HCP-MEPPO
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ORELOX

Sanofi-Aventis

Composition

Tablets of 130.45 mg cefpodoxime proxetil (INN) corresponding to 100 mg cefpodoxime.

Properties

Orelox is a semi-synthetic oral beta-lactam antibiotic belonging to the so-called third generation cephalosporins. It is the prodrug of cefpodoxime.

Following oral administration, cefpodoxime proxetil is absorbed in the intestine and rapidly hydrolyzed by non specific esterases to release cefpodoxime which is a bactericidal antibiotic.

The mechanism of action of cefpodoxime is based on the inhibition of bacterial cell wall synthesis. Cefpodoxime is stable in the presence of numerous beta-lactamases.

Antibacterial activity

Orelox possesses *in vitro* bactericidal activity against numerous Gram-positive and Gram-negative bacteria.

Usually sensitive strains: Gram-positive micro-organisms

Streptococcus pneumoniae: the sensitivity to Orelox depends on the epidemiology and the level of resistance, Streptococcus spp, Propionibacterium acnea, Corynebacterium diphtheriae.

Gram-negative micro-organisms:

Haemophilus influenzae, para-influenzae, beta lactamase and non beta-lactamase producing strains; Branhamella catarrhalis, beta-lactamase and non beta-lactamase producing strains; Escherichia coli, Neisseria meningitidis; Klebsiella pneumoniae, Klebsiella oxytoce; Proteus mirabilis; Proteus vulgaris; Citrobacter diversus; Salmonella spp; Providencia spp; Shigella spp, Pasteurella multocida; Fusobacterium.

Moderately sensitive strains:

Methicillin-susceptible staphylococci, Yersinia enterocolitica, Aeromonas hydrophila.

Resistant strains:

Enterobacter spp, Morganella morganii, Serratia marcescens, Citrobacter freundii, Acinetobacter spp, Peptostreptococcus, Enterococci, Methicillin-resistant staphylococci.

Indications

Respiratory tract infections due to susceptible organisms in adults, i.e.: chronic or recurrent tonsillitis, acute sinusitis, acute bronchitis, bacterial pneumonia, exacerbation of COPD.

Dosage

Orelox should be administered orally with food to enhance absorption

Adults: 2 tablets (200 mg) or 4 tablets (400 mg) per day in 2 doses according to severity (e.g. tonsillitis: 2 tablets daily in 2 doses, acute sinusitis: 4 tablets (400 mg) daily in 2 doses, Low respiratory tract infections: 2 or 4 tablets daily in 2 doses.

Renal impairment: No adjustment necessary if Creatinine Clearance >40 ml/min. Creatinine Clearance = 10 to 39 ml/min: 1 to 2 tablets once daily. Creatinine Clearance <10 ml/min: 1 to 2 tablets every other day. In hemodialysed patients: 1 to 2 tablets after each session.

Contraindications

Hypersensitivity to cephalosporins.

Precautions

Cross-allergy to other betalactams is possible.

Pregnancy: safety of the fetus has not been established.

Lactation: Orelox is excreted in human milk.

Warnings

Hypersensitivity reactions: Prescription of cephalosporins necessitates preliminary enquiry as to an allergic diathesis and particularly hypersensitivity to beta-lactamines. Occurrence of hypersensitivity reaction requires treatment to be stopped.

There is a cross allergy between penicillins and cephalosporins in 5 to 10% of cases. Use of Orelox should be undertaken with extreme care in penicillin-sensitive subjects: careful monitoring of the first administration is mandatory. Hypersensitivity reactions observed with betalactamines may be severe and even fatal.

Pseudomembranous colitis:

Severe or persistent diarrhea has been observed during or following antibiotic therapy. It may be indicative of pseudomembranous colitis, the diagnosis of which is confirmed by coloscopy. This event, rare with cephalosporins, but possibly fatal, requires Orelox to be stopped immediately and appropriate therapy to be started (vancomycin or metronidazole).

Drug interactions

Renal function should be monitored if potentially nephrotoxic drugs (aminoglycosides, diuretics) are co-administered.

The bioavailability is decreased by H2-blockers and antacids and increased by food intake.

Interactions with laboratory tests

Possible positive Coombs test as with other cephalosporins.

Non-enzymatic urine-sugar determinations may give false-positive results.

Side effects

Hypersensitivity reactions (skin reaction, fever, anaphylaxis).

Nausea, vomiting, abdominal pain, diarrhea, pseudomembranous colitis.

Headaches, dizzy sensations.

Thrombocytopenia, neutropenia, leucopenia, eosinophilia. Modifications of liver function tests.

As with all antibiotics, moniliasis can occur.

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ORELOX Infant and Children

Sanofi-Aventis

Presentation

Bottle: 50 ml (100 measured doses) + measuring spoon.

Composition

Each ml of the reconstituted suspension contains 8 mg of cefpodoxime (in the form of cefpodoxime proxetil).

Coloring agent: Iron oxide yellow. Preservative: Potassium sorbate. Sweetening agent: Aspartame (phenylalanine). Flavoring agent: Banana.

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Resistant strains

Enterobacter spp, Morganella morganii, Serratia marcescens, Citrobacter freundii, Acinetobacter spp, Peptostreptococcus, Enterococci, Methicillin-resistant staphylococci, Corynebacteria, groups JK, Listeria monocytogenes, Pseudomonas spp, Clostridium spp, Bacteroides fragilis and related species.

Indications

- Upper respiratory tract infections
- Tonsillitis, sinusitis, otitis media.
- Lower respiratory tract infections: Acute bronchitis, pneumonia.
- Urinary tract infections (UTI): Lower UTI, Upper UTI.
- Skin and soft-tissue infections

Contraindications

This medicine must not be used in the following cases:

Known allergy to antibiotics of the cephalosporin group. Children with phenylketonuria.

Warnings

Any allergic reaction (skin rash, itching, etc..) during treatment must be reported immediately. There is a possibility of allergy (5 to 10% of cases) in patients allergic to penicillin. Caution when history of allergy or allergic reactions which have occured during treatment with antibiotics of the penicillin group.

Because of the need to adapt the treatment, it is important to know the possibility of any kidney disease. This product is not recommended for infants under 15 days old.

Drug interactions
H_2 antagonists and antacids reduce the bioavailability of Orelox. The bioavailability of Orelox is increased if the product is administered during meals (acid pH).

Side effects and precautions
Like all active products, this medicine may cause unpleasant effects of varying degrees in some people: specially diarrhoea, but also abdominal pain, vomiting and skin rash.

Seal carefully after use and keep in the refrigerator. Shake the suspension well each time before use. Do not use after the Expiry Date.

Stability
This product is stable till the end of its expiry date, if stored correctly under the prescribed storage conditions. After opening, the reconstituted suspension must be kept in the refrigerator for not more than 10 days. Do not use after the expiry date.

Storage
The Orelox granules for oral suspension must be stored below 25°C. Keep the medicine out of the reach of children.