Cefuzime

Broad-spectrum, bactericidal cephalosporin for parenteral use

Composition

1 vial contains sterile cefuroxime sodium equivalent to 500mg or 750mg cefuroxime.

Cefuroxime is a white to faintly yellow powder. When appropriately prepared, the intramuscular suspension appears off-white while the intravenous solution is yellowish. Variations in the intensity of this color do not indicate any change in either the efficacy or safety of the product.

Properties

Cefuzime contains cefuroxime, a broad-spectrum bactericidal cephalosporin belonging to the second generation. **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 adequately penetrates into the cerebrospinal fluid.

Microbiology

Cefuzime is highly active against *Staphylococcus aureus*, including strains which are resistant to penicillin (but not the rare methicillin resistant strains), *Staph. epidermidis, Haemophilus influenzae, Klebsiella* spp., *Enterobacter* spp., *Streptococcus* pyogenes, *Escherichia coli, Str. mitis* (viridans group), *Clostridium* spp., *Proteus mirabilis, Pr. rettgeri, Salmonella typhi, S. typhimurium* and other *Salmonella* spp., *Shigella* spp., *Neisseria* spp., (including ß-lactamase producing strains of *N. gonorrhoeae*) and *Bordetella pertussis*. It is also moderately active against strains of *Pr. vulgaris, Pr. morganii* and *Bacteroides fragilis*.

In vitro the activities of **Cefuzime** and aminoglycoside antibiotics in combination have been shown to be at least additive with occasional evidence of synergy.

Indications

Cefuzime is effective in treating a wide range of infections due to susceptible microorganisms. Due to its broad-spectrum activity, **Cefuzime** may be indicated even before the infecting organism has been identified.

In addition, it is an effective prophylactic against post-operative infection in a variety of operations.

Usually **Cefuzime** will be effective alone, but when appropriate it may be used in combination with an aminoglycoside antibiotic, or in conjunction with metronidazole (orally or by suppository or injection), especially for prophylaxis in colonic surgery.

Indications include:

- Respiratory tract infections: e.g., acute and chronic bronchitis, infected bronchiectasis, bacterial pneumonia, lung abscess and post-operative chest infections.
- Ear, nose and throat infections: e.g., sinusitis, tonsillitis and pharyngitis.
- Urinary tract infections: e.g., acute and chronic pyelonephritis, cystitis and asymptomatic bacteriuria.
- Soft-tissue infections: e.g., cellulitis, erysipelas, peritonitis and wound infections.
- Bone and joint infections: e.g., osteomyelitis and septic arthritis.
- Obstetric and gynaecological infections and pelvic inflammatory diseases.
- Gonorrhoea particularly when penicillin is unsuitable.
- Other infections including septicaemia and meningitis.
- Prophylaxis against infection in abdominal, pelvic, orthopaedic, cardiac, pulmonary, oesophageal and vascular surgery where there is increased risk from infection.

Dosage and Administration

General Dosage recommendations:

Adults: Many infections will respond to 750mg t.d.s. by i.m. or i.v. injections. For more severe infections, this dose should be increased to 1.5g t.d.s i.v. The dosage interval of i.m. or i.v. injections can be increased to six-hourly if necessary, giving total doses of 3g to 6g daily.

Infants and children: Doses of 30 to 100mg/kg/day given as three or four divided doses. A dose of 60mg/kg/day will be appropriate for most infections.

Neonates: Doses of 30 to 100mg/kg/day given as two or three divided doses. In the first weeks of life the serum half-life of cefuroxime can be three to five times that in adults.

Other recommendations:

Gonorrhoea: 1.5g should be given as a single dose. This may be given as 750mg x 2 injections into different sides, e.g. each buttock.

Meningitis: Cefuzime is suitable for sole therapy of bacterial meningitis due to sensitive strains. The following dosages are recommended:

- ***Infants and children***: 200 to 240mg/kg/day i.v. in 3 or 4 divided doses. This dosage may be reduced to 100mg/kg/day i.v. after 3 days or when clinical improvement occurs.
- ***Neonates:*** The initial dosage should be 100mg/kg/day i.v. A reduction to 50mg/kg/day i.v. may be made when clinically indicated.
- ***Adults:*** 3g i.v. every 8 hours.

Prophylaxis: The usual dose is 1.5g i.v. with induction of anaesthesia for abdominal, pelvic and orthopaedic operations, but may be supplemented with two 750mg i.m. doses 8 and 16 hours later.

In cardiac, pulmonary, oesophageal and vascular operations, the usual dose is 1.5g i.v. with induction of anaesthesia continuing with 750mg i.m. t.d.s. for a further 24 to 48 hours.

In total joint replacement, 1.5g cefuroxime powder may be mixed dry with each pack of methyl methacrylate cement monomer before adding the liquid polymer.

Dosage in impaired renal function: Cefuroxime is excreted by the kidneys. Therefore, as with all such antibiotics, in patients with markedly impaired renal function it is recommended that the dosage of **Cefuzime** should be reduced to compensate for its slower excretion. However, it is not necessary to reduce the dose until the creatinine clearance falls below 20ml/min.

In adults with marked impairment (creatinine clearance 10 - 20 ml/min) 750mg b.d. is recommended and with severe impairment (creatinine clearance < 10ml/min) 750mg once daily is adequate.

