

PACKAGE LEAFLET: INFORMATION FOR THE USER

ORELOX 200mg film coated tablets
Cefpodoxime

Read all of this leaflet carefully before 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 your pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms 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.

In this leaflet:

1. What ORELOX Tablets 200mg are and what they are used for
2. What you need to know before you take ORELOX Tablets 200mg
3. How to take ORELOX Tablets 200mg
4. Possible side effects
5. How to store ORELOX Tablets 200mg
6. Contents of the pack and other information

1. WHAT ORELOX TABLETS ARE AND WHAT THEY ARE USED FOR

ORELOX Tablets are used to inhibit the growth of bacteria causing infections in the body. It belongs to a group of antibiotics called 'cephalosporins'.

The doctor has prescribed ORELOX for one (or more) of the following types of infection:

- Tonsillitis (throat inflammation), only for the 100mg tablets
- Acute sinusitis (nose inflammation)
- Acute exacerbations of chronic bronchitis (chronic pulmonary disease)
- Pneumonia (lung inflammation).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ORELOX TABLETS 200MG

Do not take ORELOX if:

- **you are allergic** to **cefpodoxime** or other cephalosporins or any of the other ingredients of this medicine (listed in section 6)
- you had a **serious** and/or immediate **allergic reaction** to **antibiotics** such as penicillin or beta-lactams.

Talk to your doctor before taking this medicine if the above applies to anyone who must take it. In cases like these, your doctor will not prescribe cefpodoxime.

Warning and precautions

Talk to your doctor or pharmacist before taking ORELOX.

In particular, please inform your doctor if:

- your kidneys do not function properly and/or you are following any type of treatment (like dialysis) for renal insufficiency. In this case, your doctor will prescribe a lower dose of cefpodoxime
- you ever had intestinal inflammation called colitis, or any other serious disease affecting the intestines

- you have to undergo certain blood tests like cross-matching and Coombs test (tests which are generally carried out before blood transfusions), as this medicine may alter the results thereof.
- you have diabetes and must frequently test your urine, as this medicinal may alter results for urine analysis to determine glucose level (like Benedict and Fehling test). Your doctor will recommend other tests to monitor diabetes while taking this medicinal
- skin or mucous disorders occur.
- you have hepatic disorders and must test ASAT, ALAT, alkaline phosphatase and bilirubin levels, as this medicinal may alter the results thereof.

Other medicines and ORELOX

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

This medicinal product can be affected by other medicines that are eliminated by the kidneys. There are various medicines that can cause this, therefore consult your doctor or pharmacist before taking this medicine.

In particular inform your doctor or pharmacist if whoever must take this medicine is taking:

- antacids (used to treat indigestion)
- medicines for treating ulcers, such as ranitidine or cimetidine
- diuretics (used to increase the flow of your urine)
- aminoglycoside antibiotics used to treat infections
- probenecid (used for the treatment of gout)
- anticoagulants such as warfarin.

Take antacids and medicines for ulcers (such as ranitidine or cimetidine) 2-3 hours after ORELOX Tablets. Your doctor knows these medicines and will change the treatment whenever he deems necessary.

Medical tests

If whoever is taking the medicine requires any medical tests (such as blood, urine tests or diagnoses) while taking this medicine, please inform your doctor, as this medicine may alter the test results (see paragraph “Warnings and precautions”).

ORELOX Tablets with food and drink

Always take this medicine with meals (see section 3 “How to take ORELOX Tablets”).

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.

Your doctor will evaluate the benefit of treatment with ORELOX, with regards to the risk to your baby.

You can take this medicine if you are breastfeeding. If the baby suffers from diarrhoea or mucous infections, please inform your doctor.

Driving and using machinery

You may feel dizziness or suffer from convulsions, confusion, altered consciousness, movement disorders (symptoms of a disorder called encephalopathy) during treatment with cefpodoxime. These effects may compromise your ability to drive (including bicycles) or use machinery. If these effects occur, do not drive or use any machinery.

Orelox Tablets contain lactose (milk sugar)

Please contact your doctor before taking this medicine if he/she has diagnosed any sugar intolerance.

3. HOW TO TAKE ORELOX TABLETS

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

Adults, adolescents (over 12 years) and elderly

The actual recommended dose is:

- in case of *tonsillitis*: 100mg (one 100mg tablet) twice a day
- in case of *acute sinusitis*: 200mg (one 200mg tablet or two 100mg tablets) twice a day
- in case of *acute exacerbations of chronic bronchitis* and *pneumonia*: 200mg (one 200mg tablet or two 100mg tablets) twice a day

A specific cefpodoxime-based preparation for babies and children is available on the market.

Adults, adolescents and elderly with renal problems

Due to the seriousness of the renal problem, you may need to take cefpodoxime less frequently, for example once daily or even every two days. Your doctor will decide the necessary dose for you.

If you are undergoing dialysis you may have to take a dose of this medicine after every dialysis session. Your doctor will tell you the dose to be taken every time.

How to take ORELOX

It is important to take the medicine at the same time every day. You must always take this medicine with food.

If you take more ORELOX than you should

If you accidentally have too much of this medicine, contact your doctor or pharmacist straight away, who will advise you on what to do.

If you forget to take ORELOX Tablets

If a dose is missed at the set time, take as soon as possible. However if it is time for a successive dose skip the missed dose. Do not take a double dose to make up for a forgotten tablet. Take the successive dose at the right time and continue the treatment as usual.

If you stop taking ORELOX Tablets

Continue taking your medicine unless your doctor advises you to stop. You should not stop taking Orelox Tablets just because you start feeling better. If you stop treatment the condition may come back or get worse again.

