

Patient Information Leaflet

Orelox[®] 40 mg/5 ml granules for oral suspension

Cefpodoxime proxetil

Read all of this leaflet carefully before you start using 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.

In this leaflet:

1. What Orelox 40 mg/5 ml granules for oral suspension are and what they are used for
2. What you need to know before you use Orelox children and infants 40 mg/5 ml granules for oral suspension
3. How to use Orelox 40mg/5 ml granules for oral suspension
4. Possible side effects
5. How to store Orelox 40 mg/5 ml granules for oral suspension
6. Contents of the pack and other information

1. WHAT ORELOX 40 mg/5 ml GRANULES ARE AND WHAT THEY ARE USED FOR

Pharmacotherapeutic group: Antibacterials for systemic use, ATC code: J01DD13.

(J: Anti-infectives).

This medicine is an antibacterial antibiotic belonging to the beta-lactam group.

This medicine is used in children to treat certain bacterial infections susceptible to this drug.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ORELOX 40mg /5 ml GRANULES

Do not use Orelox 40 mg/5 ml granules for oral suspension:

- In children with a known allergy to cephalosporin antibiotics.
- In children with phenylketonuria (hereditary disease screened for at birth), because this medicine contains aspartame.

Warnings and precautions for use

- Any signs of allergy (skin rash, itching, etc.) during treatment must be reported to your doctor immediately.
- There is a 5-10% possibility of an allergic reaction in patients who are allergic to penicillin.
- Inform your doctor of any allergy or allergic reaction that occurred during treatment with antibiotics belonging to the penicillin group.
- Diarrhea occurring during treatment with antibiotics must not be treated without seeking medical advice.
- As this medicine contains lactose, sorbitol and sucrose, it must not be given to patients with fructose intolerance, galactosemia, glucose and galactose malabsorption syndrome, or lactase or sucrose isomaltase deficiency (rare metabolic diseases).
- It is important that you inform your doctor if the child has kidney disease, as the treatment will need to be adjusted.
- Use of this medicine is not recommended in infants under 15 days old.
- This medicine contains 66.55 mg of sodium per 50 ml bottle and 133.10 mg per 100 ml bottle. This should be taken into account in patients on a strict low-salt diet.
- This medicine contains 2.17 mg of potassium per 5 ml dose of reconstituted suspension. This should be taken into account in patients following a low-potassium diet. Inform your doctor if your child has kidney failure.
- This medicine can trigger a false positive result in certain laboratory tests (urine glucose test, Coombs test).
- As with all medicine belonging to this group of antibiotics (beta-lactam), this medicine can predispose patients to encephalopathy which can be expressed as seizures, confusion, consciousness disorders or even abnormal

movements, particularly in the case of an overdose or impaired renal function. If these symptoms occur, contact your doctor or pharmacist immediately (see sections 3 and 4).

Keep out of the reach of children.

Tell your doctor or pharmacist before using Orelox 40 mg/5 ml granules for oral suspension.

Children

Not applicable.

Other medicines and Orelox 40 mg/5 ml granules for oral suspension.

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

Orelox 40 mg/5 ml granules for oral suspension with food and drink

Not applicable.

Pregnancy and breast-feeding

Not applicable.

Driving and using machines

This medicine can have a significant impact on the ability to drive or use machines as it can cause dizziness or encephalopathy (possibly causing seizures, confusion, consciousness disorders, or abnormal movements) (see sections 3 and 4).

Orelox 40 mg/5 ml granules for oral suspension contain: lactose, sucrose, sodium, aspartame (source of phenylalanine (E951), potassium, sorbitol.

3. HOW TO USE ORELOX 40 mg/5 ml GRANULES FOR ORAL SUSPENSION

Dosage

Dosage in children depends on age and weight.

As an indication, the usual dose in children is 8 mg/kg/day, without exceeding the adult dose (i.e. 200 mg/day for sore throat and 400 mg/day for all other indications), to be taken as 2 divided doses, at 12 hour intervals.

