Cefazid®

ceftazidime

PRESENTATION

Cefazid®250 mg IV/IM Injection : Each vial contains 250 mg powder of ceftazidime USP (as ceftazidime pentahydrate) with sodium carbonate. **Cefazid®500 mg IV/IM Injection :** Each vial contains 500mg powder of ceftazidime USP (as ceftazidime pentahydrate) with sodium carbonate. **Cefazid® 1gm for IV/IM Injection :** Each vial contains 1 gm powder of ceftazidime USP (as ceftazidime pentahydrate) with sodium carbonate. **Cefazid® 2 gm for IV Injection or Infusion :** Each vial contains 2 gm powder of ceftazidime USP (as ceftazidime pentahydrate) with sodium carbonate. On the addition of sterile Water for Injection USP, the powder dissolves with effervescence to produce a solution for injection.

CLINICAL PHARMACOLOGY

Mode of Action : Ceftazidime inhibits one of the enzymes involved in the bacterial cell wall synthesis. The loss of the stability conferred by the wall leads to the cell lysing. Ceftazidime is chemically closely related to pencillins, but not degraded by betalactamases.

Microbiology : Ceftazidime is a third generation cephalosporin effective against a broad range of Gram-positive and Gram negative bacteria. It is effective against bacteria resistant to ampicillin and other cephalosporins. It offers improved activity against most gram-negative enteric bacteria, particularly *Pseudomonas aeruginosa*. It penetrates well into CSF in the presence of inflammation.

Pharmacokinetics : Ceftazidime is given only parenterally and it penetrates tissues well. Its concentration in the bile is similar to that of plasma. Its excretion is reduced in renal impairment. It is not metabolised in the liver and 80% to 90% is excreted unchanged within 24 hr via the kidneys by glomerular filtration. Less than 1% is excreted via the bile. Plasma half-life is 1.8-2.2 hr and protein binding is 10%.

INDICATIONS

Ceftazidime may be indicated in an extremely wide variety of Gram-positive and Gram-negative infections of the respiratory tract, the skin, urinary and genital tracts, septicemia, the abdominal cavity, and the central nervous system, Sensitivity of the pathogen must be demonstrated first.

1. Lower respiratory tract infections (including pneumonia, pleurisy, lung abscess, bronchiectasis, infections in patients with cystic fibrosis) due to *Pseudomonas aeruginosa* and other *Pseudomonas species, Haemophilus influenzae* (including ampicillin-resistant strains) *Klebsiella species, Enterobacter species, Proteus mirabilis, E. coli, Serratia species, Citrobacter species, Streptococcus pneumoniae, Staphyloccus aureus (methicillin-susceptible strains).*
2. Skin and skin structure infections (including infected burns) due to *P. aeruginosa, Klebsiella species, E. coli, Proteus species (including P. mirabilis and indole-positive Proteus), Enterobacter species, Serratia species, S. aureus (methicillin-susceptible strains), S. pyogenes (group A_β hemolytic streptococci).*
3. UTIs (including pyelonephritis, renal abscess, prostatitis), both complicated and uncomplicated, due to *P. aeruginosa, Enterobacter species, Proteus species (including P. mirabilis and indole-positive Proteus), Klebsiella species, and E. coli, Bacterial septicemia due to P. aeruginosa, Klebsiella species, H. influenzae, E. coli, Serratia species, S. pneumoniae, S. aureus (methicillin-susceptible strains).*
4. Bone and joint infections due to *P. aeruginosa, Klebsiella species, Enterobacter species, S. aureus (methicillin-susceptible strains).*
5. Gynaeological infections (including endometritis, pelvic cellulitis, and other infections of the female genital tract), due to *E. coli.*
6. Intra-abdominal infections (including peritonitis, diverticultis, pelvic infections), due to *E. coli, Klebsiella species, S. aureus* (methicillin-susceptible strians); polymicrobial infections due to aerobic and anaeraobic organisms and Bacterioides species (many strains of B. fragilis are resistant).
7. CNS infectins (including meningitis), due to *H. influenzae and Neisseria meningtidis* (limited effect against *P. aeruginosa and S. pneumonia).*
8. Dialysis patients-Infections associated with haemo and peritoneal dialysis and with continuous ambulatory peritoneal dialysis (CAPD)
9. In severe and life-threatening infections like septicemia, bacteremia, ENT infections and infections in the immunocompromised patients, **Cefazid®** may be used alone or with aminoglycosides, vancomycin, and clindamycin

DOSAGE AND ADMINISTRATION

General dosage recommendations : Cefazid® may be used by IV or IM route at the dosage depending upon the severity, sensitivity and type of infection and the age, weight and renal function of the patient.

