

Cefuroxime & Clavulanic Acid

Composition

Famiclav™ 250 Tablet: Each film-coated tablet contains Cefuroxime 250 mg as Cefuroxime Axetil USP and Clavulanic Acid 62.50 mg as diluted Potassium Clavulanate BP.

Famiclav™ 500 Tablet: Each film-coated tablet contains Cefuroxime 500 mg as Cefuroxime Axetil USP and Clavulanic Acid 125 mg as diluted Potassium Clavulanate BP.

Famiclav™ Powder for Suspension: After reconstitution, each 5 ml suspension contains Cefuroxime 125 mg as Cefuroxime Axetil USP and Clavulanic Acid 31.25 mg as Diluted Potassium Clavulanate BP.

Pharmacology

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. 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 Famiclav™ formulations protects Cefuroxime from degradation by β -lactamase enzymes and effectively extends the antibacterial spectrum of Cefuroxime to include many bacteria normally resistant to Cefuroxime and other Cephalosporins.

Indications

- **Upper Respiratory Tract Infections:** Ear, Nose and Throat Infections such as Otitis Media, Sinusitis, Tonsillitis and Pharyngitis.
- **Lower Respiratory Tract Infection:** Acute Bronchitis, Acute Exacerbation of Chronic Bronchitis and Pneumonia.
- **Skin and Soft Tissue Infections:** Furunculosis, Pyoderma and Impetigo.
- **Genito-Urinary Tract Infections:** Pyelonephritis, Urethritis and Cystitis.
- **Gonorrhoea:** Acute Uncomplicated Gonococcal Urethritis and Cervicitis.
- **Early Lyme Disease (erythema migrane):** Caused by *Borrelia burgdorferi*.

Dosage & Administration

Infection	Dosage	Duration	
Adolescents and Adults (13 years and older)			
Pharyngitis/ tonsillitis	250 mg b.i.d.	10 days	
Acute bacterial maxillary sinusitis	250 mg b.i.d.	10 days	
Acute bacterial exacerbations of chronic bronchitis	250 or 500 mg b.i.d.	10 days	
Secondary bacterial infections of acute bronchitis	250 or 500 mg b.i.d.	5-10 days	
Uncomplicated skin and skin-structure infections	250 or 500 mg b.i.d.	10 days	
Uncomplicated urinary tract infections	125 or 250 mg b.i.d.	7-10 days	
Uncomplicated gonorrhoea	1,000 mg once	Single dose	
Early Lyme Disease	500 mg b.i.d.	20 days	
Pediatric Patients (who can swallow tablets whole)			
Acute otitis media	250 mg b.i.d.	10 days	
Acute bacterial maxillary sinusitis	250 mg b.i.d.	10 days	
Infection	Dosage	Daily Maximum Dose	Duration
Pediatric Patients (3 months to 12 years)			
Pharyngitis /tonsillitis	20 mg/kg/day divided b.i.d.	500 mg	10 days
Acute otitis media	30 mg/kg/day divided b.i.d.	1,000 mg	10 days
Acute bacterial maxillary sinusitis	30 mg/kg/day divided b.i.d.	1,000 mg	10 days
Impetigo	30 mg/kg/day divided b.i.d.	1,000 mg	10 days

OR AS DIRECTED BY THE PHYSICIAN.

Directions for reconstitution for oral suspension

1. Shake the bottle to loosen the powder
2. Add the total volume of water for reconstitution into the powder of the bottle
3. Replace the cap
4. Shake the bottle until all the powder is in suspension

Volume of water required for reconstitution for labeled volume of suspension:

Suspension	Labeled volume after reconstitution	Volume of water required for reconstitution
125 mg & 31.25 mg / 5 ml	70 ml	35 ml

Water used for reconstitution should be boiled and cooled. The reconstituted suspension must be stored at 2°-8°C temperature & should be used within 7 days after reconstitution.

Contraindications

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

Warning & Precautions

Famiclav™ should be given with care to patients receiving concurrent treatment with potent diuretics & who have history of colitis.

Side-effects

Common 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. Rare side-effects: Rarely Renal Dysfunction, Anaphylaxis, Angioedema, Pruritis, Rash and Serum Sickness like Urticaria may appear.

Use in Pregnancy & Lactation

During pregnancy: While all antibiotics should be avoided in the first trimester if possible. However, Famiclav™ can be safely used in later pregnancy to treat urinary and other infections. **During Lactation:** Famiclav™ is excreted into the breast milk in small quantities. However, the possibility of sensitizing the infant should be kept in mind.

Use in Children & Adolescents

Famiclav™ should not be used in children younger than 3 months of age.

Drug interaction

With Medicine: Concomitant administration of probenecid with Cefuroxime 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. **With food & others:** Famiclav™ may be administered without regard to meal.

Overdose

Signs and symptom: Overdose of Famiclav™ can cause cerebral irritation leading to convulsions.

Management: Serum levels of Famiclav™ can be reduced by hemodialysis and peritoneal dialysis.

Storage

Famiclav™ tablet should be kept below 30° C temperature & in a dry place, protected from light. Famiclav™ Powder for Suspension should be kept below 25° C temperature & in a dry place, protected from light. Keep all medicines out of reach of children.

Packing

Famiclav™ 250 Tablet: Each box contains 2x7 tablets in Alu-Alu blister with pouch pack.

Famiclav™ 500 Tablet: Each box contains 2x7 tablets in Alu-Alu blister with pouch pack.

Famiclav™ Powder for Suspension: Each bottle contains dry powder to reconstitute 70 ml suspension.

* Further information is available on request.