CEFUZIME

Broad-Spectrum, Bactericidal Cephalosporin Film-Coated Tablets and Granules for Oral Suspension

Composition

Film-Coated Tablets

Each tablet contains:

Active ingredient: Cefuroxime 125mg, 250mg, or 500mg as cefuroxime axetil.

Excipients: Sodium lauryl sulphate, croscarmellose, kollidon, cellulose, aerosil, cross linked starch, polyethylene glycol, hypromellose, titanium dioxide, and talc.

Suspension

Each 5mL of the reconstituted suspension contains:

Active ingredient: Cefuroxime 125mg as cefuroxime axetil.

Excipients: Sucrose, polyvinyl pyrrolidine, and mixed flavours.

Properties

Cefuroxime axetil, the active ingredient of **Cefuzime**, is a broad-spectrum bactericidal belonging to the second generation cephalosporins. **Cefuzime** is resistant to most beta-lactamases and is active against a wide range of Gram-positive and Gram-negative bacteria. Cefuroxime is characterized by being the only second generation cephalosporin that adequately penetrates into the cerebrospinal fluid.

After oral administration, cefuroxime axetil is absorbed from the 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 cefuroxime levels occur approximately 2 - 3 hours after oral dosing. The serum half-life is 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 levels of cefuroxime are reduced by dialysis.

Microbiology

Cefuzime is highly stable to beta-lactamases produced by both Gram-positive and Gram-negative organisms. It shows more activity against *Haemophilus influenzae* and *Nisseria gonorrheae*.

Cefuzime is usually active against the following organisms *in vitro:*

Aerobic, Gram-positive bacteria

Penicillinase-producing strains of *Staphylococcus aureus* and *Staphylococcus epidermidis, streptococcus pneumoniae, Streptococcus agalactiae,* and other beta-haemolytic *Streptococci,* excluding *Streptococcus faecalis.*

Aerobic, Gram-negative bacteria

Haemophilus influenzae, Neisseria (including *Neisseria meningitidis* and *Neisseria gonorrhoeae*), *Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis* and other indole-positive *Proteus* spp., *Enterobacter* spp., *Serratia,* and *Moraxella catarrhalis.*

Anaerobes

Anaerobic Gram-positive and Gram-negative cocci (including *Peptococcus* and *Peptostreptococcus* spp.), anaerobic Gram-positive bacilli (including *Clostridium* spp.) and Gram-negative bacilli (including *Bacteroides* and *Fusobacterium* spp.). Most strains of *Bacteroides fragilis* are resistant.

Indications

Cefuzime is effective in treating a wide range of infections due to susceptible Gram-positive and Gram-negative bacteria. Due to its broad-spectrum activity, **Cefuzime** may be indicated even before the infecting organism has been identified. Indications include:

- Ear, nose, and throat infections including otitis media, sinusitis, and tonsillitis.
- Respiratory tract infections (upper and lower) including pharyngitis, acute and chronic bronchitis, and bacterial pneumonia.
- Skin and soft-tissue infections such as furunculosis, pyoderma, and impetigo.
- Uncomplicated urinary tract infections, which do not respond to other drugs or which occur in pregnancy.
- Uncomplicated endocervical and urethral gonorrhea.
- Treatment of Lyme disease.

Dosage

Adults and children above 12 years:

- Most infections including mild to moderate lower respiratory tract infections (e.g. bronchitis) will respond to 250mg twice daily.
- More severe lower respiratory tract infections, or if pneumonia is suspected then 500mg twice daily is recommended.
- Urinary tract infections, a dose of 125mg twice daily is usually adequate; in pyelonephritis the recommended dose is 250mg twice daily.
- Uncomplicated gonorrhea, a single dose of 1g is usually recommended.
- Lyme disease, the recommended dose is 500mg twice daily for 20 days.

Children 3 months - 12 years:

- The usual recommended dose is 125mg twice daily.

- In otitis media, the dose may be doubled in children above 2 years of age, if necessary, to 250mg twice daily.

Notes:

- The usual course of the treatment is 5 - 10 days.
- **Cefuzime** should be taken after food to reach the optimum absorption.
- **Cefuzime** tablets should not be chewed or crushed.
- **Directions for reconstituting the oral suspension:** Shake bottle well to loosen the granules. Fill the measuring cup to the line with 20mL water. Add water to the bottle in one go and replace the cap. Invert bottle and shake well to obtain a smooth suspension.

If you miss a dose

- Take the medicine as soon as you remember.
- If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose.
- Do not take two doses at one time.

Contraindications

Hypersensitivity to cephalosporin antibiotics as well as in patients with porphyria.

Precautions

Caution should be exercised in patients having a history of hypersensitivity to penicillins as well as in those suffering from renal impairment.

Cefuroxime may cause false positive results for urinary glucose (if tested for reducing substances) and may cause false positive Coombs' test in some patients.

Pregnancy: Cefuroxime is not known to be harmful during pregnancy but, as with other drugs, it is better to be administered with caution during the early months of pregnancy.

Lactation: Cefuroxime is excreted in breast milk, usually in low concentration. However, problems in humans have not been documented to date.

Paediatrics: No paediatrics-specific problems have been documented to date.

Geriatrics: No geriatrics-specific problems have been documented to date. However, elderly patients are more likely to have an age-related decrease in renal function, which may require an adjustment of dosage and/or dosing interval in patients receiving cephalosporins.

Side Effects

Adverse reactions to cefuroxime have occurred relatively infrequent and they are generally mild and transient in nature. Headache and gastrointestinal disturbances such as nausea, vomiting, and abdominal discomfort may be experienced. Diarrhoea and rarely antibiotic-associated colitis may occur with high doses.

Occasionally, cefuroxime may lead to allergic reactions including rashes, pruritus, urticaria, serum sickness-like reactions with rashes, fever and arthralgia, and anaphylaxis.

Rarely, erythema multiforme and toxic epidermal necrolysis have been reported.

As with other broad-spectrum antibiotics, prolonged use may result in overgrowth of non-susceptible organisms, e.g., *Candida* and *Enterococci* which may require interruption of treatment.

Less frequent side effects may include eosinophilia and blood disorders including thrombocytopenia, leucopenia, agranulocytosis, aplastic anaemia, and haemolytic anaemia.

Very rarely; reversible interstitial nephritis, hyperactivity, nervousness, sleep disturbances, confusion, hypertonia, dizziness, disturbances in liver enzymes, transient hepatitis, and cholestatic jaundice have been reported.

Overdosage

Since there is no specific antidote, treatment of cefuroxime overdose should be symptomatic and supportive. Serum levels of cefuroxime can be reduced by haemodialysis and peritoneal dialysis

Drug Interactions

Probenecid may reduce the renal excretion of cefuroxime, thereby increasing its plasma concentration.

Presentations

Cefuzime film-coated tablets: Pack of 10 tablets.

Cefuzime suspension: Granules for oral suspension in 50mL bottle.

* *Store at a temperature of 15-25°C. Keep the tablets in a dry place. After reconstitution, store the suspension in the refrigerator.*

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 for you.**
- **Do not repeat the same prescription without consulting your doctor.**
- **Keep all medicaments out of reach of the children**

Council of Arab Health Minister,
Union of Arab Pharmacists

***Any information? Call Our Toll Free No.* (971) 800-4994**

Produced by: *julphar*
Gulf Pharmaceutical Industries,
Ras Al Khaimah, U. A. E.

21/08/2002