For patients on dialysis a further 750mg dose should be given at the end of each dialysis. When continuous peritoneal dialysis is being used, a suitable dosage is usually 750mg twice daily.

Reconstitution and Administration

Intramuscular: Add 2ml or 3ml Water for Injections to 500mg or 750mg **Cefuzime**, respectively. Shake gently to produce an opaque suspension.

Intravenous: Dissolve **Cefuzime** in Water for Injection using at least 6ml for 500mg or 8ml for 750mg. For short intravenous infusion (e.g. up to 30 minutes), 750mg may be dissolved in 50ml Water for Injections. These solutions may be given directly into the vein or introduced into the tubing of the giving set if the patient is receiving parenteral fluids.

Stability in IV Fluids:

Cefuzime is compatible with the more commonly used intravenous infusion fluids. It will retain potency for up to 24 hours at room temperature in Sodium Chloride injection BP 0.9% w/v, 5% Dextrose Injection BP, 0.18% w/v Sodium

Chloride plus 4% Dextrose Injection BP and Compound Sodium Lactate Injection BP (Hartmann's solution).
The pH of 2.74% w/v Sodium Bicarbonate Injection BP considerably affects the color of the solution and therefore this solution is not recommended for the dilution of **Cefuzime**. However, if required, for patients receiving Sodium Bicarbonate Injection BP by infusion, **Cefuzime** may be introduced into the tube of the giving set.
The stability of **Cefuzime** in Sodium Chloride Injection BP 0.9% w/v and 5% Dextrose Injection is not affected by the presence of hydrocortisone sodium phosphate.
Cefuzime is also compatible with aqueous solutions containing up to 1% lignocaine hydrochloride.
Suspensions of **Cefuzime** for intramuscular injection and aqueous solutions for direct intravenous injection retain their potency for five hours if kept below 25°C and for 48 hours if refrigerated. More diluted solutions, i.e. 750mg plus 50ml Water for Injections, retain satisfactory potency for 24 hours if kept below 25°C and for 72 hours if refrigerated.
Cefuzime (5mg/ml) in 5% w/v or 10% w/v xylitol injection may be stored for up to 24 hours at 25°C.
750mg **Cefuzime** constituted with 8ml Water for Injections may be added to metronidazole injection (500mg/100ml) and both retain their activity for up to 24 hours below 25°C. 750mg **Cefuzime** is compatible with azlocillin 1g (in 8ml) or 5g (in 50ml) for up to 24 hours at 4°C or 6 hours below 25°C.

Contraindications
Hypersensitivity to cephalosporin antibiotics.

Precautions
Cephalosporin antibiotics may in general be given safely to patients who are hypersensitive to penicillins, although cross-reactions have been reported.
Especial care is indicated in patients who have experienced an anaphylactic reaction to penicillin.
Cephalosporin antibiotics at high dosage should be given with caution to patients receiving concurrent treatment with potent diuretics such as furosemide, as these combinations are suspected of adversely affecting renal function. Clinical experience with cefuroxime has shown that this is not likely to be a problem at the recommended dose levels.
Pregnancy: There is no experimental evidence of embryopathic or teratogenic effects attributable to cefuroxime but, as with all drugs, it should 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.
Pediatrics: No pediatrics 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.
Cefuroxime does not interfere with enzyme-based tests for glycosuria. Slight interference with copper reduction methods (Benedict's, Fehling's, Clinitest) may be observed. However, this should not lead to false-positive results, as may be experienced with some other cephalosporins.
Cefuroxime may cause false negative-results in the ferricyanide test for glucose. This antibiotic does not interfere in the alkaline picrate assay for creatinine.

Side Effects
Adverse reactions to cefuroxime have occurred relatively infrequently and have been generally mild and transient in nature. Effects reported include rashes and gastrointestinal disturbance. As with other antibiotics, prolonged use may result in the overgrowth of non-susceptible organisms, e.g. Candida.
The principal changes in haematological parameters seen in some patients have been of decreased haemoglobin concentration and of eosinophilia. A positive Coomb's test has been found in some patients treated with cefuroxime.
Although there are sometimes transient rises in serum liver enzymes or serum bilirubin, particularly in patients with pre-existing liver disease, there is no evidence of hepatic involvement.
There may also be some variation in the results of biochemical tests of renal function, but these do not appear to be of clinical importance. As a precaution, renal function should be monitored if this is already impaired.
Transient pain may be experienced at the site of intramuscular injection. This is more likely to occur with high doses. However, it is unlikely to be a cause for discontinuation of treatment.

Overdosage
Since there is no specific antidote, treatment of cefuroxime overdose should be symptomatic.

Drug Interactions
The admixture of cefuroxime sodium injection with other antibacterial antibiotics is not recommended.
As with other beta-lactam antibacterials, the admixture of cefuroxime sodium with aminoglycosides may result in substantial mutual inactivation. If they are administered concurrently, they should be administered in separate sites. Do not mix them in the same intravenous bag or bottle.

Precautions for the Drug
Powder and solutions tend to darken, depending on the storage conditions. This does not affect their potency. But do not use if the solutions are cloudy or contain precipitates.

Presentation
Cefuzime - sterile powder for injection is available in vials containing 500mg or 750mg Cefuroxime.

* *Store at a temperature of 15 - 25°C.*

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 the reach of children.

Council of Arab Health Ministers,
Union of Arab Pharmacists.

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

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

02/02/2003