সেফুরেভ প্লাস®

সেফুরক্সিম এবং ক্লাভুলানিক এসিড

COMPOSITION:
Cefurav Plus ® 250 Tablet: Each tablet contains Cefuroxime 250 mg as Cefuroxime Axetil USP and Clavulanic Acid 62.5 mg as Potassium Clavulanate BP.
Cefurav Plus ® 500 Tablet: Each tablet contains Cefuroxime 500 mg as Cefuroxime Axetil USP and Clavulanic Acid 125 mg as Potassium Clavulanate BP.
Cefurav Plus ® Powder for Suspension (70 ml): Each 5 ml reconstituted suspension contains Cefuroxime 125 mg as Cefuroxime Axetil BP and Clavulanic Acid 31.25 mg as Potassium Clavulanate BP.

PHARMACOLOGY:
Cefuroxime is a broad spectrum second generation Cephalosporin active against a wide range of Gram-positive and Gram-negative susceptible organisms including many beta-lactamase producing strains. The bactericidal action of Cefuroxime results from inhibition of cell wall synthesis by binding to essential target proteins. Cefuroxime has good stability to bacterial beta-lactamases. Clavulanic Acid has a similar structure to the beta-lactam antibiotics but binds irreversibly to the beta-lactamase enzymes. The presence of Clavulanic Acid protects Cefuroxime from degradation by beta-lactamese enzymes and effectively extends the antibacterial spectrum of Cefuroxime to include many bacteria normally resistant to Cefuroxime and other Cephalosporins.

INDICATION:
- Pharyngitis/Tonsillitis caused by Streptococcus pyogenes.
- Acute Bacterial Otitis Media caused by Streptococcus pneumoniae, Haemophilus influenzae (including beta-lactamase producing strains), Moraxella catarrhalis (including beta-lactamase producing strains) or Streptococcus pyogenes.
- Acute Bacterial Maxillary Sinusitis caused by Streptococcus pneumoniae or Haemophilus influenzae.
- Acute Bacterial Exacerbations of Chronic Bronchitis and Secondary Bacterial Infections of Acute Bronchitis caused by Streptococcus pneumoniae, Haemo philus influenzae or Haemophilus parainfluenzae.
- Uncomplicated Skin and Skin-Structure Infections caused by Staphylococcus aureus (including beta-lactamase producing strains) ot Streptococcus pyogenes.
- Uncomplicated Urinary Tract Infections caused by Escherichia coli or Klebsiella pneumoniae.
- Uncomplicated Gonorrhea (urethral and endocervical) caused by Neisseria gonorrhoeae and Uncomplicated Gonorrhea, rectal, in females, caused by non-penicillinase producing strains of Neisseria gonorrhoeae.
- Early Lyme disease (erythema migrans) caused by Borrelia burgdorferi.
- Septicemia caused by Staphylococcus aureus, Streptococcus pneumoniae, Escherichi coli, Haemophilus influenzae (including ampicillin-resistant strains) and Klebsiella spp.
- Meningitis caused by Streptococcus pneumoniae, Haemophilus influenzae (including ampicil lin-resistant strains), Neisseria meningitidis and Staphylo coccus aureus (penicillinase and non-penicillinase producing strains).
- Switch therapy (injectable to oral).

DOSE & ADMINISTRATION:
Table : Indication & dosage for Cefurav Plus Tablets.
Adults (13 Years & Older)

Infection	Dosage	Duration(days)
Pharyngitis/Tonsillitis	250 mg b.i.d.	5-10
Acute Bacterial Maxillary Sinusitis	250 mg b.i.d.	10
Acute Bacterial Exacerbations of Chronic Bronchitis	250-500 mg b.i.d.	10
Seconday Bacterial Exacerbations of Chronic Bronchitis	250-500 mg b.i.d.	5-10
Uncomplicated Skin and Skin-Structure Infections	250-500 mg b.i.d.	10
Community Acquired Pneumoniae	250-500 mg b.i.d.	5-10
MDR Typhoid Fever	500 mg b.i.d.	10-14
Uncomplicated Urinary Tract Infections	250mg b.i.d.	7-10
Uncomplicated Gonorrhea	1000 single dose	-
Lyme Disease	500 mg b.i.d.	20

