PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ORELOX® 100 film-coated tablets

ORELOX® 200 film-coated tablets

ORELOX® JUNIOR 40 mg/5 mL granules for oral suspension

Cefpodoxime proxetil

ORELOX 100: Contains sugar (lactose monohydrate): 21,55 mg.

ORELOX 200: Contains sugar (lactose monohydrate): 43,10 mg.

ORELOX JUNIOR: Contains sugar. Lactose monohydrate 14,56 mg/5 mL and sucrose 601,33 mg/5 mL.

Read all of this leaflet carefully before you start taking ORELOX

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- ORELOX has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ORELOX is and what it is used for

In adults:

ORELOX 100 and ORELOX 200 tablets are used to treat infections of the nose, throat, sinuses, chest and lungs caused by bacteria. You can take it for infections such as bronchitis, sinusitis, tonsillitis, pharyngitis, or pneumonia.

In children:

ORELOX JUNIOR is used for the treatment of bacterial infections of the ear, throat and lungs such as otitis media, tonsillitis, pharyngitis and pneumonia.

2. What you need to know before you take ORELOX

Do not take/give ORELOX if:

- You have ever had a bad reaction or been allergic (developed a severe skin rash or skin peeling, blistering and/or mouth sores) to any antibiotics including other cephalosporins and penicillins.
- You are pregnant or are breastfeeding your baby.
- You or your child have phenylketonuria (an inherited defect of protein metabolism) as ORELOX JUNIOR contains a source of phenylalanine (a protein) in the form of aspartame.
- Your child is under 1 year old (ORELOX JUNIOR).

Warnings and precautions:

Tell your doctor if:

- You are allergic (hypersensitive) to any ingredients of ORELOX, or other antibiotics including cephalosporins and penicillins. Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of the lips, face, throat and tongue.
- You are pregnant or trying to become pregnant.
- You have ever had colitis.

- You suffer from any kidney problems.
- You have been told by your doctor that you have an intolerance to some sugars, especially lactose or sucrose, contact your doctor before taking ORELOX (see Important information about some of the ingredients of ORELOX).
- You develop diarrhoea, particularly if severe and/or persistent, occurring during treatment or in the initial weeks following treatment with ORELOX. This may be signs of a serious disease called pseudomembranous colitis (an inflammatory disease affecting the colon, caused by the bacterium, *Clostridium difficile*).
- ORELOX can cause encephalopathy, which can lead to seizures, confusion, consciousness disorders, or even abnormal movements, particularly if you have an overdose or renal impairment. If these problems occur, consult your doctor or pharmacist immediately (see sections 3 and 4).
- Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP) have been reported in association with cefpodoxime treatment. Stop using ORELOX and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

You MUST tell your doctor before taking ORELOX if any of the above apply to you.

Other medicines and ORELOX:

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

This is because some medicines, such as antacids used to treat indigestion; anti-ulcer treatments such as ranitidine or cimetidine; probenecid; warfarin; oestrogens e.g. the contraceptive pill, may interfere with ORELOX. Antacids and anti-ulcer treatments should be taken 2 - 3 hours after ORELOX.

Please ensure that your doctor knows that you are taking ORELOX if you are required to take any tests (blood, urine or diagnostic), as ORELOX may interfere with the test results.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or healthcare professional for advice before taking ORELOX.

Safety in pregnant women has not been established (see section 2).

Talk to your doctor before taking ORELOX if you are pregnant, might become pregnant or think you may be pregnant.

You should either not breastfeed or not take ORELOX if you are a mother who is breastfeeding your baby. This is because small amounts of ORELOX may pass into mothers' milk. This can be harmful to your baby.

Driving and using machines:

Care should be taken if you are going to drive or perform skilled tasks as you may experience dizziness or encephalopathy (which can lead to seizures, confusion, consciousness disorders or abnormal movements) whilst taking ORELOX.

