KFORE

Cefuroxime Axetil USP

Presentation :

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

Kfore-500 Tablet : Each film coated tablet contains Cefuroxime Axetil USP equivalent to Cefuroxime 500 mg.

Kfore powder for suspension : After reconstitution according to direction, each 5 ml suspension contains Cefuroxime Axetil USP equivalent to Cefuroxime 125 mg.

Description :

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.

Indications & 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* (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), *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, 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 strain), *Streptococcus pneumomiae, Escherichia coli, Haemophilus influenzae* (including ampicillin- resistant strain), and *Klebsiella spp*. Meningitis caused by *Streptococcus pneumoniae, Haemophilus influenzae* (including ampicillin-resistant strain), *Neisseria meningitidis* and *Staphylococcus aureus* (penicillinase and non-penicillinase producing strain).

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

Directions for reconstitution of suspension:

Shake the bottle well to loosen the powder. For 70 ml suspension, add 35 ml (with the help of supplied measuring cup) of boiled and cooled water to the dry powder in the bottle. Shake the bottle vigorously until all the powder forms a suspension. Suspension should be used within 10 days after reconstitution.

Dosage & Administration :

Oral :

INFECTIONS	DOSAGE	DURATION
Tablet		
(May be administered without regard to meals)		
Adolescents & adults (12 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 infections	125-250 mg twice daily	7-10 days
Uncomplicated gonorrhoea	1000 mg single dose	----------
Early lyme disease	500 mg twice daily	20 days
Paediatric patients		
(Upto 12 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)		
Paediatric patients (3 months to 12 years)		
Pharyngitis or Tonsillitis	20mg/kg/day in two divided doses	5-10 days
Acute otitis media	30mg/kg/day in two divided doses	10 days
Acute bacterial maxillary sinusitis	30mg/kg/day in two divided doses	10 days

Side-Effects :

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 non-susceptible microorganisms. Rarely (<0.2%) renal dysfunction, anaphylaxis, angioedema, pruritus, rash and serum sickness like urticaria may appear.

Precautions :

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

Use in Pregnancy & Lactation :

Pregnancy : 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 :

Cefuroxime is contraindicated in patients with known allergy to cephalosporins and pseudomembranous 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.

Pharmaceutical precaution :

Kfore tablet and powder for suspension should be kept in a cool (below 30°C.) and dry place, protected from light. Keep out of the reach of children.

Commercial Pack:

Kfore-250 Tablet : Each box contains 4 x 4 tablets in Alu-Alu blister pack.

Kfore-500 Tablet : Each box contains 2 x 4 tablets in Alu-Alu blister pack.

Kfore powder for suspension : Each bottle contains Cefuroxime Axetil powder to be reconstituted into 70 ml suspension.

Manufactured by :

KEMIKO PHARMACEUTICALS LTD.

Bangladesh