

# ZENON<sup>®</sup>



**cefuroxime axetil**  
**Broad – spectrum, bactericidal cephalosporin**

### PHARMACEUTICAL PRESENTATIONS:

**Zenon 125mg / Zenon 250mg - Granules for oral suspension.**  
**Zenon 250 / Zenon 500 - Tablets.**

### COMPOSITION:

#### Suspension:

**Zenon 125mg-** each 5 ml of suspension prepared as directed contains:  
cefuroxime 125 mg ( as cefuroxime axetil ).  
**Zenon 250mg-** each 5 ml of suspension prepared as directed contains:  
cefuroxime 250 mg ( as cefuroxime axetil ).

#### Tablet:

**Zenon 250** – each tablet contains: cefuroxime 250mg  
(as cefuroxime axetil).  
**Zenon 500** – each tablet contains: cefuroxime 500mg  
(as cefuroxime axetil).

### PROPERTIES:

**cefuroxime** axetil is an oral prodrug of bactericidal cephalosporin antibiotic, cefuroxime, which is resistant to most beta-lactamases and is active against a wide range of gram-positive and gram-negative bacteria. Cefuroxime axetil is characterized by being the only second generation cephalosporin adequately penetrates into cerebrospinal fluid. After oral administration, cefuroxime axetil is absorbed from gastrointestinal tract and rapidly hydrolyzed in the intestinal mucosa and blood to release cefuroxime into the circulation. Optimum absorption occurs when it is administered after a meal. Peak serum concentration of cefuroxime occurs after 2-3 hours of oral administration. The serum half-life about 1-2 hours. Approximately 50% of serum cefuroxime is protein bound. Cefuroxime is not metabolized 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 level of cefuroxime are reduced by dialysis.

### MICROBIOLOGY:

**Zenon** has bactericidal activity against a wide range of common pathogens, including many beta-lactamases producing strains. **Zenon** is stable to many bacterial beta-lactamases. **Zenon** is active against most strains of the following microorganism both *in vitro* and in clinical infections:

#### Aerobic, Gram – positive microorganisms:

*Staphylococcus aureus* (including beta-lactamase-producing strains)  
*Streptococcus pneumoniae*  
*Streptococcus Group B* (*Streptococcus agalactiae*)

#### Aerobic, Gram – negative microorganisms:

*Escherichia coli*  
*Haemophilus parainfluenzae*  
*Klebsiella pneumoniae*  
*Moraxella catarrhalis* (including beta-lactamase producing strains)  
*Neisseria gonorrhoeae* (including beta-lactamase-producing strains)

#### Anaerobic microorganisms:

Anaerobic Gram-positive and Gram-negative cocci (including *Peptococcus gonorrhoeae*), and anaerobic Gram-positive bacilli (including *Clostridium* spp) and Gram- negative bacilli (including *Bacteroides* and *Fusobacterium* spp).

### INDICATIONS:

**Zenon** is effective in treating a wide range of infections due to its broad spectrum activity.

#### Indications include:

- Ear, nose and throat infections including otitis media, sinusitis and tonsillitis.
- Respiratory tract infections (upper and lower) including pharyngitis, bronchitis and bacterial pneumonia.
- Skin and soft tissue infections: furunculosis, pyoderma and impetigo.
- Genito-urinary tract infections: pyelonephritis, cystitis, and urethritis.
- Un complicated endocervical and urethral gonorrhoea.

### DOSAGE AND ADMINISTRATION:

#### Adults:

- Most infection will respond to 250mg twice daily, in a mild to moderate lower respiratory tract infections.

For more severe lower respiratory tract infection or if pneumonia is suspected then 500mg twice daily is recommended.

#### Children:

The usual dose is 125mg twice daily. For **2 years or older** with Otitis Media; dose is 250mg twice daily to a maximum of 500 mg daily.

- **Zenon** tablet should not be crushed, which is unsuitable for children under 5 years of age.
- **Zenon** should be taken after food to reach optimum absorption.
- **Zenon Suspension: Directions for constituting suspensions in bottles:**
- Shake the bottle to loosen dry granules, add water as directed on the label and replace the cap. Invert and shake granules down into water using a rocking action, continue to shake the bottle until the suspension is well dispersed, which will bring the volume of suspension to red arrow mark on the label.

### CONTRA-INDICATIONS:

Hypersensitivity to cephalosporin antibiotics.

### DRUG INTERACTIONS:

It is recommended that either the glucose oxidase or hexokinase methods are used to determine the blood/plasma glucose levels in patients receiving cefuroxime axetil. This antibiotic does not interfere in the alkaline picrate assay for creatinine.

### PRECAUTIONS:

Caution should be exercised in patient receiving concurrent treatment with potent diuretics. Cephalosporin antibiotics, should be prescribed with caution to patients who have experienced an anaphylactic reaction to penicillins.  
**Pregnancy:** cefuroxime is not known to be harmful during pregnancy, should be administered with caution during the early months of pregnancy.  
**Lactation:** cefuroxime is excreted in breast milk usually in low concentration.  
**Paediatrics:** As such no paediatric specific problems have been reported.  
**Geriatrics:** As such no geriatric specific problems have been reported.

### SIDE EFFECTS:

Adverse reactions of cefuroxime axetil have generally been mild and transient in nature. As with other cephalosporins, there have been rare reports of interstitial nephritis, 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.

Gastrointestinal disturbances including diarrhea, nausea and vomiting have been reported. Diarrhea, although uncommon, is more likely to be associated with higher doses.

As with other broad-spectrum antibiotics, there have been occasional reports of pseudomembranous colitis.

Headache has also been reported.

There have been rare reports of thrombocytopenia and leucopenia.

Eosinophilia and transient increases of hepatic enzyme levels [ALT (SGPT), AST, (SGOT) and LDH] have noted during **Zenon** therapy.

Cephalosporins as a class tend to be absorbed on to the surface of red-cell membranes and react with antibodies directed against the drug to produce a positive Coombs test (which can interfere with cross matching of blood) and very rarely haemolytic anemia.

### OVER DOSAGE:

Over dosage of cephalosporin's can cause cerebral irritancy leading to convulsions. Serum levels of cefuroxime can be reduced by haemodialysis or peritoneal dialysis.

### PACKAGING PRESENTATIONS:

**Zenon 250 & 500 Tablets** : Pack of 10 tablets.  
**Zenon 125mg Suspension** : Granules for 100ml.  
**Zenon 250mg Suspension** : Granules for 50ml.

### STORAGE CONDITIONS:

- Store below 25°C.
- The reconstituted suspension can be kept up to 14 days, store in refrigerator between 2 & 8°C.
- Do not use after the expiry date stated on the label.
- Do not use if there is any physical change on product.
- Keep out of reach of children.

### THIS IS A MEDICAMENT

Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you. Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers  
Union of Arab Pharmacists

Mfd. by:

**MEDPHARMA**  
PHARMA. & CHEM. IND'S (L.L.C.)  
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