ORELOX contains aspartame, lactose and sucrose:

Aspartame:

ORELOX JUNIOR must not be given to children with phenylketonuria (an inherited defect of protein metabolism) since the formulation contains a source of phenylalanine (a protein) in the form of aspartame (see BEFORE TAKING ORELOX).

Lactose/sucrose:

Lactose and sucrose are types of sugars. ORELOX 100 and ORELOX 200 tablets contain lactose and ORELOX JUNIOR contain lactose and sucrose.

If you have been told by your doctor that you or your child cannot tolerate or digest some sugars, talk to your doctor before taking/giving ORELOX.

3. How to take/give ORELOX

Do not share medicines prescribed for you with any other person.

Always take/give ORELOX exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Adults and older children:

ORELOX 100 and ORELOX 200:

Infections of the nose/throat: 100 mg twice daily. Infection of the sinuses: 200 mg twice daily.

Infections of the chest and lungs: 100 mg to 200 mg twice daily. Your doctor will advise you of the correct dose for you.

It is important that you take your medicine at the right times of the day. You should always take the tablets with food because food helps the tablets to work.

Younger children and infants:

ORELOX JUNIOR:

It is important that the directions given by the patient's doctor about when to take ORELOX JUNIOR are followed. Usually this will be twice a day (morning and evening), taken with food. The amount of medicine to be taken depends on the weight and age of the child to be treated. Carefully read the pharmacist's label. Ask your pharmacist if you are unsure of the prescribed dose. ORELOX JUNIOR should be taken for the prescribed number of days. The pharmacist will usually give you the exact amount of medicine.

SHAKE THE BOTTLE BEFORE USE.

- Your doctor will tell you how long your or your child's treatment with ORELOX will last.
- Remember: keep taking/giving ORELOX until your doctor has told you to stop.
- Do not stop taking/giving it just because you or your child feel better.
- If you or your child stop taking ORELOX, your or your child's condition may reoccur or get worse.
- If you or your child have the impression that the effect of ORELOX is too strong or too weak, tell your

doctor or pharmacist.

If you take/give more ORELOX than you should:

If you have/give too much of ORELOX, talk to your doctor straight away. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take/missed a dose of ORELOX:

If you do forget to take a dose of ORELOX at the correct time, do not take twice the dose next time. Take the next dose at the correct time. Carry on as before.

If you stop taking/giving ORELOX:

Do not stop taking ORELOX without talking to your doctor. You should not stop taking ORELOX just because you feel better. This is because the infection may come back or get worse.

4. Possible side effects

ORELOX can have side effects.

Not all side effects reported for ORELOX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving ORELOX, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking ORELOX and tell your doctor immediately or go to the casualty department at your nearest hospital:

- you have an allergic reaction. The signs may include: a rash, joint pain, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- blistering or bleeding of the skin around the lips, eyes, mouth, nose and genitals. Also flu-like symptoms and fever. This may be a severe skin allergy, called Stevens-Johnson syndrome
- severe blistering rash where layers of the skin may peel off to leave large areas of raw exposed skin over

the body. Also, a feeling of being generally unwell, fever, chills and aching muscles. This may be something called toxic epidermal necrolysis

- widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome)
- a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis)
- you have a skin rash or skin lesions with a pink/red ring and a pale centre which may be itchy, scaly or filled with fluid. The rash may appear especially on the palms or soles of your feet. These could be signs of a serious skin allergy called erythema multiforme
- chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome)
- rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease)
- you get infections more easily than usual. This could be because of a blood disorder. This is more likely if you are taking ORELOX for a long time
- a severe infection of the lining of the bowel, characterised by diarrhoea, fever and abdominal pain. This may be something called pseudomembranous colitis
- yellowing of the skin, eyes or mouth and feeling tired. You may also be more pale than normal. This could be because of a serious type of anaemia.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ORELOX. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- superinfection (a second infection which occurs during the course of the existing infection, by other bacteria or organisms resistant to ORELOX), including fungal infections such as oral or vaginal thrush
- severe diarrhoea
- Serious neurological problems known as encephalopathy: seizures, confusion, consciousness disorders or

even abnormal movements, particularly in case of overdose or renal impairment (see sections 2 and 3)

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- nausea (feeling sick) or vomiting (being sick)
- stomach pains
- headaches
- feeling dizzy
- paraesthesia (pins and needles; numbness or tingling feelings)
- tinnitus (ringing in the ears)
- liver problems (fever, itching skin without rash, yellowing of the skin and eyes, feeling generally unwell)
- asthenia (unusual tiredness or weakness)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the MedSafety App (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ORELOX.

