

Cefuroxime & Clavulanic Acid Tablet

Orneontation

SECOCLAV 250: Each film coated tablet contains Cefuroxime 250 mg (as Cefuroxime Axetil BP) with Clavulanic Acid 62.5 mg (as Diluted Potassium Clavulanate BP).

SECOCLAV 500: Each film coated tablet contains Cefuroxime 500 mg (as Cefuroxime Axetil BP) with Clavulanic Acid 125 mg (as Diluted Potassium Clavulanate BP).

Pharmacodynamic properties

Cefuroxime has bactericidal activity against a wide range of common pathogens, including 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 is a naturally derived beta lactamase inhibitor produced by Streptomyces clavuligerus. Clavulanic Acid binds to and inactivates them thus preventing the destruction of cefuroxime that is a substrate for this enzyme. It has poor intrinsic antimicrobial activity, but it is an irreversible binder of \(\text{\mathbb{G}-lactamases} \) produced by a wide range of gram positive and gram negative microorganism.

Pharmacokinetic Properties

After oral administration cefuroxime axetil is absorbed from the gastrointestinal tract & rapidly hydrolyzed in the body to release cefuroxime into the circulation. Approximately 60% of an administered dose is absorbed. Cefuroxime is subsequently distributed throughout the extracellular fluids. Clavulanic Acid is extensively metabolized and eliminated in urine and faeces and as carbon dioxide in expired air. Excretion occurs mainly through the kidney both by glomerular filtration and tubular secretion.

Indications

- · Respiratory tract infections
- Urinary tract infections
- SKin & Skin Structure infections
- · Bone & joint infections
- Septicemia
- Meningitis
- Gonorrhoea

Dosage and Administration

Infections	Dosage	Duration (days)
Adolescents and Adults (13 years and older)		
Pharyngitis/tonsillitis	250 mg b.i.d.	10
Acute bacterial maxillary sinusitis	250 mg b.i.d.	10
Acute bacterial exacerbations of chronic bronchitis	250 or 500 mg b.i.d.	10
Secondary bacterial infections of acute bronchitis	250 or 500 mg b.i.d.	05-10
Community acquired pneumonia	250 or 500 mg b.i.d.	05-10
Uncomplicated skin and skin-structure infections	250 or 500 mg b.i.d.	10
Uncomplicated urinary tract infections	250 mg b.i.d.	07-10
Upper Respiratory Tract Infection	250 or 500 mg b.i.d.	
Uncomplicated gonorrhea	1,000 mg once	
Early Lyme disease	500 mg b.i.d.	20
Pediatric Patients (who can swallow tablets whole)		
Acute otitis media	250 mg b.i.d.	10
Acute bacterial maxillary sinusitis	250 mg b.i.d.	10

Contraindications

Cefuroxime Axetil products are contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

Side Effects

Generally Cefuroxime and Clavulanic Acid are well tolerated. However, a few side effects like nausea, vomiting, diarrhea, abdominal discomfort or pain may occur. As with other broad-spectrum antibiotics, prolonged administration of Cefuroxime and Clavulanic Acid combination may result in overgrowth of nonsusceptible microorganisms. Rarely (<0.2%) renal dysfunction, anaphylaxis, angioedema, pruritis, rash and serum sickness like urticaria may appear.

Precautions

Cefuroxime should be given with care to patients receiving concurrent treatment with potent diuretics & who have history of colitis.

Drug Interactions

Concomitant administration of probenecid with Secoclav increases the area under the serum concentration versus time curve by 50%. Drugs that reduce gastric acidity may result in a lower bioavailability of Cefuroxime.

Pregnancy and Lactation

Pregnancy Category B. it is excreted into the breast milk in small quantities. However, the possibility of sensitizing the infant should be kept in mind.

Over Dose

Overdosage of cephalosporins can cause cerebral irritation leading to convulsions. Serum levels of cefuroxime can be reduced by hemodialysis and peritoneal dialysis.

Storage Conditions

Store in a cool (below 25°C) and dry place, away from light. Keep out of reach of children

Commercial Pack

SECOCLAV 250: Each Box containing 3 Alu-Alu pouch of 4 tablets **SECOCLAV 500:** Each Box containing 2 Alu-Alu pouch of 4 tablets.

Manufactured by

