Roxibac Plus™

Cefuroxime and Clavulanic Acid

Jenphar Bangladesh | جنفار بنغلاديش

Composition:

Roxibac Plus™ 250 Tablet: Each film coated tablet contains Cefuroxime 250 mg as Cefuroxime Axetil USP and Clavulanic Acid 62.5 mg as diluted Potassium Clavulanate BP.

Roxibac Plus™ 500 Tablet: Each film coated tablet contains Cefuroxime 500 mg as Cefuroxime Axetil USP and Clavulanic Acid 125 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 beta-lactamase producing strains. It is indicated for the treatment of infections caused by sensitive bacteria. Clavulanic acid has a similar structure to the beta-lactam antibiotics but binds irreversibly to the beta-lactamase enzymes. The presence of clavulanic acid in Roxibac Plus formulations protects Cefuroxime from degradation by beta-lactamase enzymes and effectively extends the antibacterial spectrum of Cefuroxime to include many bacteria normally resistant to Cefuroxime and other cephalosporins.

Indication:

- 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 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 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 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), Neisseria meningitidis and Staphylococcus aureus (penicillinase and non-penicillinase producing strains)
- Switch therapy (injectable to oral) after surgery when patient's condition is improved.

Dosage & administration:

Adolescents & adults:

- 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 gonorrhea: 1000 mg single dose
- Lyme disease: 500 mg twice daily (20 days)

Pediatric 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)
- 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)

Roxibac Plus™ may be administered without regard to meals.

OR AS DIRECTED BY THE PHYSICIAN

Use in specific population:

During pregnancy: While all antibiotics should be avoided in the first trimester if possible. However, Roxibac Plus can be safely used in later pregnancy to treat urinary and other infections.

During lactation: Roxibac Plus is excreted into the breast milk in small quantities. However, the possibility of sensitizing the infant should be kept in mind.

Contra-indications:

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

Side effects:

Generally Cefuroxime and Clavulanic acid are 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 and Clavulanic acid combination may result in overgrowth of nonsusceptible microorganisms. Rarely (<0.2%) renal dysfunction, anaphylaxis, angioedema, pruritis, rash and serum sickness like urticaria may appear.

Drug interactions:

Concomitant administration of probenecid with Roxibac Plus 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.

Overdose:

Signs and symptoms: Overdosage of Roxibac Plus can cause cerebral irritation leading to convulsions.
Management: Serum levels of Roxibac Plus can be reduced by haemodialysis and peritoneal dialysis.

Storage:

Keep out of the reach of children. Store in a cool and dry place below 30^0C, protect from light.

Packing:

Roxibac Plus™ 250 Tablet: Each box contains 12 tablets in Alu-Alu blister packs.

Roxibac Plus™ 500 Tablet: Each box contains 12 tablets in Alu-Alu blister packs.

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Manufactured by:
Jenphar Bangladesh Ltd.
Sreepur, Gazipur, Bangladesh.