Roxibac Plus

Cefuroxime and Clavulanic Acid

Roxibac Plus 250: 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: Each film coated tablet contains Cefuroxime 500 mg as Cefuroxime Axetil USP and Clavulanic Acid 125 mg as diluted Potassium Clavulanate BP.

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.
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.

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

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.

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.

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 condition:
Store in a cool & dry place, protect from light. Keep out of the reach of children.

Presentation:
Roxibac Plus 250: Each box contains 2x6's tablets in Alu-Alu blister pack.
Roxibac Plus 500: Each box contains 2x6's tablets in Alu-Alu blister pack.

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

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