Clavutil

Cefuroxime + Clavulanic Acid

Composition
Clavutil 250 Tablet: Each film coated tablet contains Cefuroxime Axetil USP equivalent to 250 mg Cefuroxime and diluted Potassium Clavulanate BP equivalent to 62.5 mg Clavulanic Acid.
Clavutil 500 Tablet: Each film coated tablet contains Cefuroxime Axetil USP equivalent to 500 mg Cefuroxime and diluted Potassium Clavulanate BP equivalent to 125 mg Clavulanic Acid.
Clavutil PFS: Each 5 ml suspension contains Cefuroxime Axetil USP equivalent to 125 mg Cefuroxime and diluted Potassium Clavulanate BP equivalent to 31.25 mg Clavulanic Acid.

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 which 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 betalactamase producing strains), Moraxella catarrhalis (including beta-lactamase producing strains) or Streptococcus pyogenes.
- ❒ Acute Bacterial Maxillary Sinusitis caused by Streptococcus pneumoniae or Haemophilus influenza.
- ❒ 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).

Dosage and Administration
Adults (13 years and older)
Cefuroxime-Clavulanic Acid tablet may be taken without regard of food.

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 gm single dose	-
Lyme Disease	500 mg b.i.d.	20

Pediatric Patients (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

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, thirst, anorexia etc.

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

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

Use in Special Group
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.

Overdoasge
Overdosage can cause cerebral irritation leading to convulsions. In this case, serum levels can be reduced by hemodialysis and peritoneal dialysis.

Storage
Tablet: Keep away from light & moisture and store below 30° C temperature.
Powder for Suspension: Keep away from light & moisture and store below 25° C temperature. Reconstituted suspension should be stored in a refrigerator (2-8)° C and used within 7 days. Keep out of reach of children.

Packaging
Clavutil 250 Tablet: Each box contains 2 X 7 tablets in blister pack.
Clavutil 500 Tablet: Each box contains 1 X 7 tablets in blister pack.
Clavutil Powder for Suspension: Each bottle contains Powder for preparation of 70 ml suspension.

Apex™
A Syed Manzur Elahi Enterprise

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