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. The side effects are listed according to frequency.

STOP taking this medicine **immediately** and **CONTACT your doctor or visit the nearest hospital emergency department** if one of the following, possibly **serious**, side effects occur:

- **Serious allergic reaction.** The signs may include: **a rash and itchiness, swelling** of your face or lips which causes **breathing difficulties**.
- **Blistering skin rash** with small signs (central dark stain surrounded by a paler area, with a darker circle around the border).
- **Widespread severe blistering rash** where **layers of the skin may peel off** (these could be a sign of *Stevens-Johnson syndrome* or *toxic epidermal necrolysis*).
- **Severediarrhoea or blood in diarrhoea** (these may be a sign of pseudomembranous colitis or *Clostridium difficile* colitis).

Please contact your doctor if one of the following side effects occur in you or your child:

Very common side effects (affecting over 1 in 10 persons)

- Headache
- Stomach ache, diarrhoea

Common side effects (affecting less than 1 in 10 persons)

- Dizziness
- Ringing in the ears
- Stomach swelling, nausea, vomiting, flatulence
- Loss of appetite
- Changes in blood tests that measure liver function (increase in aspartate aminotransferase (ASAT), alanine aminotransferase (ALAT), alkaline phosphatase (PAL))
- Skin rash, urticaria, itchiness

Uncommon side effects (affecting less than 1 in 100 persons)

- Other skin and mucous allergic reactions
- tingling and numbness (paraesthesia)
- Feeling tired or weak (asthenia)
- Decrease in certain types of white blood cells (neutropenia)
- Intestinal infection (enterocolitis)
- Anaphylactic reactions, bronchospasm
- Mucocutaneous hypersensitive reactions

Rare side effects (affecting less than 1 in 1000 persons)

- Changes in blood tests that measure liver function (increase in bilirubin)
- Anaemia (reduction in haemoglobin, which carries oxygen through the bloodstream)
- Reduction in certain types of white blood cells (leukopenia)
- Increase in certain types of white blood cells (eosinophilia)
- An increase (thrombocytosis) or reduction (thrombocytopenia) in a number of small cells (platelets) that are necessary for blood coagulation.

Very rare side-effects (affecting less than 1 in 10,000 persons)

- Oedema in the face and extremities (angioneurotic edema)
- Increase in creatinine and urea levels in the blood
- Liver damage
- A type of anaemia that can be serious and caused by breakdown of red blood cells (hemolytic anaemia)
- Blistering skin rash with small signs (central dark stain surrounded by a paler area, with a darker circle around the border) (erythema multiforme)
- Widespread severe blistering rash where layers of the skin may peel off (these could be a sign of Stevens-Johnson syndrome or toxic epidermal necrolysis).

Side effects of unknown frequency (frequency cannot be estimated from the available data)

- Decrease in a type of white blood cells (agranulocytosis)
- Presence of blood in faeces (hematochezia)
- Serious intestinal inflammation (pseudomembranous colitis, *Clostridium difficile* colitis)
- Renal function disorders
- Liver damage with accumulated bile components in the liver (obstructive liver damage)
- Red-violet skin spots caused by inflamed blood vessel walls (purpura)
- Skin blistering (bullous dermatitis)
- A cycle of administration of cefpodoxime may temporarily increase the risk to get an infection caused by other types of germs (superinfections)
- Serious allergic reactions (anaphylactic shock)

- Encephalopathy (which may include convulsions, confusion, altered consciousness, movement disorders). Beta-lactam antibiotics, including cefpodoxime, increase the risk of encephalopathy, particularly in case of overdosage or decrease in renal function.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.medicinesauthority.gov.mt/adrportal

5. HOW TO STORE ORELOX TABLETS

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 after Exp. The expiry date refers to the last day of that month.

This medicine does not require any specific method of conservation.

Do not use this medicine if you notice any sign of deterioration.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What ORELOX Tablets contain

- The other ingredients are: magnesium stearate, carboxymethylcellulose calcium, hydroxypropylcellulose, sodium lauryl sulphate, **lactose**, titanium dioxide, talc, hypermellose.

ORELOX 200mg film-coated tablets

- Each tablet contains: active substance: 260.90 mg of cefpodoxime proxetil (equivalent to 200mg Cefpodoxime)
- the other ingredients are: magnesium stearate, carboxymethylcellulose calcium, hydroxypropylcellulose, sodium lauryl sulphate, **lactose**, titanium dioxide, talc, hypermellose.

What ORELOX Tablets looks like and contents of the pack

ORELOX 200mg film-coated tablets

ORELOX 200mg tablets coated in an off-white film.

The pack contains 6 tablets packaged in thermoformed aluminium/PVC blister packs.

Marketing Authorisation Holder and Manufacturer

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Manufacturer

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Medical information

Antibiotics are used to treat bacterial infections. They are ineffective against viral infections.

If your doctor has prescribed antibiotics you need them for that particular infection. Notwithstanding the administration of antibiotics, some bacteria may survive and grow. This phenomenon is called resistance: some antibiotics become inefficacious.

Improper antibiotic use increases resistance. You may even help the bacteria become more resistant and so slow down the cure or reduce the effectiveness of the antibiotics if you do not respect the following:

- Dosage
- Timing
- Duration of treatment.

Therefore, to safeguard the efficacy of this medicinal:

- 1 - Only use antibiotics with a prescription.
- 2 - Follow the prescription with great care.
- 3 - Do not retake the antibiotic without a medical prescription, even to cure a similar illness.
- 4 - Never give your antibiotic to another person; it may not be adapted for his illness.
- 5 - After finishing the treatment, return all unused medicines to the pharmacy to make sure they are disposed of in a correct manner.