Only for the use of Medical Professionals

Zitum®

Presentation

Zitum® 250mg Injection: Each vial contains Ceftazidime 250mg as Pentahydrate USP buffered with Sodium Carbonate USP.
Zitum® 500mg Injection: Each vial contains Ceftazidime 500mg as Pentahydrate USP buffered with Sodium Carbonate USP.
Zitum® 1g Injection: Each vial contains Ceftazidime 1g as Pentahydrate USP buffered with Sodium Carbonate USP.

Uses
Zitum® is a bactericidal cephalosporin antibiotic which is resistant to most beta-lactamases and is active against a wide range of gm-positive and gm-negative bacteria.

It is indicated for the treatment of single infections and for mixed infections caused by two or more susceptible organisms. Zitum®, because of its broad antibacterial spectrum, may be used alone as first choice of drug. In meningitis it is recommended that the results of a sensitivity test known before treatment with Zitum® as a single agent. It may be used for infections caused by organisms resistant to other antibiotics including aminoglycosides and many cephalosporins. When appropriate, however, it may be used safely in combination with an aminogly-coside or other beta-lactam antibiotics (for example in the presence of severe neutropenia) or with an antibiotic active against anaerobes when the presence at *Bacteroides fragilis* is suspected.

Severe infections in general: Septicemia, bacteremia, peritonitis, meningitis, infections in immunosuppressed patients with hematological or solid malignancies, cystic fibrosis

Respiratory tract infections: Pneumonia, bronchopneumonia, infected pleurisy, empyema, lung abscess, infected bronchiectasis, bronchitis and in lung infections in patients with cystic fibrosis

Ear, nose and throat infectians: Otitis media, malignant otitis externa, mastoiditis, sinusitis and other severe ear and throat infections

Urinary tract infections: Acute and chronic pyelonephritis, pyelitis, prostatitis, cystitis, bacterial urethritis, renal abscess, and infections associated with bladder and renal stones

Skin and soft tissue infections: Erysipelas, abscesses, cellulitis, infected burns and wounds, mastitis, skin ulcers

Gastrointestinal, biliary and abdominal infections: Cholangitis, cholecystitis, empyema of gall bladder, intra-abdominal abscesses, peritonitis, diverticulitis, enterocolitis, post-partum and pelvic inflammatory conditions

Bone and joint infections: Osteitis, osteomyelitis, septic arthritis, infected bursitis

Dosage and administration

Dosage

Zitum® is to be used by parenteral route. The dose is to be selected depending upon the severity, sensitivity and type of infection and the age, weight and renal function of the patient.

Adults: The adult dosage range for Ceftazidime is 1-6 g/day. For instance, 500mg given 12 or 8 hourly by IV or IM injection. In urinary tract infections and in many less serious infections, 500mg or 1g 12 hourly is usually adequate. In the majority of infections, 1g 8 hourly or 2g 12 hourly should be given. In very severe infections, especially in immunocompromised patients, including those with neutropenia, 2g 8 or 12 hourly should be administered.

Infants and children: The usual dosage range for children aged over two months is 30 to 100mg/kg/day, given in 2 or 3 divided doses. Dosage up to 150mg/kg/day (maximum 6g daily) in 3 divided doses may be given to infected immunocompromised or fibrocystic children or children with meningitis.

Neonates and children up to 2 months of age: Whilst clinical experience is limited, a dosage of 25 to 60mg/kg/day given in 2 divided doses has been proved to be effective. In the neonates the serum half life of Zitum® can be 3 to 4 times than that in adults.

Dosage in cystic fibrosis: In fibrosystic adults with normal renal function who have pseudomonal lung infections, high dosage of 100 to 150mg kg per day in three divided doses should be used. In adults with normal renal function 9g/day has been used safely.

Dosage in peritoneal dialysis: Zitum® may also be used in peritoneal dialysis and in continuous ambulatory peritoneal dialysis (CAPD). As well as using Zitum® intravenously, it can be incorporated into the dialysis fluid (usually 125 to 250mg for 2L of dialysis fluid).

Administration

Zitum® may be given intravenously (IV) or by deep intramuscular (IM) injection into a large muscle mass such as the upper outer quadrant of the gluteus maximus or lateral part of the thigh. For IM administration, Zitum® should be reconstituted with WFI as directed in the table headed by 'Preparation of Solution'. Then it should be injected through following the 'Instructions for Reconstitution' given below. For IV administration Zitum® should be reconstituted with WFI as directed and should be injected slowly into the vein over a period of 3 to 5 minutes.

