

Tazid[®]

Ceftazidime

COMPOSITION

Tazid[®] 250 mg IM / IV injection: Each vial contains Ceftazidime USP 250 mg (as a sterile mixture of Ceftazidime with Sodium Carbonate buffer).

Tazid[®] 500 mg IM / IV injection: Each vial contains Ceftazidime USP 500 mg (as a sterile mixture of Ceftazidime with Sodium Carbonate buffer).

Tazid[®] 1 gm IM / IV injection: Each vial contains Ceftazidime USP 1 gm (as a sterile mixture of Ceftazidime with Sodium Carbonate buffer).

PHARMACOLOGY

Tazid[®] (Ceftazidime) is a bactericidal cephalosporin antibiotic, which is resistant to most beta-lactamases and is active against a wide range of Gram-positive and Gram-negative bacteria. It is indicated for the treatment of single infections and for mixed infections caused by two or more susceptible organisms.

INDICATION

Single infections, Mixed infections, Severe infections in general, Respiratory tract infections, Ear, Nose and Throat infections, Skin and soft tissue infections, Gastrointestinal, Biliary and abdominal infections, Bone and joint infections, Dialysis: Infections associated with hemo and peritoneal dialysis and with continuous ambulatory peritoneal dialysis (CAPD).

DOSAGE AND ADMINISTRATION

Tazid[®] is to be used by the parenteral route, the dosage depending upon the severity, sensitivity & type of infections and the age, weight & renal function of the patient.

Adults: The adult dosage range for ceftazidime is 1 to 6 gm per day 8 or 12 hourly (IM/IV) in the majority of infections, 1gm 8 hourly or 2 gm 12 hourly should be given.

In urinary tract infections and many less serious infections, 500 mg or 1 gm 12 hourly is usually adequate. In severe infections, especially immunocompromised patients, including those with neutropenia, 2 gm 8 or 12 hourly should be administered.

When used as a prophylactic agent in prostatic surgery 1 gm should be given at the induction of anesthesia. A second dose should be considered at the time of catheter removal.

Cystic fibrosis: In fibrocystic adults with normal renal function who have pseudomonas lung infections, high doses of 100 to 150 mg/kg/day as three divided doses should be used. In adults with normal renal function 9 gm/day has been used safely.

Elderly: In view of the reduced clearance of ceftazidime in acutely ill elderly patients, the daily dosage should not normally exceed 3 gm, especially in those over 80 years of age.

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

Neonates and Children up to 2 months of age: The usual dosage range is 25 to 60 mg/kg/day as two divided doses.

Dosage in impaired renal function: Ceftazidime is excreted by the kidneys almost exclusively by glomerular filtration. Therefore, in patients with impaired renal function it is recommended that the dosage of ceftazidime should be reduced to compensate for its slower excretion, except in mild impairment, i.e., glomerular filtration rate (GFR) greater than 50 ml/min.

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

Administration

Tazid[®] may be given intravenously or by deep intramuscular injection into a large muscle.

Instruction for reconstitution

	Amount of diluent to be added	
Vial size	Intramuscular	Intravenous
250 mg	1.0 ml	2.5 ml
500 mg	1.5 ml	5 ml
1 gm	3.0 ml	10.0 ml

It is highly recommended to use the reconstituted solution immediately. During reconstitution the following procedure to be recommended and after reconstitution use within specified time line maintaining storage condition.

Step 1 : Add recommended volume of solvent slowly. Remove the syringe needle.

Step 2 : Gently shake the vial to dissolve the powder. Carbon dioxide is released & a clear solution will be obtained

Step 3 : Now insert the needle in the free space of the reconstituted vial & withdraw the pressurized air from the free space.

Step 4 : Finally withdraw the solution from the vial by syringe.

STORAGE CONDITION

Store below 30°C, protected from light and moisture. Reconstituted solutions are stable for up to 24 hours if stored between 2°C to 8°C.

CONTRAINDICATION

Ceftazidime is contraindicated in patients with known hypersensitivity to cephalosporin antibiotics.

WARNING

As with other beta-lactam antibiotics, before therapy with ceftazidime is instituted, careful inquiry should be made for a history of hypersensitivity reactions to ceftazidime, cephalosporins, penicillins, or other drugs.

PREGNANCY AND LACTATION

There is no experimental evidence of embryopathic or teratogenic effects attributable to ceftazidime, but as with all drugs it should be administered with caution during the early month of pregnancy and early infancy.

SIDE EFFECT

Clinical trial experience has shown that ceftazidime is generally well tolerated. Adverse reactions are infrequent and include: **Local:** Phlebitis or thrombophlebitis with IV administration; pain and/or inflammation after IM injection. **Hypersensitivity:** Urticarial rash, fever, pruritus, and very rarely angioedema and anaphylaxis (bronchospasm and/or hypotension). **Gastrointestinal:** Diarrhea, nausea, vomiting, abdominal pain, and very rarely oral thrush or colitis. Other adverse events which may be related to ceftazidime therapy or of uncertain etiology include: **Genito-urinary:** Candidiasis, vaginitis. **Central nervous system:** headache, dizziness, paraesthesia and bad taste.

PRECAUTION

There is no experimental evidence of embryopathic or teratogenic effects. Clinical experience with ceftazidime has shown that this is not likely to be a problem at the recommended dose levels. There is no evidence that ceftazidime adversely affects renal function at normal therapeutic doses.

DRUG INTERACTION

Increased nephrotoxicity has been reported following concomitant administration of cephalosporins and aminoglycoside antibiotics.

HOW SUPPLIED

Tazid[®] is supplied as a sterile powder in glass vials.

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SQUARE