

Sharpkil Plus

Cefuroxime USP + Clavulanic Acid BP

Composition

Sharpkil Plus 250/62.5 Tablet: Each tablet contains Cefuroxime Axetil USP equivalent to Cefuroxime 250 mg and diluted Potassium Clavulanate BP equivalent to Clavulanic Acid 62.5 mg.

Sharpkil Plus 500/125 Tablet: Each tablet contains Cefuroxime Axetil USP equivalent to Cefuroxime 500 mg and diluted Potassium Clavulanate BP equivalent to Clavulanic Acid 125 mg.

Sharpkil Plus PFS 70 ml: After reconstitution each 5 ml suspension contains Cefuroxime 125 mg as Cefuroxime Axetil USP and Clavulanic Acid 31.25 mg as diluted 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 β -lactamase producing strains. It is indicated for the treatment of infections caused by sensitive bacteria. The presence of clavulanic acid in Sharpkil Plus formulations protects Cefuroxime from degradation by β -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, acute bacterial otitis media, acute bacterial maxillary sinusitis, lower respiratory tract infections including pneumoniae, Staphylococcus aureus, acute bacterial exacerbations of chronic bronchitis and secondary bacterial infections of acute bronchitis, skin and skin-structure Infections, urinary tract infections, bone and joint infections, gonorrhoea, uncomplicated and disseminated gonococcal infections due to neisseria gonorrhoeae in both males and females, early Lyme disease, septicemia & meningitis

Dosage 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
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	---
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

Cefuroxime and Clavulanic Acid may be administered without regard to meals.

Contra-indications

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

Warning & Precautions

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

Side effects

a) *Common:* Generally Cefuroxime and Clavulanic acid are well tolerated. However, a few side effects like nausea, vomiting, diarrhea, abdominal discomfort or pain may occur.

b) *Rare:* (<0.2%) renal dysfunction, anaphylaxis, angioedema, pruritis, rash and serum sickness like urticaria may appear.

Use in Pregnancy & Lactation

During pregnancy: While all antibiotics should be avoided in the first trimester if possible.

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

Use in Children & Adolescents

Please see the dose and administration.

Drug Interactions

a) *With medicine:* Concomitant administration of probenecid with Cefuroxime and Clavulanic Acid 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:* Sharpkil plus (cefuroxime and clavulanic) usually taken with or without food.

Direction for reconstitution of suspension

Shake the bottle well to loosen the powder. Add 40 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.

Overdose

● Signs and symptoms: Overdosage of Cefuroxime and Clavulanic can cause cerebral irritation leading to convulsions.

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

Storage

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

Packing

Sharpkil Plus 250/62.5 Tablet: Each box contains 14 (2X7's) tablets in Alu-Alu blister within Alu-Alu pouch pack.

Sharpkil Plus 500/125 Tablet: Each box contains 14 (2X7's) tablets in Alu-Alu blister within Alu-Alu pouch pack.

Sharpkil Plus PFS 70 ml: Each box contains a bottle containing powder for 70 ml suspension and a measuring cup.

Manufactured by

Apex Pharma Ltd.

Shafipur, Kalakair, Gazipur, Bangladesh

for

ONE PHARMA LTD.

C-23-24, BSCIC I/A

Bogura, Bangladesh



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