Natrapharm

Cefuroxime
Zoltax®

℞

500mg film-coated tablet
Antibacterial

Formulation:
Each film-coated tablet contains Cefuroxime (as axetil) 500mg

Indications:
Cefuroxime is a second-generation cephalosporin antibiotic used in the treatment of susceptible infections. These have included bone and joint infections, bronchitis (and other lower respiratory- tract infections) gonorrhea, meningitis (although treatment failures have been reported in Haemophilus influenza meningitis), otitis media, peritonitis, pharyngitis, sinusitis, skin infections (including soft-tissue infection) and urinary tract infections.

It is also used for surgical infection prophylaxis.

Dosage and Administration:
Usual oral doses for adults are:
125mg twice daily for uncomplicated urinary-tract infections
250mg to 500mg twice daily for respiratory tract infections.

Adults with pneumonia or with acute exacerbations of chronic bronchitis may respond to sequential therapy with parenteral cefuroxime 1.5g twice daily or 750mg twice daily, respectively, followed by oral cefuroxime 500mg twice daily in each case.

For Lyme disease in adults, an oral dose of 500mg is given twice daily for 20 days. Uncomplicated gonorrhea- a single 1-g oral dose of cefuroxime and 1 g probenecid may be given.

Administration in renal impairment: Doses may need to be reduced in patients with renal impairment.

Pharmacodynamics
Cefuroxime is bactericidal and has a similar spectrum of antimicrobial action and pattern of resistance to those of cefamandole. It is more resistant to hydrolysis by beta-lactamases than cefamandole, and therefore may be more active against beta-lactamase - producing strains of, for example, *Haemophilus influenzae and Neisseria gonorrhoeae*. However, treatment failures have occurred in patients with *H. influenzae* meningitis given cefuroxime and might be associated with a relatively high minimum bacterial concentration when compared with the minimum inhibitory concentration or with a significant inoculum effect. Reduced affinity of penicillin-binding proteins for cefuroxime has also been reported to be responsible for resistance in a beta-lactamase-negative strain of H. influenza.

Cefuroxime has been demonstrated to be active against most strains of the following organisms

Aerobic Gram-Positive Microorganisms:
Staphylococcus aureus (including beta-lactamase-producing strains)
Streptococcus pneumoniae
Streptococcus pyogenes

Aerobic Gram-Negative Microorganisms:
Escherichia coli
Haemophilus influenzae (including beta-lactamase-producing strains)
Haemophilus parainfluenzae
Klebsiella pneumoniae
Moraxella catarrhalis (including beta-lactamase-producing strains)
Neisseria gonorrhoeae (including beta-lactamase-producing strains)

Spirochetes:
Borrelia burgdorferi

Cefuroxime has been shown to be active in vitro against most strains of the following microorganisms; however, the clinical significance of these findings is unknown. Cefuroxime exhibits in vitro minimum inhibitory concentrations (MICs) of 4.0 mcg/mL or less (systemic susceptible breakpoint) against most (≥90%) strains of the following microorganisms; however, the safety and effectiveness of cefuroxime in treating clinical infections due to these microorganisms have not been established in adequate and well-controlled trials.

Aerobic Gram-Positive Microorganisms:
Staphylococcus epidermidis
Staphylococcus saprophyticus
Streptococcus agalactiae

NOTE: *Listeria monocytogenes* and certain strains of enterococci, e.g., Enterococcus faecalis (formerly Streptococcus faecalis), are resistant to cefuroxime. Methicil-linresistant staphylococci are resistant to cefuroxime.

Aerobic Gram-Negative Microorganisms:
Morganella morganii
Proteus inconstans
Proteus mirabilis
Providencia rettgeri

NOTE: *Pseudomonas* spp., *Campylobacter* spp., *Acinetobacter calcoaceticus*, *Legionella* spp., and most strains of *Serratia* spp. and *Proteus vulgaris* are resistant to most first- and second-generation cephalosporins. Some strains of *Morganella morganii, Enterobacter cloacae,* and *Citrobacter* spp. have been shown by in vitro tests to be resistant to cefuroxime and other cephalosporins.

Anaerobic Microorganisms:
Peptococcus niger

NOTE: Most strains of Clostridium difficile and Bacteroides fragilis are resistant to cefuroxime.

Pharmacokinetics:
Cefuroxime axetil is absorbed from the gastrointestinal tract and is rapidly hydrolysed in the intestinal mucosa and blood to cefuroxime; absorption is enhanced in the presence of food. Peak plasma concentrations are repotted to about 2 to 3 hours after an oral dose. Up to 50% of cefuroxime in the circulations is bound to plasma proteins. The plasma half-life is about 70 minutes and is prolonged in patients with renal impairment and in neonates.

Cefuroxime is widely distributed in the body including pleural fluid, sputum, bone, synovial fluid and adequate humour, but only achieves therapeutic concentrations in the CASF when the meninges are inflamed. It crosses the placenta and has been detected in breast milk.
Cefuroxime is excreted unchanged, by glomerular filtration and renal tubular secretion, and high concentrations are achieved in the urine.

Probenicid competes for renal tubular secretion with cefuroxime resulting in higher and more prolonged plasma concentrations of cefuroxime. Small amounts of cefuroxime are excreted in bile.

Plasma concentrations are reduced by dialysis.

Food Effect on Pharmacokinetics:
Absorption of the tablet is greater when taken after food (absolute bioavailability of Cefuroxime Axetil tablets increases from 37% to 52%). Despite this difference in absorption, the clinical and bacteriologic responses of patients were independent of food intake at the time of tablet administration in 2 studies where this was assessed.

Renal Excretion:
Cefuroxime is excreted unchanged in the urine; in adults, approximately 50% of the administered dose is recovered in the urine within 12 hours. The pharmacokinetics of cefuroxime in the urine of pediatric patients have not been studied at this time. Until further data are available, the renal pharmacokinetic properties of Cefuroxime Axetil established in adults should not be extrapolated to pediatric patients.

Drug Interactions
Concomitant administration of probenecid with cefuroxime axetil tablets increases the area under the serum concentration versus time curve by 50%. The peak serum cefuroxime concentration after a 1.5-g single dose is greater when taken with 1 g of probenecid (mean= 14.8 mcg/mL) than without probenecid (mean= 12.2 mcg/mL). Drugs that reduce gastric acidity may result in a lower bioavailability of cefuroxime compared with that of fasting state and tend to cancel the effect of postprandial absorption.

In common with other antibiotics, cefuroxime axetil may affect the gut flora, leading to lower estrogen reabsorption and reduced efficacy of combined oral estrogen/progesterone contraceptives.

Adverse Effects and Precautions:
Gastrointestinal disturbances, including diarrhea, nausea, and vomiting, have occurred in some patients receiving cefuroxime axetil. There have been rare reports of erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis. Mild to moderate hearing loss has been reported in some children receiving cefuroxime for the treatment of meningitis.

In clinical trials of cefuroxime axetil, diarrhea and pseudomembranous colitis appeared to be dose-related and therefore it is recommended that higher doses should be reserved for severe infections.

Cefuroxime is considered to be unsafe in patients with porphyria although there is conflicting experimental evidence of porphyrinogenicity.

Contraindications:
Cefuroxime is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

Caution:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

"For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph"

Overdose and Treatment:
Overdosage of cephalosporins can cause cerebral irritation leading to convulsions. Serum levels of cefuroxime can be reduced by hemodialysis and peritoneal dialysis.

Availability:
500 mg film coated tablets - Alu-Alu Blister Pack x 8's (Box of 48's)

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KEEP IN COOL DRY PLACE

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