



Composition:

Xitil 500 mg Tablet: Each film coated tablet contains 500 mg of Cefuroxime as Cefuroxime Axetil BP.
Xitil 250 mg Tablet: Each film coated tablet contains 250 mg of Cefuroxime as Cefuroxime Axetil BP.
Xitil Powder for Suspension: After reconstitution each 5 ml suspension contains 125 mg of Cefuroxime as Cefuroxime Axetil USP.

Description:

Cefuroxime (**Xitil**) is a broad-spectrum second generation cephalosporin which is active against both gram (+)ve & gram (-)ve aerobes and also anaerobes. It has bactericidal activity against a wide range of common pathogens including beta-lactamase producing strains. Consequently cefuroxime is active against many ampicillin & amoxicillin resistant strains. Cefuroxime kills bacteria interfering the synthesis of bacterial cell wall by inhibiting the transpeptidase enzyme.

Pharmacokinetics:

After oral administration, cefuroxime axetil is absorbed from the gastrointestinal tract and rapidly hydrolysed to cefuroxime by nonspecific esterases in the intestinal mucosa and blood. Cefuroxime is subsequently distributed throughout the extracellular fluids. The axetil moiety is metabolised to acetaldehyde and acetic acid. It is approx. 50% protein bound & the half-life is 1.2 hrs. Absorption is greater when taken after food. The drug is excreted unchanged in the urine; in adults, approx. 50% of the administered dose is recovered in the urine within 12 hours. As cefuroxime is actively excreted, the serum half-life is prolonged in patients with reduced renal function. Despite the lower elimination of cefuroxime in geriatric patients, dosage adjustment based on age is not necessary.

Indications:

Xitil is indicated for the treatment of patients with mild to moderate infections caused by susceptible strains of the designated microorganisms in the conditions listed below:

- **Pharyngitis/Tonsillitis** caused by *Streptococcus pyogenes*
- **Acute bacterial otitis media** caused by *S. pneumoniae*, *H. influenzae* (including beta-lactamase producing strains), *M. catarrhalis* (including beta-lactamase producing strains) or *S. pyogenes*.
- **Acute bacterial maxillary sinusitis** caused by *S. pneumoniae* or *H. influenzae* (non-beta-lactamase producing strains only)
- **Acute bacterial exacerbations of chronic bronchitis and secondary bacterial infections of acute bronchitis** caused by *S. pneumoniae*, *H. influenzae* (beta-lactamase negative strains), or *H. parainfluenzae* (beta-lactamase negative strains)
- **Uncomplicated skin and skin-structure infections** caused by *S. aureus* (including beta-lactamase producing strains), or *S. pyogenes*
- **Uncomplicated urinary tract infections** caused by *E. coli* or *K. pneumoniae*
- **Uncomplicated gonorrhoea, urethral and endocervical infections** caused by penicillinase producing and non-penicillinase producing strains of *N. gonorrhoeae* and uncomplicated rectal gonorrhoea in females caused by non-penicillinase producing strains of *N. gonorrhoeae*
- **Early Lyme disease (Erythema migrans)** caused by *Borrelia burgdorferi*.
- **Obstetric and gynaecological infection**, pelvic inflammatory diseases.
- **Other infections** including septicemia and meningitis.

Dosage and Administration:

Oral: **Xitil** should be taken after food for optimum absorption.

Population	Infection	Dosage	Duration (days)
Adolescents and Adults (13 years and older)	Pharyngitis/Tonsillitis	250 mg bid	10
	Acute bacterial maxillary sinusitis	250 mg bid	10
	Acute bacterial exacerbations of chronic bronchitis	250 or 500 mg bid	10
	Secondary bacterial infections of acute bronchitis	250 or 500 mg bid	5-10
	Uncomplicated skin and skin-structure infections	250 or 500 mg bid	10
	Uncomplicated urinary tract infections	125 or 250 mg bid	7-10
	Uncomplicated gonorrhoea	1000 mg once	Single dose
Paediatric (who can swallow tablet)	Early Lyme Disease	500 mg bid	20
	Pharyngitis/Tonsillitis	125 mg bid	10
	Acute otitis media	250 mg bid	10
	Acute bacterial maxillary sinusitis	250 mg bid	10

Powder for Suspension: Usual dose: 20-30 mg/kg twice daily

Infection	Dosage	Duration (days)
Pharyngitis/Tonsillitis	20 mg/kg bid	10
Acute otitis media	30 mg/kg bid	10
Acute bacterial maxillary sinusitis	30 mg/kg bid	10
Impetigo and other skin infections	30 mg/kg bid	10

Shake the bottle vigorously before every use.

Direction for Reconstitution:

Suspension: Shake the bottle well to loosen the powder. Add 35 ml (with the help of supplied measuring cup) of boiled and cooled water to the dry mixture in the bottle. Shake the bottle vigorously until all the powder is in suspension. Always keep the bottle tightly closed.

Side effects:

Generally cefuroxime is well tolerated. However, a few side effects like nausea, vomiting, diarrhoea, abdominal discomfort or pain may occur. As with other broad-spectrum antibiotics, prolonged administration of cefuroxime may result in overgrowth of nonsusceptible microorganisms. Rarely (<0.20%) renal dysfunction, anaphylaxis, angioedema, pruritis, rash and serum sickness like urticaria may appear.

Contraindications:

It is contraindicated in patients with known hypersensitivity to the cephalosporin group of antibiotics.

Precautions:

Penicillin sensitivity; renal impairment; pregnancy & breast-feeding; false positive urinary glucose & false positive Coomb's test.

Pregnancy & Lactation:

Because cefuroxime is excreted in human milk, consideration should be given to discontinuing nursing temporarily during treatment with cefuroxime.

Drug Interactions:

Probenecid increases cefuroxime blood levels; drugs lowering gastric acidity may decrease cefuroxime bioavailability.

Storage:

Store in a dry & cool place, protected from light.

Packaging:

Xitil 500 mg Tablet: Each box contains 1x7's tablets in Alu-Alu blister pack.
Xitil 250 mg Tablet: Each box contains 2x7's tablets in Alu-Alu blister pack.
Xitil Powder for Suspension: Each bottle contains dry powder to reconstitute 70 ml suspension.

Manufactured by



Ziska Pharmaceuticals Ltd.
 Kaliakoir, Gazipur, Bangladesh