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Review Article

A Short Review on Cefuroxime Axetil Tablet

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ABSTRACT

Cefuroxime axetil is a broad-spectrum antibiotic with a simple pharmacokinetic profile. The medicine treats otitis media, pharyngitis, sinusitis, CAP, and acute exacerbations of chronic bronchitis effectively and well. Cefuroxime axetil was beneficial in intravenous/oral sequential therapy for CAP, but dosage recommendations are not accessible in some countries. Cefuroxime axetil may be used to treat community-acquired infections, including those caused by -lactamase-producing respiratory bacteria. In an era of rapidly growing bacterial resistance, empirical treatment with cefuroxime axetil may assure the proper use of newer antibacterial medicines, reducing bacterial resistance to these drugs.

Keywords: Cefuroxime axetil, Administration, Bacterial Disease, Pharmacokinetics

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INTRODUCTION

Although a variety of delivery systems are being developed for different routes of administration like the oral, parenteral, nasal, and transdermal, the oral route remains attractive for drug delivery because this mode of administration is an easy, convenient, noninvasive and familiar method of drug delivery.^[1] The common oral dosage forms include: liquid mixtures like solutions, suspensions, solid dosage forms like tablets and capsules and liquid filled capsules etc. However, patients at the extremes of age, such as children and the elderly, often experience difficulty in swallowing solid oral dosage forms. For these patients the drugs are mostly provided in liquid dosage forms such as emulsions and suspensions.^[2] These dosage forms usually lead to perceptible exposure of the active drug ingredient to taste buds and this is a very serious problem when the drug has an extremely unpleasant or bitter taste.^[3] The bitter taste of the drugs, which are orally administered, is disadvantageous in several aspects. Taste is an important parameter governing the compliance.^[4] "The worse the taste of the medication, the better the cure" was once the prevailing attitude. A change in patient attitude and development of taste masking technique has

reversed this opinion. Patients now expect and demand formulations that are pleasantly, or at least tolerably, flavoured.^[5] The disagreeable taste of drugs causes difficulties in swallowing (dysphagia) or causes patients to avoid their medication thereby resulting in low compliance of patients. Conventional taste masking techniques such as use of sweetener, amino acids, flavouring agents are often unsuccessful in masking the taste of the highly bitter drugs like quinine, barberin, antibiotics like levofloxacin, ofloxacin, sparfloxacin, ciprofloxacin, cefuroxime axetil, erythromycin, and clarithromycin. Thus taste masking technologies are considered important and developed by many researchers.^[6-9] The current work is concerned with pharmaceutical compositions containing the 1- acetoxyethyl ester of cefuroxime, which has the approved name Cefuroxime axetil. The presence of 1-acetoxyethyl esterifying group results in significant absorption of the compound from the gastro-intestinal tract, whereupon the esterifying group is hydrolysed by enzymes present to yield the antibiologically active acid. Cefuroxime axetil has therefore extended the valuable therapeutic potential of cefuroxime by making available a form of antibiotic which may be administered orally.^[10,11] A convenient means of presenting antibiotics for oral administration is in the form

of granules which may be administered as a solution or suspension.^[12] Syrups are particularly convenient for oral administration of antibiotics to children. They are particularly aimed at patients with nausea, vomiting, motion sickness and institutionalised patients. However Cefuroxime axetil has an extremely bitter taste which is long lasting and this remains a challenge^[13]

Cefuroxime Axetil Tablet

Cefuroxime axetil, a cephalosporin antibacterial medication, restricts bacterial growth by blocking penicillin-binding protein^[14] causing elongation, leakage, and cell death. In vitro, the medication is active against a wide range of Gram-positive and Gram-negative bacteria, including those associated with respiratory tract infections [e.g. *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis*, *S. pyogenes*, and MSSA].^[15]

