Cefotil™ Plus

Cefuroxime & Clavulanic Acid

COMPOSITION

Cefotil™ Plus 250 Tablet: Each tablet contains Cefuroxime 250 mg as Cefuroxime Axetil BP 300.70 mg and Clavulanic Acid 62.50 mg as Diluted Potassium Clavulanate BP 125 mg.
Cefotil™ Plus 500 Tablet: Each tablet contains Cefuroxime 500 mg as Cefuroxime Axetil BP 601.40 mg and Clavulanic Acid 125 mg as Diluted Potassium Clavulanate BP 250 mg.
Cefotil™ 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 Diluted 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-lactamase 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, Haemophilus influenzae* or *Haemophilus parainfluenzae.*
- Uncomplicated Skin and Skin-Structure Infections caused by *Staphylococcus aureus* (including beta-lactamase producing strains) or *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, Escherichia coli, Haemophilus influenzae* (including ampicillin-resistant strains) and *Klebsiella* spp.
- Meningitis caused by *Streptococcus pneumoniae, Haemophilus influenzae* (including ampicillin-resistant strains), *Neisseria meningitidis* and *Staphylococcus aureus* (penicillinase and non-penicillinase producing strains).
- Switch therapy (injectable to oral).

DOSAGE & ADMINISTRATION

Adults (13 years and 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
Secondary Bacterial Infections of Acute Bronchitis	250 - 500 mg b.i.d.	5-10
Uncomplicated Skin and Skin-Structure Infections	250 - 500 mg b.i.d.	10
Community Acquired Pneumonia	250 - 500 mg b.i.d.	5-10
MDR Typhoid Fever	500 mg b.i.d.	10-14
Uncomplicated Urinary Tract Infections	250 mg b.i.d.	7-10
Uncomplicated Gonorrhea	1,000 mg 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.

Pediatric Patients (03 months to 12 years): Must be administered with food. Shake well each time before using.

Infection	Dosage	Daily maximum dose	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.

CONTRAINDICATION

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

PRECAUTION

As with other broad-spectrum antibiotics, prolonged administration of Cefuroxime and Clavulanic Acid combination may result in overgrowth of nonsusceptible microorganisms.

SIDE EFFECT

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

USE IN PREGNANCY & LACTATION

All antibiotics should be avoided in the first trimester if possible. However, Cefuroxime-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 exercised when it is administered to a nursing mother.

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 Cefuroxime 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 CONDITION

Tablet: Store below 25° C, protected from light & moisture. Keep out of reach of children.
Suspension: Store below 25° C, protected from light and moisture. After reconstitution, keep the suspension in refrigerator (2° - 8° C) and use within 7 days.

HOW SUPPLIED

Cefotil™ Plus 250 Tablet: Each box contains 12 tablets in blister pack.
Cefotil™ Plus 500 Tablet: Each box contains 12 tablets in blister pack.
Cefotil™ Plus Powder for Suspension (70 ml): Bottle containing dry powder to reconstitute 70 ml suspension.

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
Bangladesh