# Cefurim CV

**Cefuroxime Axetil & Clavulanic Acid**

# সেফুরিম সিভি

**সেফুরক্সিম এক্সিটিল এবং ক্লাভুলেনিক এসিড**

## COMPOSITION

**Cefurim CV 250** Tablet: Each film coated tablet contains Cefuroxime 250 mg as Cefuroxime Axetil USP and Clavulanic Acid 62.50 mg as diluted Potassium Clavulanate BP.
**Cefurim CV 500** Tablet: Each film coated tablet contains Cefuroxime 500 mg as Cefuroxime Axetil USP and Clavulanic Acid 125 mg as diluted Potassium Clavulanate BP.
**Cefurim CV Powder for suspension:** Each 5 ml contains Cefuroxime 125 mg as Cefuroxime Axetil USP & Clavulanic Acid 31.25 mg as Potassium Clavulanate BP.

## PHARMACOLOGY

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 beta-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 Cefurim CV 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

- 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, E. 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, E. coli, Klebsiella spp.* and *Enterobacter spp.*
- Urinary tract infections caused by *E. 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, E. 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

**Cefurim CV** tablets can be given without regard to meal.

**Adolescents & adults**

| Bacterial Infections | Dosage | Duration |
|---|---|---|
| Pharyngitis/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 gonorrhoea | 1000 mg single dose | --- |
| Early Lyme disease | 500 mg twice daily | 20 days |

**Pediatric Patients (who can swallow tablets whole)**

| | | |
|---|---|---|
| Acute otitis media | 250 mg twice daily | 10 days |
| Acute bacterial maxillary sinusitis | 250 mg twice daily | 10 days |

**Pediatric Patients (3 months to 12 years)**

| | | |
|---|---|---|
| Pharyngitis/Tonsilitis | 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 and skin-structure infections | 30 mg/kg/day in two divided doses | 10 days |
| Uncomplicated urinary tract infections | 20 mg/kg/day in two divided doses | 7-10 days |

## USE IN PREGNANCY AND LACTATION

**During pregnancy:** Both Cefuroxime Axetil & Clavulanic Acid are USFDA approved pregnancy category B drug. While all antibiotics should be avoided in the first trimester if possible. However, **Cefurim CV** can be safely used in later pregnancy to treat urinary and other infections.
**During lactation: Cefurim CV** excreted into the breast milk in small quantities. However, the possibility of sensitizing the infant should be kept in mind

## CONTRAINDICATION

Patients with known hypersensitivity to cephalosporins and pseudomembranous colitis are contraindicated.

## SIDE EFFECT

In generally Cefuroxime Axetil/Clavulanic Acid preparation is well tolerated. However, a few side effects like nausea, vomiting, diarrhea, loose motions, abdominal discomfort or pain, flatulence, headache, thirst, anorexia may occur. As with other broad spectrum antibiotics, long term use of Cefuroxime Axetil/Clavulanic Acid preparation may result in overgrowth of nonsusceptible microorganisms. Rarely (<0.2%) renal desfunction, angioedema, anaphylaxis, pruritis, rash and urticarea may appear.

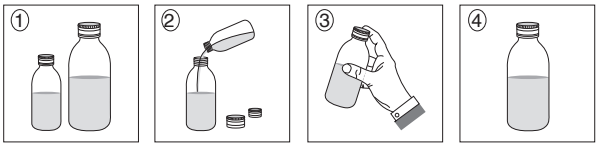
## PRECAUTION

**Cefurim CV** should be given with caution to patients receiving concurrent treatment with potent diuretics because these diuretics are suspected of adversely affecting renal function and who have history of colitis.

## DRUG INTERACTIONS

Concomitant administration of probenecid with **Cefurim CV** increases the area under the serum concentration versus time curve by 50%. Drugs that reduce gastric acidity may result in a lower bilavailability of **Cefurim CV** compared with that of fasting state and tend to cancel the effect of postprandial absorption. In common with other antibiotics, **Cefurim CV** may affect the gut flora, leading to lower estrogen reabsorption and reduced efficacy of combined oral estrogen/progesterone.

## DIRECTION FOR PREPARATION




1. The large bottle contains Cefuroxime Axetil & Clavulanic Acid and the small bottle contains the diluent for suspension.
2. Shake the bottle to loosen the powder. Open the cap of both bottles. Pour the diluent into the large bottle.
3. Tight the cap of large bottle completely and shake vigorously until it is properly mixed.
4. The suspension is ready for use. The reconstituted suspension must be stored at 2 - 8 $^{o}$C temperature and should be used within 7 days after reconstitution.

## STORAGE

- Store in cool & dry place below 25 $^{o}$C temperature, preferably in a refrigerator but do not freeze.
- Keep out of the reach of children.

## PACKAGING

**Cefurim CV 250** Tablet: Each box contains 2x6 tablets in Alu-Alu blister pack.

**Cefurim CV 500** Tablet: Each box contains 2x4 tablets in Alu-Alu blister pack.

**Cefurim CV Powder for Suspension**: Box containing two bottles. Large bottle contains Cefuroxime Axetil & Clavulanic Acid powder and small bottle contains diluent for suspension. After reconstitution as per direction bottle containing 70 ml suspension.

Manufactured by
SOMATEC PHARMACEUTICALS LTD.
SARULIA, DEMRA, DHAKA, BANGLADESH