Cefuroxime is active against penicillin-susceptible *S. pneumoniae* (MIC90 range 0.06 to 0.25 mg/L), shows some activity against intermediately susceptible *S. pneumoniae* (MIC90 range 2 to 4 mg/L), but has no activity against penicillin-resistant *S. pneumoniae* (MIC90 2 to 8 mg/L).^[16] In a recent study, cefuroxime's bactericidal activity (mean MIC90 0.25 mg/L) was equivalent to other cephalosporins.^[17] Cefuroxime axetil's MIC90 against MSSA was 2 to 4 mg/L globally. Cefuroxime is ineffective against methicillin-resistant *Staphylococcus* (including MRSA).^[18]

Cefuroxime is active against β -lactamase-positive and -negative strains of *H. influenzae* (mean MIC90 range 1 to 2 and 2 to 4 mg/L), *M. catarrhalis* (mean MIC90 2 and 0.5 mg/L), and *Neisseria gonorrhoeae* (mean MIC90 0.125 and 0.06 mg/L).^[19] Recent studies shown cefuroxime to be effective against 95% of *H. influenzae* and 99% of *M. catarrhalis*. In 2 recent studies, the drug's MIC90 against *Escherichia coli* was 4 and 8 mg/L.^[20] In a recent international survey, *E. coli* (4509 isolates) susceptibility to cefuroxime was lower than this and showed more variance, with mean MIC90 values ranging from 8 to 32 mg/L (median MIC90 16 mg/L). Cefuroxime was ineffective against *Klebsiella pneumoniae* (MIC90 16 to >16 mg/L). Cefuroxime is also ineffective against *Citrobacter* spp., *Serratia marcescens*, *Pseudomonas aeruginosa*, and *Acinetobacter* spp.^[21] Some nosocomial Enterobacteriaceae (particularly *K. pneumoniae* and *E. coli*) have developed resistance to cefuroxime and other cephalosporins by generating TEM and SHV β -lactamases. Cefuroxime is stable against *E. coli* TEM-1, TEM-2, OXA-1, and OXA-2 and SHV-1-producing *K. pneumoniae*. Pharmacodynamic/pharmacokinetic analyses suggest that the time cefuroxime concentrations are above the MIC90 for relevant pathogens (e.g., penicillin-susceptible *S. pneumoniae* isolates and β -lactamase-positive and -negative *H. influenzae* isolates)^[22] exceeds 50% of the dosage interval in most situations.

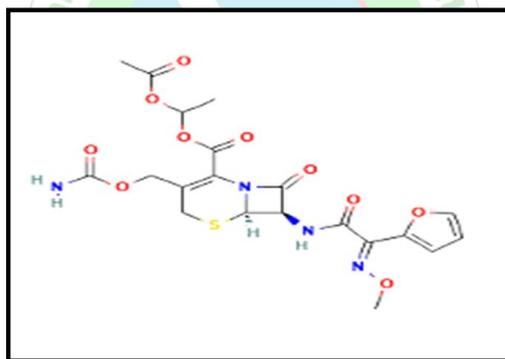


Figure: 1 Structure of Cefuroxime Axetil

Mechanism of Action

Penicillin and cefuroxime both kill bacteria.^[23] Peptidoglycan stabilises the cell wall. Gram-negative bacteria have thicker cell walls (50 to 100 molecules) than gram-positive bacteria (1 or 2 molecules). The peptidoglycan includes alternating N-acetylglucosamine and N-acetylmuramic amino sugars.^[24] Cytoplasm creates peptidoglycan precursors. A dipeptide completes the UDP-acetylmuramyl-pentapeptide synthesis (formed by racemization and condensation of L-alanine). UDP-acetylmuramyl-pentapeptide and UDP-acetylglucosamine release uridine nucleotides to form a polymer. Cross-linking requires extracellular transpeptidation. β -Lactam antibiotics decrease peptidoglycan synthesis by breaking the

lactamine $-\text{CO}-\text{N}$ link and acylating transpeptidase. β -lactams target penicillin-binding proteins. Penicillin-binding proteins synthesise peptidoglycan.^[25] Penicillin kills bacteria lytically and nonlytically. *H. influenzae*, *Neisseria meningitidis*, *Streptococcus pneumoniae*-effective. Small-scale activity targets *Escherichia coli* and *Klebsiella*. First-generation cephalosporins are weaker against staphylococci. Cefuroxime doesn't kill *Bacillus fragilis*, unlike cefoxitin, cefotetan, and cefmetazole. Cefuroxime can be given orally, intravenously, or intramuscularly to children and adults.^[26] This medicine can cure meningitis caused by susceptible organisms, however cerebrospinal fluid concentrations are barely 10% of plasma. The most usually prescribed antibiotic, ceftriaxone, is better.

