

# Sharpkil

Cefuroxime USP Tablet

## Composition

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

**Sharpkil 500 Tablet:** Each film coated tablet contains Cefuroxime Axetil USP equivalent to Cefuroxime 500 mg.

## 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.

## Indication

Indicated for the treatment of:

- 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 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)
- Gonorrhoea: 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

## Dose and Administration

a) *Route of administration:* Oral  
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
Uncomplicated skin & skin-structure infections	250-500 mg twice daily	10 days
Uncomplicated urinary tract infection	250 mg twice daily	7-10 days
Uncomplicated gonorrhoea	1000 mg single dose	—
Lyme disease	500 mg twice daily	20 days

Paediatric patients (3 months to 12 years) who can swallow the whole tablet

INFECTIONS	DOSAGE	DURATION
Pharyngitis or Tonsillitis	125 mg twice daily	5-10 days
Acute otitis media	250 mg twice daily	10 days
Acute bacterial maxillary sinusitis	250 mg twice daily	10 days

## Contra-indication

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

## Warning & Precaution

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

## Side Effects

a) *Common:* Generally Cefuroxime 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 may result in overgrowth of non-susceptible microorganisms.

b) *Rare:* Renal dysfunction, anaphylaxis, angioedema, pruritis, rash and serum sickness like urticaria may appear.

## Use in Pregnancy & Lactation

a) *During pregnancy:* All antibiotics should be avoided in the first trimester. However, Cefuroxime can be safely used in later pregnancy to treat urinary and other infections.

b) *During lactation:* Cefuroxime is excreted into the breast milk in small quantities. However, the possibility of sensitizing the infant should be kept in mind.

## Use in Children & Adolescent

*Children:* Efficacy & safety in infants aged less than six months have not been established.

*Adolescent use:* Clinical studies did not include sufficient number of subjects aged 65 and older to determine whether they respond differently than younger subjects. Other reported clinical experience has not identified difference in response between the elderly and younger patients.

## Drug Interaction

a) *With Medicine:* 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.

b) *With food & other:* Avoid eating grapefruit and drinking grapefruit juice while taking cefuroxime. Cefuroxime may cause a false-positive reaction for glucose in the urine with copper reduction.

## Overdose

*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.

## Storage

Store below 30°C. Protect from light & moisture. Keep all medicines out of reach of children.

## Packing

**Sharpkil 250 Tablet:** Each box contains 14 (2X7's) tablets in Alu-Alu blister pack.

**Sharpkil 500 Tablet:** Each box contains 14 (2X7's) tablets in Alu-Alu blister pack.

Manufactured by  
**Apex Pharma Ltd.**  
Shafipur, Kaliakair, Gazipur, Bangladesh.

for

**ONE PHARMA LTD.**

C-23-24, BSCIC I/A  
Bogura, Bangladesh



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