Pediatric Patients (03 months to 12 years, who can swallow tablet whole)

Infection	Dosage	Duration(days)
Acute Otitis Media	250 mg b.i.d.	10
Acute Bacterial Maxillary Sinusitis	250 mg b.i.d.	10

Cefuroxime-Clavulanic Acid tablet may be taken without regard of food.
Table 2: Indication & dosage for Cefurav Plus Suspension.
Pediatric Patients (03 months to 12 years, must be administrated with food shake well each time before using)

Infection	Dosage	Daily Max. Dosage	Duration (days)
Pharyngitis/Tonsillitis	20 mg kg/day divided b.i.d	500 mg	10
Acute Otitis Media	30 mg kg/day divided b.i.d	1,000 mg	10
Acute Bacterial Maxillary Sinusitis	30 mg kg/day divided b.i.d	1,000 mg	10
Impetigo	30 mg kg/day divided b.i.d	1,000 mg	10

DIRECTION FOR RECONSTITUTION: For Suspension: Shake the bottle well before adding water. Then add 35 ml of boiled and cooled water (with the help of the provided cup) to the bottle. Then continue shaking the bottle until the powder Is dissolved properly.
Or as Directed by the Physician.

CONTRA-INDICATION:
Cefuroxime-Clavulanic Acid is contraindicated in patients with known allergy to Cephalosporins & in patients with Pseudomembranous Colitis.

WARNING AND PRECAUTION:
As with other broad-spectrum antibiotics, prolonged administration of Cefuroxime and Clavulanic Acid combination may result in over growth of nonsusceptible microorganisms.

SIDE EFFECTS:
Generally Cefuroxime-Clavulanic Acid is well tolerated. Major adverse reactions which may occur are diarrhea, nausea, vomiting, transient elevation in AST, ALT, IDH and eosinophilia. Other adverse events that may occur are abdominal pain, abdominal cramps, flatulence, indigestion, headache, vaginitis, rash, itching, dysuria, insomnia, thirst, anorexia etc.

USE IN PREGNANCY & LACTATION:
All antibiotics should be avoided in the first trimester if possible. However, Cefurox-ime-Clavulanic Acid can be safely used in later pregnancy to treat Urinary Tract and other infections.
Cefuroxime-Clavulanic acid is excreted into the breast milk in small quantities and consequently caution should be taken when it is administered to a nursing mother.

USE IN CHILDREN & ADOLESCENTS:
No special precautions are necessary. Old age is not an indication for dose adjustment. Cefurav Plus supension may be administered to pediatric patients ranging in age from 3 months to 12 years, according to dosage in table 2.

DRUG INTERACTION:
Concomitant administration of Probenecid with Cefuroxime-Clavulanic Acid increases the area under the serum concentration versus time curve by 50%. Drug that reduces gastric acidity may result in a lower bioavailability of Cefurox-ime and tend to cancel the effect of postprandial absorption.

OVERDOSE: Excessively large doses of all Cephalosporins can cause cerebral irritation and may cause convulsions. This complication is unlikely to occur in routine practice unless the patient is in renal failure. Cefuroxime can be removed by hemodialysis or peritoneal dialysis.

STORAGE:
Cefurav Plus ® Tablet should be stored below 30^0 C and away from direct sunlight.
Cefurav Plus ® Powder for Suspension: Prior to reconstitution, store below 30^0 C. After reconstitution, the suspension may be kept for 14 days under refrigeration $(2\text{-}8)^0$ C or at room temperature maximum 7 days.

PACKING:
Cefurav Plus ® 250 Tablet: Each box contains 2x7's tablets in Alu-Alu blister pack.
Cefurav Plus ® 500 Tablet: Each box contains 2x7's tablets in Alu-Alu blister pack.
Cefurav Plus ® 70 ml PFS: Each bottle containing dry powder to reconstitute 70 ml suspension with 10 ml measuring cup and 5 ml dropper.

Manufactured by
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IST-C001