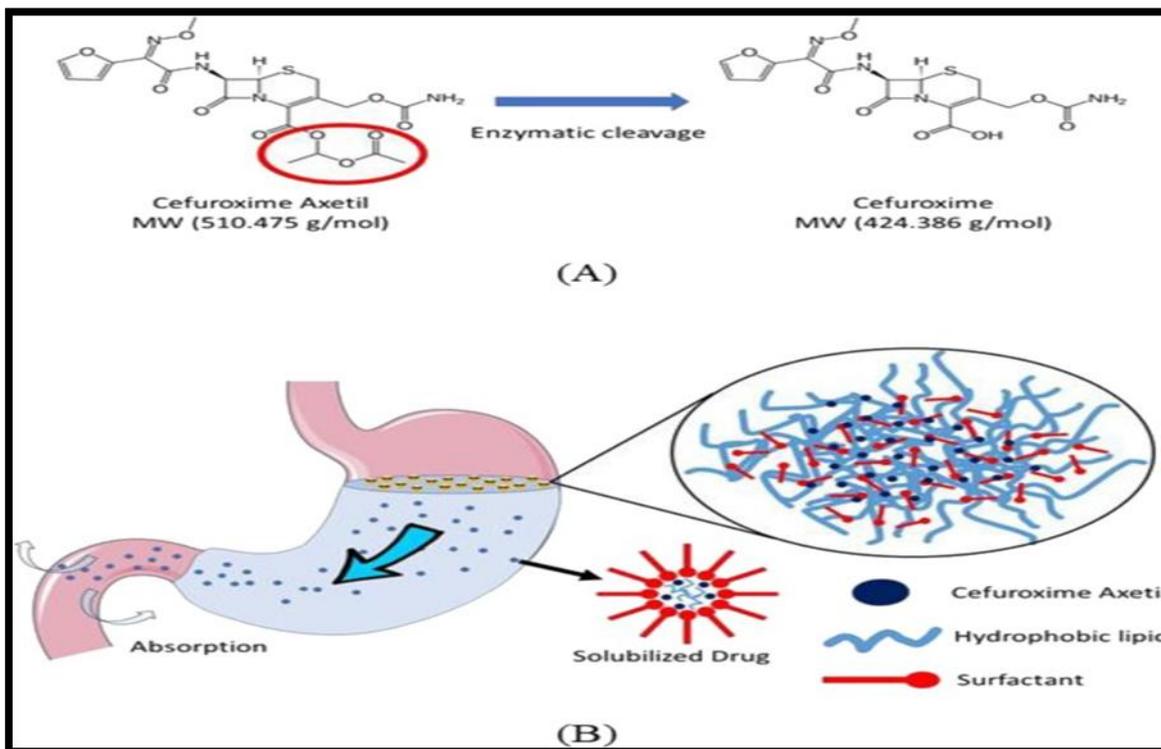


Figure: 2 Mechanism of Action

Pharmacokinetics of Cefuroxime Axetil

Children's pharmacokinetics of cefuroxime axetil suspension are similar to tablets. Cefuroxime axetil solution is less bioavailable than the tablet formulation, although the C_{max} in paediatric patients receiving a 10- or 15-mg/kg dose is equivalent to the C_{max} obtained for adults receiving a single 250-mg tablet. 20 mg/kg of cefuroxime axetil suspension is similar to a 500 mg tablet for adults. Our kids on 15 or 20 mg/kg cefuroxime axetil suspension had a C_{max} similar to those on broken tablets in 85% sucrose⁽²⁷⁾. C_{max} and AUC rose correspondingly over 10-20 mg/kg. This is like adult cefuroxime axetil tablets. Twelve healthy people took 125, 250, 500, and 1,000 mg of cefuroxime axetil after a meal (3). Cefuroxime axetil dose affects C_{max} linearly. Finn et al. (3) found that meals improved cefuroxime axetil absorption^{[28][29]}. Based on this facts, we chose to give cefuroxime axetil with milk or formula. Cefuroxime's MIC for 90% of 3-lactamase-positive *Haemophilus influenzae* and *Moraxella (Branhamella) catarrhalis* strains is 1.0 g/ml, while 90% of tested respiratory strains are below this dosage.^[30] Serum cefuroxime concentrations exceeding 1 ug/ml rose with dosage. Regardless of dose, cefuroxime's $t_{1/2}$ was 1.4 to 1.9 h. This is longer than the $t_{1/2}$ s of cefaclor (42.5 min), cephalexin (0.98 h), and cephadrine (1.0 h) in paediatric patients and the mean $t_{1/2}$ (1.1 to 1.4 h) for children receiving crushed cefuroxime axetil tablets^[31]. Infants and children with otitis media and group A streptococcal pharyngitis take cefuroxime axetil twice daily. 10- or 15-mg/kg doses of cefuroxime axetil suspension yield serum cefuroxime concentrations similar to a 250-mg tablet, hence it may be useful twice day. Clinical studies show that twice-daily cefuroxime axetil suspension is helpful in healthy adults with mild to moderate infections caused by sensitive microorganisms^[32]. Infants and children's blood lacked complete cefuroxime axetil. Cefuroxime axetil is hydrolyzed

