

Xiclav

Cefuroxime USP + Clavulanic Acid BP

Presentation:

Xiclav 250: Each film coated tablet contains Cefuroxime Axetil USP equivalent to Cefuroxime 250 mg and Potassium Clavulanate BP equivalent to Clavulanic Acid 62.5 mg.

Xiclav 500: Each film coated tablet contains Cefuroxime Axetil USP equivalent to Cefuroxime 500 mg and Potassium Clavulanate BP equivalent to Clavulanic Acid 125 mg.

Xiclav Granules for Suspension: Each 5 ml of reconstituted suspension contains Cefuroxime Axetil BP equivalent to Cefuroxime 125 mg and Potassium Clavulanate BP equivalent to Clavulanic Acid 31.25 mg.

Description:

Cefuroxime is a broad-spectrum second generation cephalosporin which is active against both gram (+)ve & gram (-)ve aerobes and also anerobes. It has bactericidal activity against a wide range of common pathogens including β -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 β -lactamase enzymes and inactivates them. Clavulanic acid in **Xiclav** gives protection of cefuroxime from degradation by β -lactamase enzyme and provides a solution for treatment of bacterial infections caused by beta lactam resistant pathogens.

Indications and uses:

- * Pharyngitis/Tonsillitis caused by *Streptococcus pyogenes*.
- * Acute Bacterial Otitis Media caused by *Streptococcus pneumoniae*, *Haemophilus influenzae* (including β -lactamase-producing strains), *Moraxella catarrhalis* (including β -lactamase-producing strains), or *Streptococcus pyogenes*
- * Acute Bacterial Maxillary Sinusitis caused by *Streptococcus pneumoniae* or *Haemophilus influenzae* (non- β -lactamase-producing strains only)
- * Acute Bacterial Exacerbations of Chronic Bronchitis and Secondary Bacterial Infections of Acute Bronchitis caused by *Streptococcus pneumoniae*, *Haemophilus influenzae* (β -lactamase negative strains), or *Haemophilus parainfluenzae* (β -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*
- * Gonorrhoea: Uncomplicated and disseminated gonococcol 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*
- * Impetigo caused by *Staphylococcus aureus* (including β -lactamase-producing strains) or *Streptococcus pyogenes*.
- * Switch therapy (injectable to oral) after surgery when patients condition is improved

Dosage & Administration:

Xiclav should be taken after food for optimum absorption.

Xiclav Tablets :

Population	Infections	Dosage	Duration (days)
Adolescents and Adults (13 years and older)	Pharyngitis/tonsillitis	250 mg twice daily	10
	Acute bacterial maxillary sinusitis	250 mg twice daily	10
	Acute bacterial exacerbations of chronic bronchitis	250 or 500 mg twice daily	10
	Secondary bacterial infections of acute bronchitis	250 or 500 mg twice daily	5-10
	Uncomplicated skin and skin-structure infections	250 or 500 mg twice daily	10
	Uncomplicated urinary tract infections	250 mg twice daily	7-10
	Uncomplicated gonorrhoea	1000 mg	Single dose
	Early Lyme disease	500 mg twice daily	20

Population	Infections	Dosage	Duration (days)
Paediatric patients (who can swallow tablet whole)	Acute otitis media	250 mg twice daily	10
	Acute bacterial maxillary sinusitis	250 mg twice daily	10

Xiclav Granules for Suspension

Population	Infections	Dosage	Maximum daily dose	Duration (days)
Paediatric patient (3 months to 12 years)	Pharyngitis/tonsillitis	20 mg/kg/day in two divided doses	500 mg	10
	Acute otitis media	30 mg/kg/day in two divided doses	1000 mg	10
	Acute bacterial maxillary sinusitis	30 mg/kg/day in two divided doses	1000 mg	10
	Impetigo	30 mg/kg/day in two divided doses	1000 mg	10

Side effects :

Generally cefuroxime and clavulanic acid are 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 & clavulanic acid combination may result in overgrowth of nonsusceptible microorganisms. Rarely (<0.20%) renal dysfunction, anaphylaxis, angioedema, pruritis, rash and serum sickness like urticaria may appear.

Precautions :

Xiclav should be given with care to patients receiving concurrent treatment with potent diuretics and who have history of colitis

Use in pregnancy & lactation :

During Pregnancy: While all antibiotics should be avoided in the first trimester if possible, however **Xiclav** can be safely used in later pregnancy to treat urinary and other infections. During lactation: Because **Xiclav** 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 hypersensitivity to cephalosporins & pseudomembraneous colitis are contraindicated.

Drug Interactions :

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

Overdosage :

Signs and symptoms: Overdosage of **Xiclav** can cause cerebral irritation leading to convulsions. Management: Serum levels of **Xiclav** can be reduced by haemodialysis and peritoneal dialysis.

Storage :

Xiclav Tablet : Store in a cool (below 25^o C) and dry place, protected from light.

Xiclav Granules for suspension : Before reconstitution, store dry granules between 2^o & 25^o C. After reconstitution immediately store suspension between 2^o & 8^o C in a refrigerator. Discard after 07 days.

Packaging :

Xiclav 250 mg Tablet: Each box contains 2x5's tablets in Alu-Alu blister pack within a pouch pack.

Xiclav 500 mg Tablet: Each box contains 1x8's tablets in Alu-Alu blister pack within a pouch pack.

Xiclav Granules for Suspension: Each carton contains a large bottle containing Cefuroxime and Clavulanic acid dry granules for reconstituting 70 ml of suspension and a small bottle containing diluent along with a measuring cup, a spoon and a dropper.

Manufactured by:

ZISKA
Pharmaceuticals

Ziska Pharmaceuticals Ltd,
Kaliakoir, Gazipur, Bangladesh