

Composition

Furotil Plus<sup>®</sup> 125 mg tablet: Each film-coated tablet contains Cefuroxime Axetil USP equivalent to Cefuroxime 125 mg and diluted Potassium Clavulanate BP equivalent to Clavulanic Acid 31.25 mg.  
Furotil Plus<sup>®</sup> 250 mg tablet: Each film-coated tablet contains Cefuroxime Axetil USP equivalent to Cefuroxime 250 mg and diluted Potassium Clavulanate BP equivalent to Clavulanic Acid 62.5 mg.  
Furotil Plus<sup>®</sup> 500 mg tablet: Each film-coated tablet contains Cefuroxime Axetil USP equivalent to Cefuroxime 500 mg and diluted Potassium Clavulanate BP equivalent to Clavulanic Acid 125 mg.  
Furotil Plus<sup>®</sup> powder for Suspension: Each 5 ml reconstituted suspension contains Cefuroxime Axetil USP equivalent to Cefuroxime 125 mg and diluted Potassium Clavulanate BP equivalent to Clavulanic Acid 31.25 mg.

Pharmacology

Cefuroxime Axetil is a second generation semi-synthetic cephalosporin and a beta-lactam antibiotic with bactericidal activity. It exerts its bactericidal effect by binding to an enzyme penicillin-binding proteins (PBPs) involved in bacterial cell wall synthesis. This binding results in inhibition of bacterial cell wall synthesis and subsequent cell death. Clavulanic acid is a beta Lactamase Inhibitor. It is a suicidal inhibitor of beta-lactamase enzymes from Streptomyces clavuligerus. It contains a beta-lactam ring and binds strongly to beta-lactamase at or near its active site, thereby hindering enzymatic activity.

What does Clavulanic acid do?

It has only weak antibacterial activity against most organisms, but given in combination with other beta-lactam antibiotics it inactivates beta-lactamase thereby enhancing their antibacterial effects.

Indications

Pharyngitis/tonsillitis, Acute bacterial otitis media, Acute bacterial maxillary sinusitis, Acute bacterial exacerbations of chronic bronchitis and secondary bacterial infections of acute bronchitis, Uncomplicated skin and skin-structure infections, Uncomplicated urinary tract infections, Uncomplicated gonorrhea, Early Lyme disease, Impetigo

Dose and Administration

- a. Route of administration: Orally
- Administer tablets with or without food
  - Administer oral suspension with food

Adult Patients and Pediatric Patients (13 years and older) Furotil Plus Tablets		
Infection	Dosage	Duration (Days)
Pharyngitis/tonsillitis (mild to moderate)	250 mg every 12 hours	10
Acute bacterial maxillary sinusitis (mild to moderate)	250 mg every 12 hours	10
Acute bacterial exacerbations of chronic bronchitis (mild to moderate)	250 or 500 mg every 12 hours	10
Secondary bacterial infections of acute bronchitis	250 or 500 mg every 12 hours	5 to 10
Uncomplicated skin and skin-structure infections	250 or 500 mg every 12 hours	10
Uncomplicated urinary tract infections	250 mg every 12 hours	7 to 10
Uncomplicated gonorrhea	1,000 mg	single dose
Early Lyme disease	500 mg every 12 hours	20

Pediatric Patients younger than 13 years (who can swallow tablets whole)		
Acute bacterial otitis media	250 mg every 12 hours	10
Acute bacterial maxillary sinusitis	250 mg every 12 hours	10

Pediatric Patients (3 months to 12 years) (Oral Suspension)			
Infection	Recommended Daily Dose	Maximum Daily Dose	Duration (Days)
Pharyngitis/tonsillitis	20 mg/kg every 12 hours	500 mg	10
Acute bacterial otitis media	30 mg/kg every 12 hours	1,000 mg	10
Acute bacterial maxillary sinusitis (mild to moderate)	30 mg/kg every 12 hours	1,000 mg	10
Impetigo	30 mg/kg every 12 hours	1,000 mg	10

Contraindications

Hypersensitivity to other Beta-lactams antibiotics.

Warnings and Precautions

Serious hypersensitivity (anaphylactic) reactions: In the event of a serious reaction, discontinue Furotil Plus and institute appropriate therapy.  
Clostridium difficile-associated diarrhea (CDAD): If diarrhea occurs, evaluate patients for CDAD.

Side-Effects

- a.Common: Diarrhea, nausea/vomiting, dislike of taste  
b.Rare: Headache and dizziness, Transient increases of hepatic enzyme levels

Pregnancy and Lactation

While all antibiotics should be avoided in the first trimester if possible. However, Furotil Plus can be safely used in later pregnancy to treat urinary and other infections.  
Because Cefuroxime is excreted in human milk, consideration should be given to discontinuing nursing temporarily during treatment with Cefuroxime

Use in children and adolescents

The safety and effectiveness of Furotil Plus<sup>®</sup> have been established for pediatric patients aged 3 months to 12 years.  
Geriatric/ adolescents Use  
Care should be taken in dose selection, and it may be useful to monitor renal function.

Drug Interactions

- a) With medicine: Oral Contraceptives, effects on gut flora may lower estrogen reabsorption and reduce efficacy of oral contraceptives. Co-administration with probenecid increases systemic exposure to Furotil Plus and is therefore not recommended, Drugs that reduce gastric acidity may lower the bioavailability of Furotil Plus.  
b) With food and others: No

Renal Impairment

Reducing the dosage of Furotil Plus<sup>®</sup> is recommended for adult patients with severe renal impairment (creatinine clearance <30 mL/min).

Overdose

Over-dosage of cephalosporins can cause cerebral irritation leading to convulsions or encephalopathy. Serum levels of cefuroxime can be reduced by hemodialysis and peritoneal dialysis.

Storage

Furotil Plus<sup>®</sup> Tablet: Should be stored at a temperature not exceeding 25 °C in a dry place. Protect from light and moisture.  
Furotil Plus<sup>®</sup> Suspension: Should be stored at a temperature not exceeding 25 °C in a dry place. Protect from light and moisture. Once reconstituted suspension should be kept in a cool place preferably in refrigerator 2-8 °C (but not frozen) and should be used by 7 days.

Packing

Furotil Plus<sup>®</sup> 125 mg tablet: Each box contains 4x4's tablets in Alu-Alu blister pack.  
Furotil Plus<sup>®</sup> 250 mg tablet: Each box contains 3x4's tablets in Alu-Alu blister pack.  
Furotil Plus<sup>®</sup> 500 mg tablet: Each box contains 3x4's tablets in Alu-Alu blister pack.  
Furotil Plus<sup>®</sup> powder for Suspension: Bottle contains dry powder to make 70 ml suspension.

Medicine: Keep out of reach of children