

	Version N°	1	Type Article	Notice triple	N° version Logo/Name	SCV A2-20.06.2007	
crée le par modifié le par	05/02/2009 JY Prigent	Nom du produit Référence article Dosage Quantité	Orelox R764020 50 ml / 100 ml Poudre pédiatrique	N° version Country Ex. N° plan Dimensionnel N° plan positionnement Dimensions Taille mini caractères	JS A2-02.12.2003 1-606094a 606094-1a 180 x 210 mm 8 pts	Code sécurité R764020	
Laboratoires Pays	Sanofi-Aventis Export		Couleur Nbre/Réf.	1	Bleu Reflex Blue	Numéro de Pages 3 - 4	

ORELOX 40 mg / 5 ml

Children and infants
cefepodoxime

Granules for oral suspension

sanofi aventis

What Orelox 40 mg/5 ml, granules for oral suspension are

Composition
Cefepodoxime proxetil.....10.43 mg/ml
Equivalent to..... 8.00 mg/ml
cefepodoxime in the reconstituted suspension.
Excipients: carmellose calcium, sodium chloride, sodium glutamate, aspartame, yellow iron oxide, carmellose sodium, sucrose, citric acid monohydrate, hydroxypropylcellulose, sorbitan trioleate, talc, colloidal anhydrous silica, potassium sorbate, lactose monohydrate, banana flavoring.

Pharmaceutical form

Granules for oral suspension containing 40 mg/5 ml.
Bottles of 50 ml (i.e. 100 dose-graduations) or bottles of 100 ml (i.e. 200 dose-graduations) of reconstituted suspension, with a measuring spoon.

Pharmacotherapeutic group

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

Operating company

sanofi-aventis France
1-13, boulevard Romain Rolland
75014 Paris
France

Manufacturer

Sanofi Winthrop Industrie
56, route de Choisy-au-Bac
60205 Compiègne
France

What Orelox 40 mg/5 ml, granules for oral suspension are used for

This medicine is used in children to treat certain bacterial infections caused by sensitive micro-organisms.

Before using Orelox 40 mg/5 ml, granules for oral suspension

Do not use Orelox 40 mg/5 ml in the following situations

This medicine must not be used:
- Allergy to antibiotics in the cephalosporin group,
- Phenylketonuria (hereditary disease screened for at birth) since this medicine contains aspartame.

IF YOU HAVE ANY DOUBTS, IT IS ESSENTIAL THAT YOU ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Take special care with Orelox 40 mg/5 ml

- Any signs of allergy (skin rash, itching, etc.) during treatment must be reported to your doctor immediately.
- Subjects allergic to penicillin may be allergic to this medicine (5% to 10% of cases).

- Inform your doctor of any allergy or allergic symptoms 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 sucrase-isomaltase deficiency (rare metabolic diseases).

Precautions for use

- It is important that you inform the doctor of any kidney disease since treatment will need to be adjusted accordingly.
- Use of this medicine is not recommended in infants aged under 15 days.
- This medicine contains 66.55 mg of sodium per 50 ml bottle and 133.10 mg per 100 ml bottle. This must be taken into account in patients following a strict low-salt diet.
- This medicine contains 2.17 mg of potassium per 5 ml dose of reconstituted suspension. This must be taken into account in patients following a low-potassium diet. Inform the doctor if the patient has kidney failure.
- This medicine may give false-positive results for certain laboratory tests (urine glucose, antiglobulin test).

KEEP OUT OF THE REACH OF CHILDREN.

IF IN DOUBT, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Taking other medicines or other substances

TO AVOID ANY INTERACTION BETWEEN DIFFERENT MEDICINES, YOU MUST ALWAYS INFORM YOUR DOCTOR OR PHARMACIST OF ANY OTHER TREATMENT YOU MAY BE TAKING.

Driving and using machines

If you experience dizziness after taking this medicine, you must not drive or operate machines.

List of excipients that must be taken into account for safe use in some patients

Lactose – Sucrose – Sodium – Aspartame (source of phenylalanine) (E 951) – Potassium – Sorbitol.

How to use Orelox 40 mg/5 ml, granules for oral suspension

How much Orelox 40 mg/5 ml should be given

The dosage depends on the age of the patient.
As an indication, the usual dosage in children is 8 mg per kg body weight and per day, to be taken as 2 divided doses, 12 hours apart.

The amount per dose is indicated on the measuring spoon reservoir, by graduations corresponding to the child's weight in kg (graduated from 5 to 25 kg). The amount per dose is therefore shown directly. Hence, the mark indicates the amount for one dose.

Two doses are required per day.
For example, graduation no. 12 corresponds to the amount to be given per dose for a child weighing 12 kg, twice daily.

Over 25 kg (200 mg/day), the 100 mg tablet can be used.