to cefuroxime quickly. Four kids' urine had intact cefuroxime axetil, although less than 0.1% of the dose. In children, cefuroxime axetil hydrolysis is fast, with little prodrug excreted unchanged. Unlike cefuroxime axetil, some antibiotic prodrugs are removed by the kidneys. In newborns and toddlers, chloramphenicol bioavailability after intravenous succinate varied.^[33] 7 to 42% of the dose was unaltered chloramphenicol succinate.

Dosage and administration

Upper and lower respiratory infections produced by susceptible bacteria last 7 to 10 days. Cefuroxime axetil is food-absorbable. Cefuroxime axetil needs greater CAP (usually 500mg twice daily).^[34] US prescribing information lacks intravenous/oral cefuroxime axetil dosage. AECB patients in the UK receive intravenous or intramuscular cefuroxime 750mg twice daily for 2 to 3 days, then oral cefuroxime axetil 500mg twice daily for 7 days.^[35] 1.5g twice-daily cefuroxime is followed by 500mg cefuroxime axetil for 7 days. 1g cefuroxime cures gonorrhoea. 500 mg twice a day for 20 days is recommended for early Lyme. In the UK, the recommended dosage of cefuroxime axetil tablet and suspension formulations for children aged 3 months with upper respiratory tract infections r impetigo is 125mg and 10 mg/kg twice daily, respectively; patients aged 2years with acute otitis media may require a higher dosage (usually 250mg and 15 mg/kg twice daily, respectively).^[36] In the US, the recommended dosage for children >3 months with pharyngitis/tonsillitis is 125mg and 10 mg/kg twice daily in tablet and suspension forms; for acute otitis media, acute maxillary sinusitis, or impetigo, it's 250mg and 15 mg/kg twice daily. No treatment guidelines exist for Cefuroxime axetil in 3-month-olds.^[37]

Clinical Applications

Even with the advent of advanced surgical procedures, SSIs remain a major postoperative complication. In this article, the evidence supporting use of cefuroxime is restricted to general surgery and limited to gastrointestinal, abdominal and urological surgeries.

