Kilmax®

Cefuroxime Axetil Film Coated Tablets, Powder for Suspension
Cefuroxime for Injection USP

DESCRIPTION

Kilmax® is a product of the bactericidal cephalosporin antibiotic Cefuroxime, which is resistant to most beta-lactamases and is active against a wide range of gram-positive and gram-negative organisms. The bactericidal action of Cefuroxime results from inhibition of cell-wall synthesis by binding to essential target proteins.

INDICATIONS

Kilmax® is indicated for the treatment of infections caused by sensitive bacteria.

1. **Pharyngitis/Tonsillitis** caused by *Streptococcus pyogenes.*
2. **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.*
3. **Acute Bacterial Maxillary Sinusitis** caused by *Streptococcus pneumoniae* or *Haemophilus influenzae* (non-beta-lactamase producing strains only).
4. **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).
5. **Uncomplicated Skin and Skin-Structure Infections** caused by *Staphylococcus aureus* (including beta-lactamase producing strains) or *Streptococcus pyogenes*.
6. **Uncomplicated Urinary Tract Infections** caused by *Escherichia coli* or *Klebsiella pneumoniae*.
7. **Uncomplicated Gonorrhoea, urethral and endocervical** caused by penicillinase-producing and non-penicillinase producing strains of *Neisseria gonorrhoeae* and uncomplicated gonorrhoea, rectal, in females, caused by non-penicillinase producing strains of *Neisseria gonorrhoeae.*
8. **Early Lyme Disease (erythema migrans)** caused by *Borrelia burgdorferi.*

DOSAGE AND ADMINISTRATION

Oral:

Population	Infection	Dosage	Duration (days)
Adolescents and adults (13 years and older)	Pharyngitis/tonsillitis	250 mg b.i.d.	10
	Acute bacterial maxillary sinusitis	250 mg b.i.d.	10
	Acute bacterial exacerbations of chronic bronchitis	250 or 500 mg b.i.d.	10
	Secondary bacterial infections of acute bronchitis	250 or 500 mg b.i.d.	5-10
	Uncomplicated skin and skin-structure infections	250 or 500 mg b.i.d.	10
	Uncomplicated urinary tract infections	125 or 250 mg b.i.d.	7-10
	Uncomplicated gonorrhoea	1,000 mg once	single dose
	Early Lyme disease	500 mg b.i.d.	20
Paediatric patients (who can swallow tablet)	Acute otitis media (Under 2 years)	125 mg b.i.d.	10
	Acute otitis media (2-12 years)	125 mg b.i.d.	10
	Acute bacterial maxillary sinusitis	250 mg b.i.d.	10

Population / Infection	Dosage	Duration (days)
Paediatric Patients (3 months to 12 years)		
Pharyngitis/tonsillitis	20 mg/kg/day divided b.i.d.	10
Acute otitis media	30 mg/kg/day divided b.i.d.	10
Acute bacterial maxillary sinusitis	30 mg/kg/day divided b.i.d.	10
Impetigo	30 mg/kg/day divided b.i.d.	10

Parenteral:

General doses and recommendation

Adults: Many infections respond to 750 mg three times daily by IV injection. For more severe infections the dose should be increased to 1.5 g IV three times daily. The frequency of administration may be increased to 6 hourly if necessary, giving total daily doses of 3 to 6 g.

Infants and Children: 30 - 100 mg/kg/day given as 3 or 4 divided doses. A dose of 60 mg/kg/day is appropriate for most infections.

Neonates: 30 - 100 mg/kg/day given as 2 or 3 divided doses.

Other recommendation

Meningitis: Cefuroxime sodium for injection is suitable for sole therapy of bacterial meningitis due to sensitive strains.

Adults: 3 g IV every eight hours.

Infants and Children - 150-250 mg/kg/day IV in 3 or 4 divided doses.

Neonates - The dosage should be 100 mg/kg/day IV.

Surgical Prophylaxis: The usual dose is 1.5 g of Cefuroxime intravenously before the procedure.

In bone and joint infections, a 1.5 g dose every 8 hours is recommended.

