ZINEX

Tablets

Composition

Each tablet contains Cefuroxime (as axetil) 250 or 500 mg

Action

Cefuroxime axetil owes its bactericidal activity to the parent compound cefuroxime. Cefuroxime is a well-characterized and effective antibacterial agent that has bactericidal activity against a wide range of common pathogens, including β-lactamase producing strains.

Cefuroxime has good stability to bacterial β-lactamase, and consequently is active against many ampicillin-resistant or amoxycillin-resistant strains. The bactericidal action of cefuroxime results from inhibition of cell wall synthesis by binding to essential target proteins.

Cefuroxime is usually active against the following organisms:

Aerobes Gram-negative

- *Haemophilus influenzae (including ampicillin-resistant strains)*
- *Haemophilus parainfluenzae*
- *Moraxella (Branhamella) catarrhalis*
- *Neisseria gonorrhoeae (including penicillinase and non- penicillinase producing strains)*
- *Escherichia coli*
- *Klebsiella spp.*
- *Proteus mirabilis*
- *Providencia spp.*
- *Proteus rettgeri.*

Aerobes Gram-positive

- *Staphylococcus aureus* and *Staphylococcus epidermidis* (including penicillinase producing strains but excluding methicillin resistant strains)
- *Streptococcus pyogenes* (and other β-haemolytic streptococci)
- *Streptococcus pneumoniae*
- Streptococcus Group B (Streptococcus agalactiae)

Anaerobes

- Gram-positive and Gram-negative cocci (including Peptococcus and Peptostreptococcus species)
- Gram-positive bacilli (including Clostridium species) and Gram- negative bacilli (including Bacteroides and Fusobacterium species)
- Propionibacterium spp.

Other organisms

- *Borrelia burgdorferi*

The following organisms are not susceptible to Cefuroxime:-

- *Clostridium difficile*
- *Pseudomonas spp.*
- *Campylobacter spp.*
- *Acinetobacter calcoaceticus*
- *Listeria monocytogenes*
- Methicillin resistant strains of Staphylococcus aureus and Staphylococcus epidermidis.
- *Legionella spp.*

Some strains of the following genera are not susceptible to Cefuroxime:-

- Enterococcus (Streptococcus) faecalis
- *Morganella morganii*

- *Proteus vulgaris*
- Enterobacter spp.
- Citrobacter spp.
- Serratia spp.
- *Bacteroides fragilis.*

Pharmacokinetics
Cefuroxime axetil is an oral prodrug of Cefuroxime. After oral absorption, Cefuroxime axetil is hydrolyzed in the intestinal mucosa and blood to release Cefuroxime into the plasma. Oral absorption is optimal when administered with food. Peak serum levels of cefuroxime occur approximately 2 to 3 hours after oral dosing, when taken with food. Protein binding is approximately 33% to 50%. Cefuroxime is not metabolized and is excreted unchanged in the urine by glomerular filtration and tubular secretion. The elimination half-life is between 1 and 1,5 hours after oral dosing. The elimination half-life is prolonged with renal impairment. Serum levels of Cefuroxime are reduced by dialysis.

Indications

Zinex is indicated for the treatment of infections caused by susceptible strains of the following organisms in the following infections:

- Pharyngitis and tonsillitis caused by *Streptococcus pyogenes*.
- Otitis media caused by *Streptococcus pneumoniae, Haemophilus influenza* (ampicillin- sensitive and resistant strains), *Moraxella (Branhamella) catarrhalis* and *Streptococcus pyogenes.*
- Sinusitis caused by *Streptococcus pneumoniae* and *Haemophilus influenza*.
- Acute and chronic bronchitis caused by *Streptococcus pneumoniae*, *Haemophilus influenza* (ampicillin-sensitive strains) and *Haemophilus parainfluenzae* (ampicillin-sensitive strains).
- Acute uncomplicated cystitis caused by *Escherichia coli* and *Klebsiella pneumoniae.*
- Lyme disease caused by *Borrelia burgdorferi*.

Contraindications

- Hypersensitivity to cephalosporin antibiotics or to any components of the formulation.
- Hypersensitivity to penicillin and other beta-lactam antibiotics.

Warnings

Cefuroxime should be used with caution in patients with:

- A history of gastrointestinal disease, especially ulcerative colitis, regional enteritis or pseudomembranous colitis.
- Renal function impairment - A reduced dose may be required.
- Porphyria: Safety has not been established.

Pseudomembranous colitis may occur. Patients who develop abdominal or stomach cramps, abdominal tenderness, severe and watery diarrhea (which may be bloody) and fever, should be investigated for this diagnosis. If the diagnosis of pseudomembranous colitis is suspected, Cefuroxime should be stopped immediately and appropriate therapy initiated.

Adverse Reactions

Hematological: Eosinophilia

Neurological: Headache

Gastrointestinal: Nausea, vomiting, abdominal pain, diarrhea, in some cases accompanied by blood in stools, which may be a symptom of enterocolitis. A particular form of enterocolitis is pseudomembranous colitis .

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

Precautions

Prolonged use of Cefuroxime may result in the overgrowth of non-susceptible organisms (e.g. Candida, Enterococci, or Clostridium difficile).
Pseudomembranous colitis has been reported with the use of Cefuroxime. Patients who develop abdominal or stomach cramps, abdominal tenderness, severe and watery diarrhea (which may be bloody) and fever should be investigated for this diagnosis.
The Jarisch-Herxheimer reaction has been reported following treatment with Cefuroxime for Lyme disease. This reaction is a common and usually self-limiting consequence of antibiotic treatment for Lyme disease.

Pregnancy
Category B
Safety and efficacy in pregnancy and lactation have not been established.

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

Drug Interactions

Concurrent administration of probenecid increases the area under the mean serum concentration time-curve by 50%.

Diagnostic Interference
It is recommended that glucose either oxidase or hexokinase methods be used to determine blood/plasma glucose levels in patients receiving Cefuroxime.
This medicine may give false-negative test results with ferricyanide blood glucose test. Cefuroxime does not interfere in the alkaline picrate assay for creatinine.
A false-positive Coombs reaction may appear in patients who receive large doses of Cefuroxime.

Dosage and Administration

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 Zinex in children under 3 months of age.
3 months to 2 years of age: 125 mg twice daily
Over 2 years of age: 250 mg twice daily

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

Over Dosage

Overdosage of cephalosporins can cause cerebral irritation leading to convulsions.

Serum levels of cefuroxime can be reduced by haemodialysis or peritoneal dialysis.

Presentation

Zinex 250
Box of 10 tablets

Zinex 500
Box of 10 tablets