Cefaclav®

Cefuroxime + Clavulanic Acid

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Presentation
Cefaclav® 125 tablet: Each film coated tablet contains Cefuroxime Axetil USP equivalent to Cefuroxime 125 mg and diluted Potassium Clavulanate BP equivalent to Clavulanic Acid 31.25 mg.
Cefaclav® 250 tablet: Each film coated tablet contains Cefuroxime Axetil USP equivalent to Cefuroxime 250 mg and diluted Potassium Clavulanate BP equivalent to Clavulanic Acid 62.5 mg.
Cefaclav® 500 tablet: Each film coated tablet contains Cefuroxime Axetil USP equivalent to Cefuroxime 500 mg and diluted Potassium Clavulanate BP equivalent to Clavulanic Acid 125 mg.
Cefaclav® 70 ml powder for suspension: After reconstitution each 5 ml suspension contains Cefuroxime Axetil USP equivalent to Cefuroxime 125 mg and diluted Potassium Clavulanate BP equivalent to Clavulanic Acid 31.25 mg.

Description
Cefuroxime is one of the bactericidal second generation cephalosporin antibiotics, which is active against a wide range of Gram-positive and Gram-negative susceptible organisms including many β-lactamase producing strains. It is indicated for the treatment of infections caused by sensitive bacteria.

Clavulanic acid has a similar structure to the beta-lactam antibiotics but binds irreversibly to the beta-lactamase enzymes.

The presence of clavulanic acid in Cefaclav formulations 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.

Indications and Uses
- 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* (non-beta-lactamase-producing strains only)
- Lower respiratory tract infections including pneumoniae, caused by *Streptococcus pneumoniae*, *Haemophilus influenzae* (including beta lactamase-producing strains), *Klebsiella spp.*, *Staphylococcus aureus* (penicillinase- and non-penicillinase-producing strains), *Streptococcus pyogenes*, *Escherichia coli*
- Acute bacterial exacerbations of chronic bronchitis and secondary bacterial infections of acute bronchitis caused by *Streptococcus penumoniae*, *Haemophilus influenzae* (beta-lactamase negative strains) or *Haemophilus parainfluenzae* (beta-lactamase negative strains)
- Skin and Skin-Structure Infections caused by *Staphylococcus aureus* (penicillinase- and non-penicillinase-producing strains), *Streptococcus pyogenes*, *Escherichia coli*, *Klebsiella spp.* and *Enterobacter spp*.
- Urinary tract infections caused by *Escherichia coli* or *Klebsiella pneumoniae*
- Bone and Joint Infections caused by *Staphylococcus aureus* (penicillinase and non-penicillinase producing strains)
- Gonorrhea: Uncomplicated and disseminated gonococcal infections due to *Neisseria gonorrhoeae* (penicillinase- and non-penicillinase-producing strains) in both males and females
- Early Lyme disease (erythema migrans) caused by *Borrelia burgdorferi*
- Septicemia caused by *Staphylococcus aureus* (penicillinase and non-penicillinase producing strains), *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) after surgery when patient's condition is improved

Dosage and Administration

Adolescents & adults

INFECTIONS	DOSAGE	DURATION
Pharyngitis or Tonsillitis	250 mg twice daily	5-10 days
Acute bacterial maxillary sinusitis	250 mg twice daily	10 days
Acute bacterial exacerbation of chronic bronchitis	250-500 mg twice daily	10 days
Secondary bacterial infections of acute bronchitis	250-500 mg twice daily	5-10 days
Community-acquired pneumonia	250-500 mg twice daily	5-10 days
Uncomplicated skin & skin-structure infections	250-500 mg twice daily	10 days
MDR Typhoid fever	500 mg twice daily	10-14 days
Uncomplicated urinary tract infection	250 mg twice daily	7-10 days
Uncomplicated gonorrhea	1000 mg single dose	---
Lyme disease	500 mg twice daily	20 days

Paediatric patients (3 months to 12 years)

INFECTIONS	DOSAGE	DURATION
Pharyngitis or Tonsillitis	20 mg/kg/day in two divided doses	5-10 days
Acute otitis media	30 mg/kg/day in two divided doses	10 days
Acute bacterial maxillary sinusitis	30 mg/kg/day in two divided doses	10 days
Community-acquired pneumonia	30 mg/kg/day in two divided doses	5-10 days
MDR Typhoid fever	30 mg/kg/day in two divided doses	10-14 days
Uncomplicated skin & skin-structure infections	30 mg/kg/day in two divided doses	10 days
Uncomplicated urinary tract infection	20 mg/kg/day in two divided doses	7-10 days

Cefaclav may be administered without regard to meals.

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

Contraindications
Patients with known allergy to cephalosporins & pseudomembranous colitis are contraindicated.

Use in pregnancy & lactation
During pregnancy: While all antibiotics should be avoided in the first trimester if possible. However, Cefaclav can be safely used in later pregnancy to treat urinary and other infections.
During lactation: Cefaclav is excreted into the breast milk in small quantities. However, the possibility of sensitizing the infant should be kept in mind.

Drug interactions
Concomitant administration of probenecid with Cefaclav 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.

Overdosage
Signs and symptoms: Overdosage of Cefaclav can cause cerebral irritation leading to convulsions.
Management: Serum levels of Cefaclav can be reduced by haemodialysis and peritoneal dialysis.

Direction for reconstitution of suspension
Shake the bottle well to loosen the powder. Add 35 ml of boiled and cooled water to the dry powder of the bottle. For ease of preparation, add water to the bottle in two proportions. Shake the bottle well after each addition until all the powder is in suspension.
Note: **The reconstituted suspension must be stored at 2-8 °C temperature and should be used within 7 days after reconstitution. Shake the suspension well before each use.** Keep the bottle tightly closed.

Storage
Do not store tablet above 30 °C and powder for suspension above 25 °C. Keep away from light and out of the reach of children.

Commercial Pack
Cefaclav®125 tablet: Each box contains 3 Alu-Alu blisters of 7 tablets.
Cefaclav®250 tablet: Each box contains 2 Alu-Alu blisters of 7 tablets.
Cefaclav®500 tablet: Each box contains 2 Alu-Alu blisters of 7 tablets.
Cefaclav® 70 ml powder for suspension: Each box contains a bottle containing powder for 70 ml suspension and a measuring cup.

Manufactured by
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Savar, Dhaka, Bangladesh
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