Sequential therapy:

Pneumonia:

1.5 g three times daily or twice daily (given intravenously) for 48-72 hours, followed by 500 mg twice daily oral therapy for 7-10 days.

Acute exacerbations of chronic bronchitis:

750 mg three times daily or twice daily (given intravenously) for 48-72 hours, followed by 500 mg twice daily oral therapy 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.

In impaired renal function:

Cefuroxime Sodium for injection should be reduced in renal impairment.

It is not necessary to reduce the standard dose (750 mg - 1.5 g three times daily) until the creatinine clearance falls to 20 mL/min or below. In adults with marked impairment (creatinine clearance 10- 20 mL/min) 750 mg twice daily is recommended and with severe impairment (creatinine clearance < 10 mL/min) 750 mg once daily is adequate.

For patients on haemodialysis a further 750 mg dose should be given IV at the end of each dialysis. In addition to parenteral use, Cefuroxime can be incorporated into the peritoneal dialysis fluid.

DIRECTION FOR RECONSTITUTION:

***Kilmax*® 750 IV Injection:**

Add 8 ml sterile water for Injection to the vial and shake vigorously. The solution slowly injected directly into a vein over a 3 to 5 minutes period.

***Kilmax*® 1.5 g IV Injection:**

Add 16 ml sterile water for Injection to the vial and shake vigorously. The solution slowly injected directly into a vein over a 3 to 5 minutes period.

CONTRAINDICATION

Cefuroxime is contraindicated in patients with hypersensitivity to cephalosporin group of antibiotics.

USE IN PREGNANCY AND LACTATION

There is no experimental evidence of embryopathic or teratogenic effects attributable to Cefuroxime but as with all drugs, it should be administered with caution during early months of pregnancy. Cefuroxime is excreted in human milk and consequently caution should be exercised when Cefuroxime is administered to a nursing mother.

SIDE-EFFECTS

Adverse drug reactions to Cefuroxime are generally mild and transient in nature. Common side-effects may include eosinophilia, hypersensitive reaction, headache, diarrhoea, vomiting, transient increase of hepatic enzyme. Less common side-effects may include thrombocytopenia, urticaria, pruritus, jaundice and hepatitis.

OVERDOSAGE

Overdosage of cephalosporins can cause cerebral irritancy leading to convulsions. Serum levels of Cefuroxime can be reduced by haemodialysis or peritoneal dialysis.

PHARMACEUTICAL PRECAUTIONS

Store in a cool (below 30°C) and dry place, keep away from light. Keep out of the reach of children. In case of injection, use freshly prepared solution. Reconstituted solution is stable for 2 hours at room temperature and for 24 hours in a refrigerator at 2°to 8°C.

PACKAGING

***Kilmax*® 125** Tablet	:	Box containing 2 strips of 7 tablets each. Each film coated tablet contains amorphous Cefuroxime Axetil USP equivalent to Cefuroxime 125 mg.
***Kilmax*® 250** Tablet	:	Box containing 2 strips of 8 tablets or 10 strips of 7 tablets each. Each film coated tablet contains amorphous Cefuroxime Axetil USP equivalent to Cefuroxime 250 mg.
***Kilmax*® 500** Tablet	:	Box containing 1 strip of 8 tablets or 10 strips of 7 tablets each. Each film coated tablet contains amorphous Cefuroxime Axetil USP equivalent to Cefuroxime 500 mg.
***Kilmax*®** Powder for Suspension	:	Bottle containing Powder for the preparation of 70 ml Suspension. Each 5 ml suspension contains amorphous Cefuroxime Axetil USP equivalent to Cefuroxime 125 mg.
***Kilmax*® 750** IV Injection	:	Box containing one vial of 750 mg Cefuroxime as sterile Cefuroxime Sodium USP and one ampoule of 10 ml sterile water for Injection USP.
***Kilmax*® 1.5 g** IV Injection	:	Box containing one vial of 1.5 g Cefuroxime as sterile Cefuroxime Sodium USP and two ampoules of 10 ml sterile water for Injection USP.

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