Gastro-intestinal Surgery

A randomized study evaluating antibiotic effect of cefuroxime in 150 patients undergoing elective gastrointestinal surgery showed that a single preoperative dose of cefuroxime without addition of metronidazole can significantly reduce wound sepsis after surgeries involving the upper gastrointestinal tract.^[38] However, the microbiological flora in the large bowel is predominantly anaerobic and in recto-colonic surgery metronidazole is undeniably more effective compared to cefuroxime. In line with the above study, a prospective randomized controlled trial (RCT) in patients undergoing gastric surgery compared single-dose systemic cefuroxime or intra-incisional cefuroxime versus a control group.^[39] In this study, approximately 7% of the patients who received systemic cefuroxime developed wound sepsis with no cases of abscess or septicemia compared to those with intra-incisional cefuroxime (4% wound sepsis, 19% abscess and 4% septicemia) and control (35% wound sepsis, 29% abscess and 21% septicemia). Another randomized study demonstrated that administration of 1.5 g cefuroxime i.v. was effective in reducing wound sepsis following biliary surgery.^[40] Further, a randomized, controlled, double-blind multicenter trial compared the prophylactic effect of a two-dose regimen of cefuroxime in patients undergoing biliary surgery who had a high risk of infection. No significant difference was found between one- and three-dose cefuroxime regimens in preventing postoperative wound infection.^[41] Overall, data showed that one dose of short-acting agent preoperatively is as effective as a three-dose regimen to prevent major wound infections after biliary surgery. A prospective, randomized, double-blind study was undertaken to compare the prophylactic efficacy of ciprofloxacin and cefuroxime in 155 patients undergoing elective cholecystectomy. In this study, patients were randomly assigned to prophylactic cefuroxime, no antibiotic, prophylactic ciprofloxacin, or postoperative ciprofloxacin.^[42,43,44]

Abdominal surgery

In a double-blind, placebo-controlled, RCT, the efficacy of a pre-operative single dose of cefuroxime (1.5 g) was assessed in 1234 patients for the prevention of SSIs after surgery for herniated disc over a 6-month period. Eight (1.3%) patients in the cefuroxime group and 18 patients (2.8%) in the placebo group developed SSIs ($p=0.073$). A diagnosis of spondylodiscitis or epidural abscess was made in 9 patients in the placebo group, but none in the cefuroxime group.^{[45][46]}

Urological surgery

Prophylactic antibacterial therapy is recommended for urethral catheterization, endoscopy of the urinary tract, prostate biopsy, transurethral surgery, and selected open urologic procedures. 48 Most often, broad-spectrum cephalosporins and penicillins are used in these

surgeries.^[47] A systematic review including 28 trials comprising 4694 patients showed that prophylactic antibiotics significantly reduced the incidence of bacteriuria post-transurethral resection of prostate (RR: -0.17 [95% CI -0.20, -0.15]), high fever (-0.11 [-0.15, -0.06]), bacteremia (-0.02 [-0.04, 0.00]) and additional antibiotic treatment (-0.20 [-0.28, -0.11]). A RCT compared sulbactam-ampicillin and cefuroxime for prophylaxis of percutaneous nephrolithotomy and assessing optimal regimen for antibiotic maintenance to prevent systemic inflammatory response syndrome (SIRS). Incidence of SIRS was similar in sulbactam/ampicillin and cefuroxime groups (43.3% vs. 56.7%; $p=0.44$).^[48] Further, a prospective randomized study in patients starting peritoneal dialysis showed no microbial growth in dialysis fluid during the postoperative period in patients who received prophylactic treatment of 1.5 g i.v. pre- and 250 mg i.p. perioperative cefuroxime compared to the control (no prophylactic antibiotic) group (30%, $p=0.021$).^[49,50]

CONCLUSIONS

Cefuroxime axetil is a broad spectrum 13-lactam antibiotic. It has many approved indications, however, it is considered a second-line alternative. It is not the drug of choice for any infection, particularly those encountered in the field of obstetrics and gynecology. It is safe to use in pregnancy and has a low adverse effect profile, but due to its excessive acquisition cost and better therapeutic alternatives, it should be reserved for select cases.

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