

EvoDoxim® (Cefpodoxime)

ایوو ڈوکسیم

COMPOSITION:

EvoDoxim Tablet 100 mg:

Each film coated tablet contains: Cefpodoxime...100mg as Cefpodoxime proxetil USP.

EvoDoxim Granules for Oral Suspension:

Each 5 ml volume of reconstituted suspension contains: Cefpodoxime...40mg as Cefpodoxime proxetil USP.

INDICATIONS:

EvoDoxim is indicated in the treatment of the infections caused by the following microorganisms susceptible to Cefpodoxime.

MICROORGANISM:

- Staphylococcus aureus (including penicillinase-producing strains)
- Staphylococcus saprophyticus
- Streptococcus pneumoniae
- Streptococcus pyogenes
- Escherichia coli
- Haemophilus influenzae (including a-lactamase-producing strains)
- Klebsiella pneumoniae
- Moraxella (Branhamella) catarrhalis
- Neisseria gonorrhoeae (including penicillinase-producing strains)
- Proteus mirabilis

Cefpodoxime is inactive against most strains of Enterococcus, Pseudomonas and Enterobacter.

INFECTIONS:

Respiratory Tract Infections

- recurrent tonsillitis and/or amygdalitis (chronic inflammation of amygdalae), pharyngitis, sinusitis.
- acute purulent bronchitis, bacterial pneumonia (lung affections), exacerbations of chronic obstructive bronchopneumonia (lung and bronchus disease with congestion).

Uncomplicated skin and skin structure infections

Uncomplicated urinary tract infections

DOSAGE AND ADMINISTRATION:

Tablets

EvoDoxim tablets should be administered orally with food to enhance absorption. For dosage follow table below:

Adults and Adolescents (age 12 years and older):

Type of Infection	Total Daily Dose	Dose Frequency	Duration
Pharyngitis and/or tonsillitis	200 mg	100 mg Q 12 hours	5 to 10 days
Acute maxillary sinusitis	400 mg	200 mg Q 12 hours	10 days
Acute community-acquired pneumonia	400 mg	200 mg Q 12 hours	14 days
Acute bacterial exacerbations of chronic bronchitis	400 mg	200 mg Q 12 hours	10 days
Uncomplicated gonorrhoea (men and women) and rectal gonococcal infections (women)	200 mg	single dose	
Uncomplicated urinary tract infection	200 mg	100 mg Q 12 hours	7 days
Skin and skin structure	800 mg	400 mg Q 12 hours	7 to 14 days

Granules for oral suspension:

The average recommended dosage is 8 mg per kg per day to be taken in two divided doses at 12 hours intervals. Beyond 200 mg per day (25kg), the 100 mg tablet may be used. It is recommended to administer the product during a meal.

Patients with Renal Dysfunction:

For patients with severe renal impairment (<30 ml/min creatinine clearance), the dosing intervals should be increased to Q 24 hours. In patients maintained on haemodialysis, the dose frequency should be 3 times/week after haemodialysis.

CONTRAINDICATIONS:

- Known allergy to cephalosporin antibiotics.
- Children with phenylketonuria, since the formulation contains Aspartame.

PRECAUTIONS:

Drug Interactions

Antacids: Concomitant administration of high doses of antacids (sodium bicarbonate and aluminum hydroxide) or H2 blockers reduces peak plasma levels by 24% to 42% and the extent of absorption by 27% to 32%, respectively.

Probenecid: As with other beta-lactam antibiotics, renal excretion of cefpodoxime was inhibited by probenecid and resulted in an approximately 31% increase in AUC and 20% increase in peak cefpodoxime plasma levels.

Drug/Laboratory Test Interactions

Cephalosporins including cefpodoxime proxetil, are known to occasionally induce a positive direct Coombs test.

Carcinogenesis, Mutagenesis

Long-term animal carcinogenesis studies of cefpodoxime proxetil have not been performed. Mutagenesis studies of cefpodoxime were all negative.

Pregnancy-Teratogenic Effects

There are no adequate and well-controlled studies of cefpodoxime proxetil use in pregnant women; this drug should be used during pregnancy only clearly needed.

Labour and Delivery

Cefpodoxime proxetil has not been studied for use during labour and delivery. Treatment should only be given if clearly needed.

Nursing Mothers

Cefpodoxime is excreted in human milk. Because of the potential for serious reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

Safety and efficacy in infants less than 5 months of age have not been established.

WARNINGS:

- The doctor should be immediately notified of the appearance of any allergic manifestation during the treatment (cutaneous eruption, pruritus)
- There is a possible allergy (in 5 to 10% of cases) in subjects sensitive to penicillins.
- Notify your doctor of any allergic symptom or allergy already happened during a previous treatment with penicillin.
- In case of diarrhoea, consult your doctor.

OVERDOSAGE:

In the event of serious toxic reaction from overdosage, hemodialysis or peritoneal dialysis may aid in the removal of cefpodoxime from the body, particularly if renal function is compromised.

ADVERSE REACTIONS:

- Essentially, diarrhoea, nausea, vomiting and abdominal pain.
- As with other broad spectrum antibiotics, there have been rare reports of pseudomembranous colitis (disease of the large intestine characterized by the evacuation of false membranes or mucus, accompanied by constipation and abdominal pain).
 - More rarely:
 - headache
 - allergic symptoms: cutaneous eruption, pruritus, angioneurotic edema (type of urticaria consisting in abrupt fluid infiltration of the face or mucous membrane)
 - hepatobiliary manifestations: slight and transient increase in certain liver enzyme levels (AST, ALT, alkaline phosphatases)
 - renal manifestations: slight increase in serum BUN and creatinine level
 - hematological manifestations: thrombocytosis, thrombocytopenia, leukopenia and hypereosinophilia (abnormal increase or decrease in the number of certain formed elements of the blood).

DIRECTIONS FOR RECONSTITUTION:

To reconstitute, add mineral water, or previously boiled cool water with given measuring cup fully filled with water and shake well to make suspension. Reconstituted suspension can be used within 10 days when stored in a refrigerator.

STORAGE:

Store below 30°C. Protect from light and moisture.

Keep all medicines out of the reach of children.

PRESENTATION:

EvoDoxim Tablet 100mg: Pack of 10 film coated tablets.

EvoDoxim Granules for Oral Suspension: Bottle of 50 ml suspension.

دوا بنانے کا طریقہ:

سپینشن بنانے کے لئے دیئے گئے کپ میں معدنی پانی یا ابال کر ٹھنڈا کیا ہوا پانی بوتل میں ڈالیں اور اچھی طرح ہلایں تاکہ تمام پاؤڈر پانی میں یکساں طور پر ہو جائے۔ تیار شدہ اسپینشن ریفریجریٹر میں رکھنے کی صورت میں 10 ایوم کے اندر استعمال کیا جاسکتا ہے۔

ہدایات:

استعمال سے پہلے بوتل کو اچھی طرح ہلایں۔

ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔

دوا کو روشنی سے محفوظ، ٹھنڈی اور خشک جگہ پر 30 ڈگری

سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔

تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