The amount per dose is indicated on the plunger of the oral syringe by graduation marks corresponding to the child's weight in kg (graduation marks from 5 to 25 kg). Therefore, the amount per dose can be read directly and the graduation mark indicates the amount for one dose.

The amount for one dose is therefore obtained by pulling the plunger to the graduation mark corresponding to the child's weight (the dose can be read on the neck of the syringe).

Two doses are required per day.

For example, the graduation mark 12 kg indicates the amount to be given per dose for a child weighing 12kg, twice daily.

Your doctor will adjust the dose in children with kidney disease

Method and route of administration

This medicine is administered orally with a syringe graduated in kg corresponding to the child's weight (the graduation marks can be read directly on the syringe).

The medicine must be given during meals.

Before using the medicine:

- Press down to unscrew the bottle.



- Remove the dehydrating capsule, which protects the granules from moisture, by pulling on the two small tear tabs, then discard.



- Fill with water half way to the gauge mark.
- Shake well.
- Fill up to the gauge mark with water, and shake well again until thoroughly mixed



- Then, shake the suspension well before each use.
- Once mixed with the water, **use the oral syringe contained in the pack** to obtain the necessary amount of solution in the bottle.

How to use the oral syringe

It is important to use the oral syringe provided in the pack, to administer the correct dose to your child. The oral syringe must not be re-used for another medicine because the graduation marks on the oral syringe are specifically for this drug.

The amount per dose is indicated on the plunger of the oral syringe by graduation marks in kg (graduation marks from 5 to 25 kg).

The amount per dose corresponds to the child's weight.

The amount for one dose is therefore obtained by pulling the plunger to the graduation mark corresponding to the child's weight. The dose can be read on the neck of the syringe.

For example, the graduation mark 12 kg corresponds to the amount to be given per dose for a child weighing 12 kg, twice daily (two daily doses are required).

Close the bottle carefully after each use. Rinse the oral syringe well and dry after each use.

Frequency of administration

Two doses per day, during meals.

Duration of treatment

In order to work properly, this medicine must be used regularly at the prescribed doses and for as long as your doctor has advised.

If fever or other symptoms disappear, this does not mean that you have completely recovered.

Any feeling of tiredness is not caused by the antibiotic treatment but by the infection itself. Reducing or stopping your treatment would have no effect on this feeling and would delay recovery.

Special case: the duration of treatment for some types of sore throat is 5 days.

If you use more Orelox 40 mg/5 ml granules for oral suspension than you should

As with all medicines belonging to this group of antibiotics (beta-lactam), administration of this medicine can predispose patients to encephalopathy which can cause seizures, confusion, consciousness disorders or even abnormal movements, particularly in the case of an overdose or impaired renal function. If these symptoms occur, contact your doctor or pharmacist immediately (see sections 2 and 4).

If you forget to take Orelox 40 mg/5 ml granules for oral suspension

Not applicable.

If you stop taking Orelox 40 mg/5 ml granules for oral suspension

Not applicable.

4. POSSIBLE SIDE EFFECTS

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

Main side effects:

- Diarrhea, vomiting, stomach pain.
- Widespread skin rash, angioedema (sudden swelling of the face and neck caused by an allergic reaction).

Rarer side effects:

- Digestive symptoms: as with other broad-spectrum antibiotics, rare cases of enterocolitis (inflammation of the intestines) with bloody diarrhea have been reported, as well as rare cases of pseudomembranous colitis (a disease of the large intestine characterized by the passing of false membranes or mucus, constipation and stomach pains).
- Moderate increase in liver enzyme concentrations.
- Allergic effects: skin rash, itching, hives and allergic shock.
- Skin disorders: various types of rash, localized bullous rash, erythema multiforme (disease involving

reddening of the skin), Stevens-Johnson syndrome and toxic epidermal necrolysis (peeling of the skin, which can rapidly spread to the whole of the body and be very serious).

