

CEFORIX  
Cefuroxime Axetil Tablets USP 250 mg  
Cefuroxime Axetil Tablets USP 500 mg  
Cefuroxime Axetil for Oral Suspension USP 125 mg

Description:

Cefuroxime is a semisynthetic broad spectrum cephalosporin antibiotic given orally contains Cefuroxime Axetil, which is bactericidal against many common pathogens, including many beta-lactamase strains.

Formulation:

Each film coated tablet contains:

Cefuroxime Axetil (Amorphous) USP	
eq. to Cefuroxime	250 mg
Excipients	q.s.
Approved colour added	

Each film coated tablet contains:

Cefuroxime Axetil (Amorphous) USP	
eq. to Cefuroxime	500 mg
Excipients	q.s.
Approved colour added.	

Each 5 ml of the reconstituted suspension contains:

Cefuroxime Axetil (Amorphous) USP	
eq. to Cefuroxime	125 mg
Excipients	q.s.
In flavoured syrupy base	

Pharmacological Action

Cefuroxime axetil is an oral prodrug of the bactericidal cephalosporin antibiotic, cefuroxime, which is resistant to most  $\beta$ -lactamases and is active against a wide range of Gram-positive and Gram-negative organisms.

The bacterial action of cefuroxime results from inhibition of cell wall synthesis by binding to essential target proteins.

Pharmacokinetics

After oral administration, cefuroxime is absorbed from the gastro-intestinal tract and rapidly hydrolysed in the intestinal mucosa and blood to release cefuroxime into the circulation. Optimum absorption occurs when it is administered after a meal. Peak serum levels (2-3 mg/mL for a 125 mg dose, 4-5 mg/mL for a 250 mg dose, 5-7 mg/mL for a 500 mg dose) occur approximately two to three hours after dosing when taken after food. The serum half-life is between 1 and 1.5 hours. Protein binding has been variously stated as 33-50% depending on the methodology used. Cefuroxime is not metabolised and is excreted by glomerular filtration and tubular secretion.

Concurrent administration of probenecid increases the area under the mean serum concentration time-curve by 50%. Serum levels of cefuroxime are reduced by dialysis.

**Indications:**

CEFUROXIME AXETIL TABLETS & CEFUROXIME AXETIL FOR ORAL SUSPENSION are indicated only for the treatment of infections caused by susceptible strains of the following organisms in the following infections:

**Dosage and directions for use:**

**Adults:**

Sinusitis & acute or chronic bronchitis:

250 mg twice daily for seven days (Range 5-10 days)

Acute - uncomplicated cystitis:

125 mg twice daily for seven days (Range 5-10 days)

Lyme disease:

Adults and children over 12 years of age: 500 mg twice daily for 20 days

**Children:**

There is no experience with Cefuroxime in children under 3 months of age.

Cefuroxime should be taken half an hour after food for optimum absorption.

**Contra-indications:**

Use of it is contraindicated in patients with a known hypersensitivity to any component of the tablet.

**Warnings:**

Special care is indicated in patients who have experienced an allergic reaction to penicillins or other beta-lactams.

As with other antibiotics, use of cefuroxime may result in the overgrowth of *Candida*. Prolonged use may also result in the overgrowth of non-susceptible organisms (e.g. *Enterococci* and *Clostridium difficile*), which may require interruption of treatment.

Pseudomembranous colitis has been reported with the use of broad-spectrum antibiotics; therefore, it is important to consider its diagnosis in patients who develop serious diarrhoea during or after antibiotic use.

The Jarisch-Herxheimer reaction has been seen following Cefuroxime treatment of Lyme disease.

Pregnancy and Lactation: There is no experimental evidence of embryopathic or teratogenic effects attributable to cefuroxime but, as with all drugs, it should be administered with caution during early months of pregnancy.

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

Drug interactions:

In common with other antibiotics, Cefuroxime may affect the gut flora, leading to lower oestrogen reabsorption and reduced efficacy of combined oral contraceptives.

As a false negative result may occur in the ferricyanide test, it is recommended that either the glucose oxidase or hexokinase methods are used to determine blood/plasma glucose levels in patients receiving cefuroxime. This antibiotic does not interfere in the alkaline picrate assay for creatinine.

Concurrent administration of probenecid increases the area under the mean serum concentration time curve by 50%. Serum levels of cefuroxime are reduced by dialysis.

A positive Coomb's test has been reported during treatment with cephalosporins. This phenomenon can interfere with cross matching of blood.

Adverse effects:

Haematological: Eosinophilia

Neurological: Headache

Gastrointestinal: Nausea, vomiting, abdominal pain, diarrhoea, in some cases accompanied by blood in stools, which may be a symptom of enterocolitis.

Kidney/Genitourinary: Vaginal candidiasis

Liver: Transient increases in hepatic enzyme levels

Skin: Erythema multiforme, Stevens Johnson syndrome, toxic epidermal necrolysis

Other: Hypersensitivity reactions including skin rashes, urticaria, pruritus, bronchospasm, drug fever, serum sickness, and anaphylaxis

Overdosage & Treatment:

Symptoms: Seizures have been reported.

Treatment: Treatment is symptomatic and supportive. Serum levels of Cefuroxime can be reduced by haemodialysis or peritoneal dialysis.

Storage Instructions:

Store below 25°C, Protected from light & moisture.

Keep the medicine out of reach of children.

Presentation:

1 x 10 Alu/Alu blister in a unit carton with package insert.

Powder for Oral Suspension (125mg/5ml)

Glass Bottle containing powder for preparation of 60 ml suspension.

Mfg. Lic. No. : MB/06/308

Mfg. In India by :

M/s ASSOCIATED BIOTECH

Vill krishanpura, PO Gurumajra Baddi Distt Solan.