

Probac[®]

Cefuroxime

PRESENTATION

Probac[®] 250 : Each film coated tablet contains Cefuroxime Axetil USP equivalent to Cefuroxime 250 mg

Probac[®] 500 : Each film coated tablet contains Cefuroxime Axetil USP equivalent to Cefuroxime 500 mg

Probac[®] Dry Powder for Suspension (70ml) : After reconstitution according to direction, each 5 ml suspension contains Cefuroxime Axetil USP equivalent to Cefuroxime 125 mg.

DESCRIPTION

Cefuroxime is a semi-synthetic, broad-spectrum second-generation cephalosporin antibiotic for oral administration. Cefuroxime has bactericidal activity against a wide range of common pathogens, both gram positive and gram negative including many beta-lactamase-producing strains.

INDICATIONS AND USAGE

- ☑ **Pharyngitis/Tonsillitis** caused by *S. pyogenes*.
- ☑ **Acute Bacterial Otitis Media** caused by *S. pneumoniae*, *H. influenzae* (including beta-lactamase-producing strains), *M. catarrhalis* (including beta-lactamase-producing strains), or *S. pyogenes*.
- ☑ **Acute Bacterial Maxillary Sinusitis** caused by *S. pneumoniae* or *H. influenzae* (non-beta-lactamase-producing strains only).
- ☑ **Acute Bacterial Exacerbations of Chronic Bronchitis and Secondary Bacterial Infections of Acute Bronchitis** caused by *S. pneumoniae*, *H. influenzae* (beta-lactamase negative strains), or *H. parainfluenzae* (beta-lactamase negative strains).
- ☑ **Uncomplicated Skin and Skin-Structure Infections** caused by *S. aureus* (including beta-lactamase-producing strains) or *S. pyogenes*.
- ☑ **Uncomplicated Urinary Tract Infections** caused by *E. coli* or *K. pneumoniae*.
- ☑ **Uncomplicated Gonorrhoea**, urethral and endocervical, caused by penicillinase-producing and non-penicillinase-producing strains of *N. gonorrhoeae* and uncomplicated gonorrhoea, in females, caused by non-penicillinase-producing strains of *N. gonorrhoeae*.
- ☑ **Early Lyme Disease** (erythema migrans) caused by *Borrelia burgdorferi*.
- ☑ **Septicemia** caused by *S. aureus* (penicillinase- and non-penicillinase-producing strains), *S. pneumoniae*, *E. coli*, *H. influenzae* (including ampicillin resistant strains), and *Klebsiella* spp.
- ☑ **Meningitis** caused by *S. pneumoniae*, *H. influenzae* (including ampicillin resistant strains), *N. meningitidis*, and *S. 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 : **Probac[®]** should be taken after food for optimum absorption

Infection	Dosage	Duration (days)
Tablet		
Adolescents and Adults (13 years and older)		
Pharyngitis/tonsillitis	250 mg bid	10
Acute bacterial maxillary sinusitis	250 mg bid	10
Acute bacterial exacerbations of chronic bronchitis	250 or 500 mg bid	10
Secondary bacterial infections of acute bronchitis	250 or 500 mg bid	5-10
Uncomplicated skin and skin-structure infections	250 or 500 mg bid	10
Uncomplicated urinary tract infections	250 mg bid	7-10
Uncomplicated gonorrhoea	1,000 mg once	single dose
Early Lyme disease	500 mg bid	20
Pediatric Patients (who can swallow tablets whole)		
Pharyngitis/Tonsillitis	125 mg bid	10
Acute otitis media	250 mg bid.	10
Acute bacterial maxillary sinusitis	250 mg bid	10
Suspension		
(Must be administered with food)		
Usual dose: 125mg b.i.d. or 10-15 mg/kg b.i.d.		
Pediatric Patients (3 months to 12 years)		
Pharyngitis/Tonsillitis	10 mg/kg b.i.d.	10
Acute otitis media	15 mg/kg b.i.d.	10
Acute bacterial maxillary sinusitis	15 mg/kg b.i.d.	10
Impetigo and other skin infections	15 mg/kg b.i.d.	10

SIDE EFFECT

Generally Cefuroxime is well tolerated. However a few side effects like nausea, vomiting, diarrhea, abdominal discomfort or pain may occur. Prolonged administration of Cefuroxime may result in overgrowth of nonsusceptible microorganisms. Rarely (<0.2%) renal dysfunction, anaphylaxis, angioedema, rash and serum sickness like urticaria may occur.

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 indications.

LACTATION: Cefuroxime is excreted in human milk, consideration should be given to discontinuing nursing temporarily during treatment with Cefuroxime axetil.

CONTRAINDICATIONS

Patients with known allergy to cephalosporins & pseudomembranous colitis are contraindicated

DRUG INTERACTIONS

Concomitant administration of probenecid with Cefuroxime axetil tablets increases the area under the serum concentration versus time curve by 50%.

Drugs that reduce gastric acidity may result in a lower bioavailability of Cefuroxime compared with that of fasting state and tend to cancel the effect of postprandial absorption.

OVERDOSAGE

Signs and Symptoms: Overdose of Cefuroxime can cause cerebral irritation leading to convulsions.

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

DIRECTION FOR PREPARATION OF SUSPENSION

Shake the bottle well to loosen powder. To prepare 70 ml suspension add 35 ml (7 - teaspoonful) of boiled and cooled water in to the bottle. Then continue shaking the bottle until the powder completely mixes with the water.

Discard the reconstituted suspension after 10 days.

Shake the bottle well before each use

STORAGE

Store in a cool and dry place at a temperature below 30°C.

Replace cap securely after each opening.

Keep away from sunlight.

Keep out of the reach of children.

Commercial Pack

Probac[®] 250 : Each box contains 4 Alu-Alu blister strip of 4 tablets

Probac[®] 500 : Each box contains 2 Alu-Alu blister strip of 4 tablets

Probac[®] Dry Powder for Suspension : Bottle containing cefuroxime axetil dry powder to reconstitute 70 ml suspension.

Silva
Pharmaceuticals Limited
Majdee, Noakhali, Bangladesh

Manufactured for :
Silva Pharmaceuticals Limited
Majdee, Noakhali, Bangladesh
By Pharmasia Limited
Gojariapara, Bhawal Mirzapur, Gazipur.