5. How to store ORELOX

ORELOX 100 and ORELOX 200:

Store at or below 25 °C (at normal room temperature). Protect from light and moisture.

Do not store in a bathroom.

Do not use your medicine after the expiry date shown on the blister and carton. Keep it in the pack in which it was given to you.

ORELOX JUNIOR:

Store in the refrigerator (between 2 °C – 8 °C).

DO NOT FREEZE.

SHAKE BOTTLE BEFORE USE.

Any liquid remaining after 10 days should be discarded.

Only give ORELOX JUNIOR to the patient that the doctor prescribed it for.

Returned all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What ORELOX contains:

ORELOX 100:

The active substance is cefpodoxime proxetil.

The other ingredients are: Carboxymethylcellulose calcium, hydroxypropylcellulose, lactose monohydrate, magnesium stearate, sodium lauryl sulfate.

Film-coating: Hydroxypropyl methylcellulose, talc, titanium dioxide.

ORELOX 200:

The active substance is cefpodoxime proxetil.

The other ingredients are: Carboxymethylcellulose calcium, hydroxypropylcellulose, lactose monohydrate, magnesium stearate, sodium lauryl sulfate.

Film-coating: Hydroxypropyl methylcellulose, talc, titanium dioxide.

ORELOX JUNIOR:

The active substance is cefpodoxime proxetil.

The other ingredients are: Anhydrous colloidal silica, aspartame, banana flavour, carboxymethylcellulose calcium, carboxymethylcellulose sodium, citric acid monohydrate, hydroxypropylcellulose, iron oxide yellow, lactose monohydrate, monosodium glutamate, potassium sorbate, sodium chloride, sorbitan trioleate, sucrose and talc.

What ORELOX looks like and contents of the pack:

ORELOX 100:

Biconvex, cylindrical practically white tablets, 9 mm in diameter with "208" and beneath "A" engraved on one side. A broken tablet shows a pale yellow core surrounded by a white film- coating.

The film-coated tablets are available in polyamide/aluminium/polyvinyl chloride/aluminium blister packs, inserted into an outer printed cardboard carton containing 10 tablets (1 strip x 10 tablets).

ORELOX 200:

Biconvex, cylindrical, practically white tablets, 11 mm in diameter with "208" and beneath "C" engraved on one side.

A broken tablet shows a pale yellow core surrounded by a white film-coating.

The film-coated tablets are available in polyamide/aluminium/polyvinyl chloride/aluminium blister packs, inserted into an outer printed cardboard carton containing 10 tablets (1 strip x 10 tablets) or 20 tablets (2 strips x 10 tablets).

ORELOX JUNIOR:

Pale, yellow granules for reconstitution. The reconstituted suspension is pale yellow in colour and has a banana flavour and odour.

ORELOX JUNIOR is packed into a 75 mL or 150 mL type lll amber glass bottle, fitted with a dehydrating internal transparent capsule, stoppered by a pilfer proof ring and child-proof white opaque plastic screw- cap fitted with a white polyethylene plastic joint. The bottle is inserted into an outer printed cardboard carton.

The 75 mL or 150 mL bottles contain granules for reconstitution up to 50 mL or 100 mL of suspension, respectively.

Holder of the certificate of registration:

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NAMIBIA:	**BOTSWANA:**
Scheduling status: NS2	Scheduling status: S2
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Access to the corresponding Professional Information:

An electronic copy of the Professional Information (PI) is available on the Equity website

http://www.equitypharmaceuticals.co.za or http://www.sahpra.org.za.