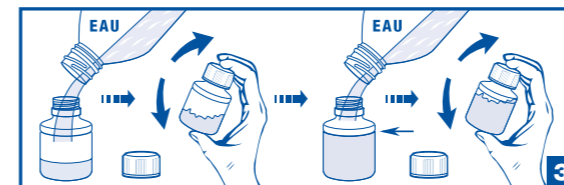
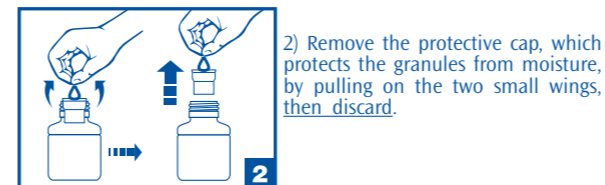
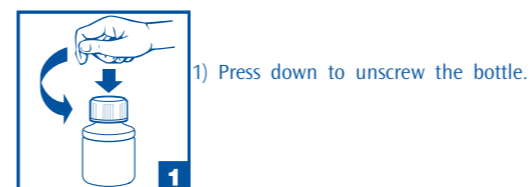
The dosage must be adjusted in patients with kidney failure.

IN ALL CASES, FOLLOW YOUR DOCTOR'S PRESCRIPTION.

How Orelox 40 mg/5 ml should be taken

Oral route.

Read the following instructions carefully before opening the bottle.



3) Fill with water **halfway** to the gauge mark and shake well.
Fill up to the gauge mark with water, and shake again well until thoroughly mixed.

4) Close carefully after use. Shake the suspension before each use. Use the measuring spoon to give this medicine to children.

WARNING: the measuring spoon must not be re-used for another medicine since the marks on the spoon are specifically for this drug.

When and how often Orelox 40 mg/5 ml should be given

This medicine must be taken twice a day during meals.

How long should Orelox 40 mg/5 ml be taken

To be effective, this antibiotic must be taken regularly at the prescribed doses, and for as long as the doctor has advised. If the fever or any other symptom disappears, this does not mean that the patient has completely recovered. Any feeling of tiredness is not caused by the antibiotic treatment but by the infection itself. Reducing or suspending treatment would have no effect on this feeling and would delay recovery.
Special cases: treatment duration for some sore throats is 5 days.

If you use more Orelox 40 mg/5 ml than you should

IMMEDIATELY INFORM YOUR DOCTOR.

Unwanted and unpleasant effects

These mainly include:

- diarrhea, vomiting, stomach pain,
- widespread skin rash, angioedema (sudden allergic swelling in the face and neck).

More rarely:

- digestive effects: as with other broad-spectrum antibiotics, rare cases of enterocolitis (inflammation of the intestine) with bloody diarrhea have been reported, as well as rare cases of pseudomembranous colitis (disease involving the large intestine characterized by the passing of membrane-like materials or thick mucus in the feces, constipation and stomach pain),

- moderately increased liver enzyme levels,
- allergic reactions: skin rash, itching, hives and allergic shock,
- skin effects: various types of rash, localized bullous rash, erythema multiforme (skin disorder appearing as reddening of the skin), Stevens-Johnson syndrome and Lyell's syndrome (detachment of the skin which may rapidly and very seriously spread to the whole body),
- headache,
- dizziness,
- moderately increased blood creatinine levels,
- blood effects: decreased hemoglobin levels, decreased platelets, decreased or increased number of white blood cells, considerable but exceptional decrease in the number of certain white blood cells (granulocytes).

IF YOU NOTICE ANY SIDE EFFECTS NOT MENTIONED IN THIS LEAFLET, PLEASE INFORM YOUR DOCTOR OR PHARMACIST.

Storing Orelox 40 mg/5 ml, granules for oral suspension

DO NOT EXCEED THE EXPIRY DATE INDICATED ON THE OUTER PACKAGING.

Special precautions for storage

This medicine must be stored at a temperature below 25°C. After first opening, the suspension can be stored for 10 days between 2°C to 8°C.

Recommendations/Health education

What you should know about antibiotics

Antibiotics are effective in fighting infections caused by bacteria. They are not effective against those caused by viruses. 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 an antibiotic. This is known as resistance and makes some antibiotic treatments ineffective.

Inappropriate or excessive use of antibiotics increases resistance. You may promote the growth of resistant bacteria and thus slow down your recovery, or even make this medicine ineffective, if you do not comply with the following:

- prescribed dose,
- administration times,
- duration of treatment.

Therefore, for this medicine to be effective:

- 1) **Only use an antibiotic when your doctor has prescribed it for you.**
- 2) **Comply strictly with your prescription.**
- 3) **Do not reuse an antibiotic without a medical prescription even if you think you are fighting an apparently similar disease.**
- 4) **Never give your antibiotic to someone else. It may not be appropriate for their disease.**
- 5) **Once your treatment is completed, bring all opened boxes back to your pharmacist for proper disposal of this medicine.**

THIS LEAFLET WAS LAST REVISED IN

July 2008.

R764020 - NOT ORELOX 50/100ML SWI XE/XD

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This document has been digitally signed by the following people within the VISTAlink system, following the sanofi-aventis group guidelines.

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