# Cefurim

Cefuroxime Axetil

## DESCRIPTION

Cefuroxime is one of the bactericidal second-generation cephalosporin antibiotic, 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.

## COMPOSITION

**Cefurim 250** Tablet: Each film-coated tablet contains Cefuroxime Axetil USP equivalent to Cefuroxime 250 mg.

**Cefurim 500** Tablet: Each film-coated tablet contains Cefuroxime Axetil USP equivalent to Cefuroxime 500 mg

**Cefurim** Powder for suspension : After reconstitution, each 5ml suspension contains Cefuroxime Axetil USP equivalent to Cefuroxime 125mg

## 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* (beta-lactamase-producing strains only)

Lower respiratory tract infections including pneumonia, 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 pneumoniae, 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 migrains) 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).

Surgical Prophylaxis: Prophylaxis against infections in abdominal, pelvic, orthopedic, cardiac, pulmonary, esophageal and vascular surgery where there is increased risk for infection.

## DOSAGE AND ADMINISTRATION

Adolescents & adults (13 years, above)

| | | |
|---|---|---|
| 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 |
| Uncomplicated skin & skin-structure infections | 250-500 mg twice daily | 10 days |
| Uncomplicated urinary tract infection | 125-250 mg twice daily | 7-10 days |
| Uncomplicated gonorrhoea | 1000 mg single dose | --- |
| Lyme disease | 500 mg twice daily | 20 days |

**Paediatric patients (Up to 12 years)**

(Who can swallow tablets whole)

| | | |
|---|---|---|
| Pharyngitis or Tonsilitis | 125mg twice daily | 5-10 days |
| Acute otitis media | 250 mg twice daily | 10 days |
| Acute bacterial maxillary sinusitis | 250 mg twice daily | 10 days |

Suspension

(Must be administered with food. Shake the bottle well before each use)

**Paediatric patients (3 months to 12 years)**

| | | |
|---|---|---|
| Pharyngitis or 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 |

**Sequential therapy in adults**

Pneumonia: 500 mg twice daily (oral) for 7-10 days.

Acute exacerbations of chronic bronchitis: 750 mg twice daily for 2-3 days, followed by 500 mg twice daily (oral) for 5-10 days. Duration of oral therapy is determined by the severity of the infection and the clinical status of the patient.

## USE IN PREGNANCY & LACTATION

Cefuroxime has been safely used in later pregnancy to treat urinary and other infections. Nursing mothers: Cefuroxime is excreted into the breast milk in small quantities. However, the possibility of sensitizing the infant should be kept in mind.

## CONTRAINDICATION

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

## SIDE EFFECT

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

## PRECAUTION

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

## DRUG INTERACTION

Concomitant administration of probenecid with Cefuroxime 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 Cefuroxime can cause cerebral irritation leading to convulsions.

Management: Serum levels of Cefuroxime can be reduced by haemodialysis and peritoneal dialysis.

## DIRECTIONS FOR RECONSTITUTION

Suspension: Shake the bottle well to loosen the powder. Add required amount (with the help of supplied measuring cup) of cool boiled water to the dry mixture in the bottle. Shake the bottle well until all the powder is in suspension.

Note: Shake the bottle well before each use. Keep the bottle tightly closed. The reconstituted suspension should be stored in a cool and dry place, preferably in a refrigerator and used within 10 days after reconstitution.

## STORAGE

Cefuroxime tablet, powder for suspension should be kept in a cool ($15^{o}$C- $30^{o}$C) and dry place and protected from light.

## PACKAGING

Cefurim 250 Tablet: Each box contains 3 x 4's Tablets in alu-alu blister pack.

Cefurim 500 Tablet: Each box contains 2 x 4's Tablets in alu-alu blister pack.

Cefurim Powder for suspension: Each bottle contains Cefuroxime powder to be reconstituted into 70ml suspension.

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