

CEFPROZ[®]



SUSPENSION
(cefprozil)

PHARMACEUTICAL PRESENTATIONS:

CEFPROZ 125mg/5ml - Dry powder for oral suspension
CEFPROZ 250mg/5ml - Dry powder for oral suspension

COMPOSITION:

A powder, after reconstitution as directed, each 5 ml contains: cefprozil equivalent to 125mg or 250mg anhydrous cefprozil.

DESCRIPTION:

CEFPROZ is a semi-synthetic broad-spectrum cephalosporin antibiotic. cefprozil is a cis and trans isomeric mixture ($\geq 90\%$ cis). The chemical name for the monohydrate is (6R, 7R)-7- [(R)-2-amino-2-(p-hydroxy-phenyl)acetamido]-8-oxo-3-propenyl-5-thia-1-azabicyclo[4.2.0] oct-2-ene-2- carboxylic acid monohydrate.

MICROBIOLOGY:

Cefprozil has *in vitro* activity against a broad range of gram-positive and gram-negative bacteria. The bactericidal action of cefprozil results from inhibition of cell-wall synthesis.

INDICATIONS AND USAGES:

CEFPROZ is indicated for the treatment of patients with mild to moderate infections caused by susceptible strains of the designated microorganisms in the conditions listed below:

INFECTION

Upper Respiratory Tract
Pharyngitis / Tonsillitis
Otitis Media

CAUSED BY

Streptococcus pyogenes
Streptococcus pneumoniae
Haemophilus influenzae (including β -lactamase-producing strains).
Moraxella (Branhamella)
Catarrhalis (including β -lactamase-producing strains)

Acute Sinusitis

Streptococcus pneumoniae
Haemophilus influenzae β -lactamase producing strains)
Moraxella (Branhamella)
Catarrhalis (including β -lactamase-producing strains)

Lower Respiratory Tract

Secondary bacterial infection of acute bacterial exacerbation of chronic bronchitis.

Streptococcus pneumoniae
Haemophilus (including β -lactamase producing strains).
Moraxella (Branhamella).
Catarrhalis (including β -lactamase-producing strains)

Skin and skin structure

Staphylococcus aureus (including penicillinase-producing strains)
Streptococcus pyogenes.

DOSAGE AND ADMINISTRATION:

Indication	Dosage	Duration (Days)
Children (2 years-12 years)		
Upper Respiratory Tract Pharyngitis / Tonsillitis	7.5 mg/kg for 12 hours	10
Skin and Skin Structure uncomplicated skin and skin structure	20 mg/kg for 24 hours	10

Adults (13 years and older)		
Upper Respiratory Tract Pharyngitis / Tonsillitis Acute sinusitis (for moderate to severe infections, the higher dose should be used)	500mg for 24 hours 250mg for 12 hours or 500mg for 12 hours	10 10
Lower Respiratory Tract Secondary bacterial infection of Acute Bronchitis and Acute Bacterial Exacerbation of Chronic Bronchitis.	500mg for 12 hours	10
Skin and Skin Structure uncomplicated infection	250mg for 12 hours or 500mg for 24 hours or 500mg for 12 hours	10
Infants & Children (6months-12years)		
Upper Respiratory Tract Otitis media Acute sinusitis (for moderate to severe infections, the higher dose should be used)	15mg/kg for 12 hours 7.5mg/kg for 12 hours or 15 mg/kg for 12 hours	10 10

CONTRA-INDICATIONS:

Cefprozil is contraindicated in patients with known allergy to the cephalosporin class of antibiotics.

PRECAUTIONS:

GENERAL

In the absence of proven or strongly suspected bacterial infections or a prophylactic indication is unlike to provide benefits to the patient and increases the risk of the development of drug-resistant bacteria.

In patients with known or suspected renal impairment CEFPROZ should be given with caution to patients receiving concurrent treatment with potent diuretics since these agents are suspected of adversely affecting renal function.

ADVERSE REACTIONS:

Following mild adverse effect may be observed during the treatment.

Gastrointestinal: diarrhea, nausea, vomiting and abdominal pain.

Hypersensitivity: rashes and urticaria.

CNS: dizziness, hyperactivity, headache, nervousness, insomnia confusion and somnolence.

STORAGE CONDITION:

- Store below 25°C.
- Shake well before use.
- Keep out of reach of children.

PACKAGING PRESENTATIONS:

CEFPROZ 125mg/ 5 ml Suspension-50ml amber coloured glass bottle.

CEFPROZ 250mg/5 ml Suspension-50ml amber coloured glass bottle.

THIS IS A MEDICAMENT

Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.

Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists

Mfd. by:
MEDPHARMA
PHARMA.& CHEM. INDS (L.L.C)
SHARJAH-U.A.E.

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