


B. PACKAGE LEAFLET

Package leaflet: Information for the patient

Orladeyo 150 mg hard capsules berotralstat

 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Orladeyo is and what it is used for
2. What you need to know before you take Orladeyo
3. How to take Orladeyo
4. Possible side effects
5. How to store Orladeyo
6. Contents of the pack and other information

1. What Orladeyo is and what it is used for

Orladeyo is a medicine that contains the active substance berotralstat. It is used to **prevent angioedema attacks** in adults, and adolescents aged from 12 years with hereditary angioedema.

What hereditary angioedema is

Hereditary angioedema is a condition that often runs in families. It can limit your daily activity by causing attacks of swelling and pain in different parts of your body including:

- hands and feet
- face, eyelids, lips or tongue
- voice-box (larynx), which may make breathing difficult
- genitals
- stomach and intestines

How Orladeyo works

In hereditary angioedema your blood does not have enough of a protein called C1 inhibitor, or the protein does not work properly. This leads to too much of the enzyme plasma kallikrein, which in turn increases the levels of bradykinin in your bloodstream. Too much bradykinin leads to symptoms of hereditary angioedema. Berotralstat, the active substance in Orladeyo, blocks the activity of plasma kallikrein and so reduces bradykinin. This prevents the swelling and pain that hereditary angioedema can cause.

2. What you need to know before you take Orladeyo

Do not take Orladeyo

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Orladeyo if you:

- have moderate or severely reduced liver function which can increase blood levels of berotralstat
- have severely reduced kidney function
- are at risk for a certain heartbeat abnormality, known as QT prolongation

Treat a hereditary angioedema attack with your regular rescue medicine without taking additional doses of Orladeyo. It is not known if Orladeyo works for immediate treatment of attacks of hereditary angioedema.

Children and adolescents

Orladeyo is not recommended in children under 12 years. This is because it has not been studied in this age group.

Orladeyo has not been studied in adolescents weighing less than 40 kg.

Other medicines and Orladeyo

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

Particularly, tell your doctor before taking Orladeyo if you are using:

- thioridazine or pimozide, medicines to treat mental disorders
- amlodipine, a medicine to treat high blood pressure or a type of chest pain called angina
- ciclosporin, a medicine to suppress the immune system, treat severe skin diseases and severe eye or joint inflammation
- dabigatran, a medicine to prevent blood clotting
- rifampicin, a medicine to treat tuberculosis or certain other infections
- desipramine, citalopram, escitalopram, St. John's wort and other medicines to treat depression called tricyclic antidepressants such as amitriptyline
- dextromethorphan, a cough-relieving medicine
- digoxin, a medicine to treat heart problems and irregular heartbeat
- fentanyl, a strong painkiller
- midazolam, a medicine to treat sleeping disorders and for anaesthesia
- tolbutamide, a medicine to reduce blood sugar
- ondansetron, a medicine to prevent and treat nausea and vomiting
- oral contraceptives, medicines used for birth control

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 or pharmacist for advice before taking this medicine.

There is limited information on the use of Orladeyo during pregnancy and breast-feeding. As a precaution, it is preferable to avoid the use of Orladeyo during pregnancy and breast-feeding. Your doctor will discuss with you the risks and benefits of taking this medicine.

Women of childbearing potential must use effective contraception during treatment and for at least 1 month following the last dose. Orladeyo is not recommended in women of childbearing potential not using contraception.

Driving and using machines

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

3. How to take Orladeyo

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

The recommended dose for adults and adolescents from 12 years weighing ≥ 40 kg is one capsule once daily.

Orladeyo is not recommended in patients with moderate or severely reduced liver function.

If your kidney function is severely reduced, treatment with Orladeyo should be avoided. However, if your doctor considers that treatment with Orladeyo is needed, then additional monitoring, including monitoring of your heart rhythm with tests such as an electrocardiogram (ECG, a test of the heart's electrical activity), may be required. If you are on dialysis due to kidney disease, treatment with Orladeyo should be avoided.

Method of administration

Take the capsule with food and one glass of water at the same time each day. This can be at any time of the day.

If you take more Orladeyo than you should

Contact your doctor immediately if this occurs.

If you forget to take Orladeyo

Do not take a double dose to make up for a forgotten capsule. Take a missed dose as soon as you remember; however, do not take more than one dose per day.

If you stop taking Orladeyo

It is important to **take** this medicine on a regular basis and for **as long as your doctor prescribes it**. Do not stop taking it without approval from your doctor.

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

4. Possible side effects

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

Side effects can occur with the following frequencies:

Very common, may affect more than 1 in 10 people

- headache
- stomach pain, including abdominal (belly) discomfort, abdominal tenderness
- diarrhoea and frequent bowel movements

Common, may affect up to 1 in 10 people

- vomiting
- heartburn
- wind
- blood tests showing increased levels of liver enzymes called ALT and AST
- rash

Not known, frequency cannot be established from the available data

- nausea (feeling sick)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 Orladeyo

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 carton and blister 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 Orladeyo contains

- The active substance is berotralstat. Each capsule contains 150 mg berotralstat (as dihydrochloride).
- The other ingredients are:
 - starch, pregelatinised, crospovidone (type A), silica, colloidal anhydrous, magnesium stearate, gelatin, titanium dioxide (E 171)
 - colourants: indigo carmine (E 132), black iron oxide (E 172), red iron oxide (E 172)
 - edible printing ink: black iron oxide (E 172), potassium hydroxide, shellac, propylene glycol (E 1520)

What Orladeyo looks like and contents of the pack

Orladeyo capsules have a white opaque body imprinted with “150” and light blue opaque cap imprinted with “BCX” (19.4 mm × 6.9 mm). They are packed in plastic/aluminium blisters in a carton with 7 capsules per blister.

Pack size: 28 hard capsules

Marketing Authorisation Holder and Manufacturer

- **Marketing Authorisation Holder**
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- **Manufacturer**
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