Kilbac®

Cefuroxime

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Presentation

Kilbac® 125 tablet: Each film coated tablet contains Cefuroxime Axetil USP equivalent to Cefuroxime 125 mg.
Kilbac® 250 tablet: Each film coated tablet contains Cefuroxime Axetil USP equivalent to Cefuroxime 250 mg.
Kilbac® 500 tablet: Each film coated tablet contains Cefuroxime Axetil USP equivalent to Cefuroxime 500 mg.
Kilbac® powder for suspension: After reconstitution according to direction, each 5 ml suspension contains Cefuroxime Axetil USP equivalent to Cefuroxime 125 mg.
Kilbac®DS powder for suspension: After reconstitution according to direction, each 5 ml suspension contains Cefuroxime Axetil USP equivalent to Cefuroxime 250 mg.
Kilbac® 250 IM/IV injection: Each vial contains sterile powder of Cefuroxime Sodium USP equivalent to Cefuroxime 250 mg.
Kilbac® 750 IM/IV injection: Each vial contains sterile powder of Cefuroxime Sodium USP equivalent to Cefuroxime 750 mg.
Kilbac® 1.5 IV injection: Each vial contains sterile powder of Cefuroxime Sodium USP equivalent to Cefuroxime 1.5 gm.

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.

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* (nonbeta-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 *Neiseria 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), *Neisseira 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

Oral :

INFECTIONS	DOSAGE	DURATION
Tablet: May be administered without regard to meals.		
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 gonorrhea	1000 mg single dose	- - -
Lyme disease	500 mg twice daily	20 days
Paediatric patients (Upto12 years) (Who can swallow tablets whole)		
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
Suspension (Must be administered with food. Shake the bottle well before each use)		
Paediatric patients (3 months to 12 years)		
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

Injection :

Adult: 750 mg three times daily by IM or IV injection. In severe infections, dose can be increased upto 1.5 gm three times daily by IV injection. The frequency may be increased to four times daily, if necessary, giving total daily doses of 3 to 6 gms.
Children (above 3 months of age): 30 - 100 mg/kg/day given in 3 or 4 equally divided doses. A dose of 60 mg/kg/day is appropriate for most infections.
Neonate: 30 - 100 mg/kg/day given in 2 or 3 equally divided doses.
Surgical prophylaxis: 1.5 gm by IV injection at induction of anaesthesia; up to 3 further doses of 750 mg may be given by IV/IM injection every 8 hours for high risk procedures.

Sequential therapy in adults

Pneumonia: 1.5 gm IV injection twice daily for 2-3 days, followed by 500 mg twice daily (oral) for 7-10 days.
Acute exacerbations of chronic bronchitis: 750 mg twice daily (IM or IV injection) for 2-3 days, followed by 500 mg twice daily (oral) for 5-10 days. (Duration of both parenteral and oral therapy is determined by the severity of the infection and the clinical status of the patient).

Other recommendations

In Gonorrhoea: Adult: 1.5 gm as a single dose (as 2 x 750mg injections intramuscularly with different sites, e.g. each buttock).
In Meningitis: Adults: 3 gm IV injection three times daily. *Children (above 3 months of age):* 200-240 mg/kg/day by IV injection in 3 or 4 divided doses reduced to 100 mg/kg/day after 3 days or on clinical improvement. *Neonate:* 100 mg/kg/day by IV injection reduced to 50 mg /kg/day.
In bone and joint infections: Adult: 1.5 gm IV injection four times daily. *Children (above 3 months of age):* 150 mg/kg/day (not to exceed the maximum adult dose) in equally divided doses every 8 hours.
In impaired renal function: A reduced dose must be employed when renal function is impaired. Dosage in adults should be determined by the degree of renal impairment and the susceptibility of the causative organism according to the table below -

Creatinine clearance (ml/min)	Dose	Frequency
> 20	750 mg - 1.5 gm	q8h
10-20	750 mg	q12h
< 10	750 mg	q24h*

* Since Cefuroxime is dialyzable, patients on hemodialysis should be given a further dose at the end of the dialysis.
In paediatric patients with renal insufficiency, the frequency of dosing should be modified consistent with the recommendations for adults.

Side-effects

Generally Cefuroxime is 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 nonsusceptible microorganisms. Rarely (<0.2%) renal dysfunction, anaphylaxis, angioedema, pruritis, rash and serum sickness like urticaria may appear.

Precautions

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

Use in pregnancy & lactation

Pregnancy: While all antibiotics should be avoided in the first trimester if possible. However, 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.

Contraindications

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

Drug interactions

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	Water for reconstitution
Kilbac	37 ml
Kilbac DS	27.5 ml

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

Kilbac 250 IM/IV Injection :

Intramuscular injection : Add 1 ml of supplied water for injection BP to the vial and shake.
Intravenous injection: Add 2 ml of supplied water for injection BP to the vial and shake. The solution should be slowly injected directly into a vein over a 3 to 5 minutes period.

Kilbac 750 IM/IV Injection :

Intramuscular injection : Add 3 ml of supplied water for injection BP to the vial and shake.
Intravenous injection: Add 8 ml of supplied water for injection BP to the vial and shake. The solution should be slowly injected directly into a vein over a 3 to 5 minutes period.

Kilbac 1.5 IV Injection :

Intravenous injection: Add 16 ml of supplied water for injection BP to the vial and shake. The solution should be slowly injected directly into a vein over a 3 to 5 minutes period.

Storage

Do not store above 30°C. Keep away from light and out of the reach of children.

Commercial Pack

Kilbac® 125 tablet: Each box contains 4 Alu-Alu blister strips of 6 tablets.
Kilbac® 250 tablet: Each box contains 3 Alu-Alu blister strips of 6 tablets.
Kilbac® 500 tablet: Each box contains 3 Alu-Alu blister strips of 4 tablets.
Kilbac® powder for suspension: Each bottle contains Cefuroxime Axetil powder to be reconstituted into 70 ml suspension.
Kilbac® DS powder for suspension: Each bottle contains Cefuroxime Axetil powder to be reconstituted into 50 ml suspension.
Kilbac® 250 IM/IV injection: Each box contains one combipack, one 5 ml disposable syringe and one baby needle. The combipack contains one vial of Cefuroxime 250 mg and one ampoule of water for injection BP 5 ml.
Kilbac® 750 IM/IV injection: Each box contains one combipack and one 10 ml disposable syringe. The combipack contains one vial of Cefuroxime 750 mg and one ampoule of water for injection BP 10 ml.
Kilbac® 1.5 IV injection: Each box contains one combipack and one 20 ml disposable syringe. The combipack contains one vial of Cefuroxime 1.5 gm and two ampoules of water for injection BP 10 ml.

Manufactured by
Incepta Pharmaceuticals Ltd
Savar, Dhaka, Bangladesh

V.N.06

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