Roxibac[™]

Composition:

Roxibac[™] 250 Tablet: Each film coated tablet contains Cefuroxime Axetil USP equivalent to Cefuroxime 250 mg. Roxibac[™] 500 Tablet: Each film coated tablet contains Cefuroxime Axetil USP equivalent to Cefuroxime 500 mg.

Description:

Roxibac[™] (Cefuroxime) is a well-characterized and effective antibacterial agent, which has broad-spectrum bactericidal activity against a wide range of common pathogens, including β-lactamase producing strains. Cefuroxime has good stability to bacterial β-lactamase and consequently is active against many ampicillin-resistant and amoxicillin-resistant strains.

Indications:

Roxibac[™] is indicated for the treatment of:

- Upper respiratory tract infections: Otitis media, sinusitis, tonsillitis and pharyngitis.
- Lower respiratory tract infections: Acute bronchitis, acute exacerbations of chronic bronchitis and pneumonia.
- Skin and soft tissue infections: Furunculosis, pyoderma and impetigo.
- Genito-urinary tract infections: Pyelonephritis, urethritis and cystitis.
- Gonorrhea: Acute uncomplicated gonococcal urethritis and cervicitis.
- Early Lyme disease & subsequent prevention of late Lyme disease.

Dosage & Administration: Oral (tablet):

Adolescents & adults (13 years & older)	Dosage	Duration (Days)
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 & skin-structure infections	250 or 500 mg b.i.d.	10
Uncomplicated urinary tract infections	125 mg b.i.d	7-10
Uncomplicated gonorrhea	1000 mg once	Single Dose
Pyelonephritis	250 mg b.i.d.	7-10
Early Lyme disease	500 mg b.i.d.	14-21
Pediatric Patients: (who can swallow tablet	s) Dosage	Duration (Days)
Acute otitis media	250 mg b.i.d.	10
Acute bacterial maxillary sinusitis	250 mg b.i.d.	10

OR AS DIRECTED BY THE PHYSICIAN.

Side Effects:

Cefuroxime has been associated with nausea and vomiting in a small number of patients.

Precautions:

As with other antibiotics, prolonged use of Cefuroxime may result in the over growth of non-susceptible organisms (e.g. *Candida, Enterococci & Clostridium difficile*), which may require interruption of treatment.

Pregnancy: Pregnancy category B. 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.

Lactation: Cefuroxime is excreted in human milk and consequently caution should be exercised when Cefuroxime is administered to a nursing mother.

Contraindications:

Cefuroxime is contraindicated in patients with known hypersensitivity to Cephalosporins.

Drug Interactions:

No potentially hazardous interactions have been reported. In common with other antibiotics Cefuroxime may affect the gut flora, leading to lower oestrogen reabsorption and reduced efficacy of combined oral contraceptives.

Storage Condition:

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

Presentation:

Roxibac[™] 250 Tablet: Each box contains 2 X 6's tablets in blister pack.

Roxibac[™] 500 Tablet: Each box contains 2 X 6's tablets in blister pack.