- Headache.
- Dizziness.
- Serious neurological disorders called encephalopathy, causing seizures, confusion, consciousness disorders, or even abnormal movements, particularly in the case of an overdose or impaired renal function (see sections 2 and 3).
- Moderate increase in blood creatinine.
- Effects on blood cells: decreased hemoglobin, decreased platelet count, decreased or increased number of white blood cells, considerable but extremely rare decrease in the number of certain white blood cells (granulocytes).

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 via ADR www.medicinesauthority.gov.mt/adrportal.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE ORELOX 40 mg/5 ml GRANULES FOR ORAL SUSPENSION

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

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

Store below 25°C.

Before opening the bottle for the first time:

- Store below 25°C.
- Do not use Orelox after the expiry date stated on the box. The expiry date refers to the last day of that month. After opening the bottle for the first time:
- Store in a refrigerator between 2°C and 8°C. The suspension may be stored for 10 days.

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 Orelox 40 mg/5 ml granules for oral suspension contain:

- The active ingredient is:

Cefpodoxime proxétel 6.261 g

Equivalent to cefpodoxime 4.800 g

For 100 g of granules.

8.35 g of granules is equivalent to 50 ml of reconstituted suspension, i.e. 100 graduated doses.

16.7 g of granules is equivalent to 100 ml of reconstituted suspension, i.e. 200 graduated doses.

- The other ingredients are:

Carmellose calcium, sodium chloride, sodium glutamate, aspartame, yellow iron oxide, carmellose sodium, sucrose, citric acid monohydrate, hydroxypropylcellulose, sorbitane trioleate, talc, colloidal anhydrous silica, banana flavor (isoamyle acetate, isoamyle isovalerate, ethyle butyrate, geranyle formate, acetaldehyde, citral, nonyl aldehyde, orange oil, vegetable gum, sorbitol, maltodextrin), potassium sorbate, lactose monohydrate.

What Orelox 40 mg/5 ml granules for oral suspension look like and contents of the pack

Orelox Enfants et Nourrissons is supplied as granules for oral suspension. Each box contains a 50 ml or 100ml bottle and an oral syringe graduated in kg corresponding the child's weight bearing the word "Cefpodoxime".

Marketing Authorization Holder

Sanofi S.r.L

V.le L. Bodio 37/b, 20158

Milan (Italy)

Manufacturer

Opella Healthcare

International SAS

56, Route de Choisy,

60200, Compiègne,

France

Names of the medicinal product in the Member States of the European Economic Area

Not applicable.

This leaflet was last revised in: July 2021.

Other information

Detailed information about this medicine is available on the website of the French Medicines Agency (ANSM).

HEALTH INFORMATION AND ADVICE

WHAT YOU SHOULD KNOW ABOUT ANTIBIOTICS

Antibiotics are effective in fighting infections caused by bacteria. They are not effective against infections caused by a virus.

Your doctor has therefore chosen to prescribe this antibiotic for you because it is specifically suitable for you and for the disease you have.

Bacteria are able to survive or to reproduce despite the effect of antibiotics. This is known as resistance: and makes some antibiotic treatments ineffective.

If you use too many antibiotics or use them carelessly, resistance can increase.

Failure to observe the prescription concerning the following points can accelerate the growth of resistant bacteria, slow down your recovery, or even make the medicine ineffective:

- Applied dose,
- Dosing times,
- And duration of treatment.

Therefore, to maintain the efficacy of this medicine:

1- Only use an antibiotic if your doctor has prescribed it to you.

2- Comply strictly with your prescription.

3- Do not reuse an antibiotic without a medical prescription even if you think you have the same disease.

4- Never give your antibiotic to someone else – it may not be appropriate for their disease.

5- Once your treatment is over, take all the open boxes to the pharmacist who will dispose of them properly