Preparation of solution:

Strength	Route of administration	WFI to be added (ml)
25Omg	IM	1.0
	IV	2.5
5OOmg	IM	1.5
	IV	5.0
1g	IM	3.0
	IV	10.0

Instruction for Reconstitution:

1. Inject WFI and shake well to dissolve. The vials may contain a vacuum to assist injection of WFI.
2. Carbon dioxide is released as the antibiotic dissolve, generating pressure within the vial. The solution will become clear within 1 to 2 minutes.
3. Invert the vial, insert needle into ii and withdraw contents of the vial in the usual manner.
4. The withdrawn solution may contain carbon dioxide bubble, which should be expelled from the syringe before administration.

Contraindications, warnings, etc.

Contraindications: Zitum® is contraindicated in patients with known hypersensitivity to cephalosporin antibiotics.

Warnings: As with other beta-lactam antibiotics, before therapy with Zitum® is instituted, careful inquiry should be made for a history of hypersensitivity reaction to Zitum®, other cephalosporins, penicillins or other drugs. Zitum® should be given only with specific caution to patients with Type-1 or immediate hypersensitivity reaction to peniciilin. If an allergic rerction to Zitum® occurs, discontinue the drug.
Serious hypersensitivity reactlons may require epinephrin ((adrenaline), hydrocortisone, antihistamine or other emergency measures.

Precuations: Cephalosporin antibiotics at high dosage should be with caution to patients receiving concurrent treatment with nephrotoxic drugs e.g. aminoglycoside antibiotics, or potent diuretics such as frusemide, as these combinations are suspected of adversely affecting renal function'. Clinical experience with Zitum® has shown that this is not likely to be a problem at the recommended dose levels. There is no evidence that Zitum® affects adversely renal function at normal therapeutic doses; however, as for ail antibiotics eliminated via kidneys, it is necessary to reduce the dosage according to the degree of reduction in renal function to avoid the clinical consequences of elevated antibiotic levels, e.g. convulsions.

There is no experimental evidence of embryopathic or teratogenic effects attributable to Zitum® . But, as with all drugs, it should be administered with caution during the early months of pregnancy and in early infancy. Use in pregnancy requires the anticipated benefit be weighed against the possible risks. Zitum® is excreted in human milk in low concentrations and consequently caution should be exercised when Zitum® is administered to a nursing mother.

Zitum® does not interfere with enzyme-based tests for glycosuria. Slight interference with copper reduction methods may be onserved. Zitum® does not interfere in the alkaline picrate assay for creatinine. As with other broad spectrum antibiotics, prolonged use of Zitum® may result in the over-growth of non-susceptible organisms which may require interruption of treatment or adoption of appropriate measures. Repeated evaluation of the patient's condition is essential.

Side effecfs: Clinical trial experience has shown that Zitum® is generally well tolerated.

Adverse reactions are infrequent. They include:

Local: Phlebitis or thrombophlebitis with IV administration; pain and/or inflammation after IM injection.

Hypersensitivity: Maculopapular or urticarial rash, fevere, pruritus, and very rarely angioedema and anaphylaxis (bronchospasm and/or hypotension).
Gastrointestinar: Diarrhea, nausea, vomiting, abdominal pain, and very rarely oral thrush or colitis.
Other adverse events which may be related to Zitum® therapy or of uncertain aetiology include:
Genito-urinary system: Candidiasis, vaginitis
Central nervous system: Headache, dizziness, paraesthesia and bad taste.
There have been a few reports of convulsions occurring in patients with renal impairment in whom the dose of Zitum® has not been appropriately reduced.

Over dosage: Serum levels of Zitum® are reduced by dialysis.

Pharmaceutical Precautions
Vials of Zitum® for injection as supplied are under reduced pressure; a positive pressure is produced on reconstitution due to the release of carbon dioxide. See Administration section for recommended techniques of reconstitution.

Store between 15-30C. Protect from light.

Package quantities
Zitum® 250mg Injection: Each combipack contains 1 vial of ceftazidime 250mg dry powder for injection as Pentahydrate USP buffered with Sodium Carbonate USP and 1 ampoule of 5ml WFI BP and 1 disposable syringe (3ml/cc).

Zitum® 500mg Injection: Each combipack contains 1 vial of ceftazidime 500mg dry powder for injection as Pentahydrate USP buffered with Sodium Carbonate USP and 1 ampoule of 5ml WFI BP and 1 disposable syringe (5ml/cc).

Zitum® 1g Injection: Each combipack contains 1 vial of ceftazidime 1g dry powder for injection as Pentahydrate USP buffered with Sodium Carbonate USP and 1 ampoule of 5ml WFI BP and 1 disposable syringe (5ml/cc).

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