if voxelotor passes into breast milk and could affect the baby.

Driving and using machines

Oxbryta has no or negligible influence on the ability to drive and use machines.

Oxbryta contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose of three tablets, that is to say essentially 'sodium-free'.

3. How to take Oxbryta

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

The recommended dose for adults and children from 12 years is:

Three 500 mg tablets taken 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 bad taste.

If you take more Oxbryta than you should

Contact your doctor immediately.

If you forget to take Oxbryta

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

If you stop taking Oxbryta

Do not stop taking this medicine without your doctor's advice. It is important to take Oxbryta daily.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Oxbryta and inform your doctor or get emergency medical help immediately if you experience any of the following serious side effects:

Uncommon (may affect up to 1 in 100 people)

- **allergic reactions**
Symptoms are for example rash, including nettle rash (hives), shortness of breath and swelling of the face.

Not known (frequency cannot be estimated from the available data)

- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

Other side effects may occur with the following frequency:

Very common (may affect more than 1 in 10 people)

- headache

- diarrhoea
- abdominal (belly) pain
- nausea
- rash

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Oxbryta

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle and carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Oxbryta contains

- The active substance is voxelotor. One tablet contains 500 mg voxelotor.
- The other ingredients are:
 - microcrystalline cellulose (E460)
 - croscarmellose sodium (E468)
 - sodium laurilsulfate (E487)
 - silica, colloidal anhydrous (E551)
 - magnesium stearate (E470b)
 - polyvinyl alcohol (E1203)
 - titanium dioxide (E171)
 - polyethylene glycol (E1521)
 - talc (E553b)
 - iron oxide yellow (E172)

What Oxbryta looks like and contents of the pack

Light yellow to yellow, oval-shaped, biconvex, film-coated tablets, debossed with “GBT 500” on one side. Tablet dimensions: approximately 18 mm × 10 mm.

Oxbryta is packaged in a plastic bottle with a child-resistant cap. Each bottle contains 90 film-coated tablets. The bottle also contains coil and a silica gel desiccant canister to help keep your medicine dry. The bottle is delivered in a carton.

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This leaflet was last revised in 06/2023.

Other sources of information

For any information about this medicine, please contact:
Medical Information, Pfizer Ltd, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS.
Telephone 01304 616161.

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