

# Cefuroxime Axetil Tablets

## USP 250 mg

RX

Special warning

Prescription only.

Read the instructions thoroughly before use.

Do not exceed the prescribed dosage.

If encountering with any side effects, please contact physician

Consult Physician for further information.

Do not use the Expiry drugs.

Keep the medicine out of reach of children.

**DESCRIPTION :** Cefuroxa is an antibacterial drug. It is available as Tablets for oral administration.

### COMPOSITION :

Each film-coated tablet contains :

Cefuroxime Axetil USP equivalent to Cefuroxime 250 mg

Excipients q.s.

Approved colour used

**CLINICAL PHARMACOLOGY :** Cefuroxime Axetil is an oral drug 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. Cefuroxime axetil owes its in vivo bactericidal activity to the parent compound cefuroxime. It is a well characterized and effective antibacterial agent which has bactericidal activity against a wide range of common pathogens, including  $\beta$ -lactamase-producing strains. Cefuroxime has good stability to  $\beta$ -lactamase and consequently is active against many ampicillin-resistant or amoxicillin-resistant strains. The bactericidal action results from inhibition of cell wall synthesis by binding to essential target proteins. After oral administration, cefuroxime axetil is absorbed from the gastrointestinal 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 (2.9 mg/L for a 125-mg dose, 4.4 mg/L for a 250-mg dose) occur approximately 2.4 hrs after dosing when taken with food. The serum half-life is between 1 and 1.5 hrs. 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.

**INDICATIONS :** Lower respiratory tract infections, eg acute and acute exacerbation of chronic bronchitis and pneumonia. Upper respiratory tract infections, eg ear, nose, and acute throat infections, eg otitis media, sinusitis, tonsillitis and pharyngitis, Genitourinary tract infections, eg pyelonephritis, cystitis and urethritis, Skin and soft tissue infections.

**CONTRAINDICATIONS :** Patients with known hypersensitivity to cephalosporin antibiotics.

**PRECAUTIONS :** Special care is indicated in patients who have experienced an allergic reaction to penicillins or other  $\beta$ -lactams. As with other antibiotics, prolonged use of cefuroxime axetil may result in the overgrowth of nonsusceptible organisms (eg. Candida, Enterococci, 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 it for diagnosis in patients who develop serious diarrhoea during or after antibiotic use.

**USE IN PREGNANCY :** It should be administered with caution during the early months of pregnancy.

**USE IN LACTATION :** Cefuroxime is excreted in human milk and consequently, caution should be exercised when cefuroxime axetil is administered to a nursing mother.

**ADVERSE EFFECTS :** Adverse reactions to cefuroxime axetil have been generally mild and transient in nature. As with other cephalosporins, there have been rare reports of erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (exanthematic necrolysis) and hypersensitivity reactions including skin rashes, urticaria, pruritus, drug fever, serum sickness and very rarely anaphylaxis. A small portion of patients receiving cefuroxime axetil have experienced gastrointestinal disturbances, including diarrhoea, nausea and vomiting.

**DRUG INTERACTIONS :** Probenecid reduces the renal clearance of cefuroxime.

**MANAGEMENT OF OVERDOSAGE :** Overdosage of cephalosporins can cause cerebral irritation leading to convulsions. Serum levels of cefuroxime can be reduced by haemodialysis or peritoneal dialysis.

**DOSAGE AND ADMINISTRATION :** Milder infections of upper and lower respiratory tract, Skin and soft tissue infection : Adult: 125-500 mg twice a day. According to severity : Child : 125 mg twice a day.

**OTITIS MEDIA :** Child : Children over 2 years : 250 mg twice a day.

Uncomplicated Gonorrhoea : Adult : Single dose of 1.0 g

or as directed by the physician.

**STORAGE :** Store at a temperature not exceeding 30°C. protect from light & moisture.

**PACKING :** 10 Tablets of Alu-Alu pack.

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