PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

ORELOX® 100 (tablets)

Cefpodoxime proxetil

ORELOX® 200 (tablets)

Cefpodoxime proxetil

ORELOX® JUNIOR (40 mg/5 ml granules for oral suspension)

Cefpodoxime proxetil

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, ask your doctor or pharmacist.
- 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 ORELOX CONTAINS:

ORELOX 100:

The active ingredient: Each film-coated tablet contains 130,45 mg of an active ingredient called cefpodoxime proxetil (equivalent to 100 mg cefpodoxime).

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

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

Film-coating: Hydroxypropyl methyl-cellulose, talc, titanium dioxide.

ORELOX 200:

The active ingredient: Each film-coated tablet contains 260,90 mg of an active ingredient called cefpodoxime proxetil (equivalent to 200 mg of cefpodoxime).

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

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

Film-coating: Hydroxypropyl methyl-cellulose, talc, titanium dioxide.

ORELOX JUNIOR:

The bottle contains granules which have been diluted with water, by your pharmacist, to form a banana flavour medicine ready for use.

The active ingredient: Each 5 ml spoonful of liquid contains 52,18 mg of the active ingredient cefpodoxime proxetil (equivalent to 40 mg cefpodoxime).

Contains sugar: Lactose monohydrate 14,56 mg/5 ml;

Sucrose 601,33 mg/5 ml.

Contains aspartame: 20 mg/5 ml.

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 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.

BEFORE TAKING ORELOX:

Do not take/give ORELOX if:

- You have ever had a bad reaction, or been allergic 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).

Take special care with ORELOX:

Tell your doctor if:

- You are pregnant or trying to become pregnant.
- You have ever had colitis.
- You suffer from any kidney problems.
- 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 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*).

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

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 BEFORE TAKING ORELOX).
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 machinery:

Care should be taken if you are going to drive or perform skilled tasks as you may experience dizziness whilst taking ORELOX.

Important information about some of the ingredients of ORELOX:

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.

Taking other medicines with ORELOX:

Always tell your healthcare professional if you are taking any other medicines. (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.

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 fo 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 hopsital 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, don't take twice the dose next time. Take the next dose at the correct time. Carry on as before.

Effects when treatment with ORELOX is stopped:

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.

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 taking ORELOX, please consult your doctor, pharmacist or other healthcare professional 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'**
- 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'**
- 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

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.

STORING AND DISPOSING OF 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 presrcibed 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.

PRESENTATION OF ORELOX:

ORELOX 100:

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:

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:

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.

IDENTIFICATION OF ORELOX:

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.

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.

ORELOX JUNIOR:

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

REGISTRATION NUMBERS:

ORELOX 100:	Z/20.1.1/7
ORELOX 200:	A38/20.1.1/0406
ORELOX JUNIOR:	27/20.1.1/0564

THE NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE:

sanofi-aventis south africa (pty) ltd.

2 Bond street

Midrand, 1685

South Africa.

DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

To be allocated.