Adults : Most infections : 500 mg or 1 gm 8 hourly or 2 gm 12 hourly. In UTI and other less serious infections : 500 mg or 1 gm 12 hourly is usually adequate. In very severe infections including immunocompromised or neutropenic patients, 2 gm 8 hourly may be given. In pseudomonal lung infections in cystic fibrosis with normal renal function: 100 to 150 mg/kg/day may be used in three divided doses, not to exceed 9 gm/day.

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

Elderly : Considering the reduced renal clearance in elderly, the daily dosage should not exceed 3 gm, especially in those over 80 years of age.

Neonates, infants, and children : Neonates and children up to 2 months : 25 to 60 mg/kg/day IV in two divided doses, not to exceed the adult dose. Infants and children, (2 months-12 years) 30-100 mg/kg/day given in two or three divided doses. Doses up to 150 mg/kg/day may be given in three divided doses, not to exceed 6 gm/day immunocompromised patients or patients with cystic fibrosis or meningitis.

Dosage in renal insufficiency : Dose should be modified according to creatinine clearance as below :

Creatinine clearance ml/min	Recommended unit dose of Ceftazidime	Frequency of dosing
50-31	1gm	12 hourly
30-16	1gm	24 hourly
15-6	0.5 gm	24 hourly
< 5	0.5 gm	48 hourly

Dosage in peritoneal dialysis : Usually 125 to 250 mg given for 2 L of dialysis fluid.

Reconstitution of solution

Vial Size	Route of administration	Amount of diluent to be added
250 mg	Intramuscular (IM)	1 mL
	Intravenous (IV)	2.5 mL
500 mg	Intramuscular (IM)	1.5 mL
	Intravenous (IV)	5.0 mL
1 gm	Intramuscular (IM)	3.0 mL
	Intravenous (IV)	10 mL
2 gm	Intravenous bolus	10 mL
	Intravenous Infusion	50 mL*

* For intravenous infusion, add 50 ml WFI or infusion fluid** with 2 gm powder, Addition should be in two stages first 10 ml and then 40 ml. After the powder has been dissolved, a gas relief needle is to be inserted through the vial closure to relieve the internal pressure of carbon dioxide and to obtain a clear solution in 1 to 2 minutes.

** Infusion fluid (BP standards): 0.9% NaCl solution, 5% or 10% Dextrose solution, 0.18% NaCl plus 4% Dextose solution, 0.225% or 0.45% or 0.9% NaCl plus 5% Dextrose solution, 10% Dextran 40 plus 0.9% Nacl or 5% Dextrose solution, 6% Dextran 60 plus 0.9% NaCl or 5% Dextrose solution.

SIDE EFFECTS

Ceftazidime is generally well tolerated, adverse reactions are infrequent and include : **Local:** phlebitis, thrombophlebitis, pain at injection site. **Hypersensitivity:** skin rash, urticaria, fever and very rarely angioedema and anaphylaxis. **Gastrointestinal:** diarrohoea, nausea, vomiting, abdominal pain and very rarely pseudomembranous colitis. **Genitourinary:** candidiasis, vaginitis. **CNS:** headache, dizziness, paraesthesia, bad taste. **Hematological:** neutropenia, thrombocytopenia, eosinophilia, leucopenia, positive direct Coombs test and blood urea. **Hepatic:** rise in liver enzymes

CONTRAINDICATIONS

Ceftazidime is contraindicated in patients with known hypersensitivity to ceftazidime, other cephalosporins or beta lactam antibiotics.

PRECAUTION

A sodium carbonate formulation should be used if the drug is indicated for children less than 12 years of age. At high doses should be given 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. As with other broad spectrum antibiotics, prolonged use of Ceftazidime may result in over-growth of non-susceptible organisms (e.g. Candida, Enterococci) which may require interruption of treatment or adoption of appropriate measures. Repeated evaluation of patient's condition is essential. Precautions to be taken in acutely ill elderly patients.

Pregnancy and lactation : There is no risk of teratogenicity in foetus, still as with all other antibiotics **Cefazid®** should be used with caution.

OVERDOSAGE

Serum levels of Ceftazidime are reduced by dialysis.

DRUG INTERACTIONS

When cephalosporins used for prolonged treatments in combination with high levels of aminoglycoside antibiotics or potent diuretics, nephrotoxicity has been observed. Ceftazidime should not be used in combination with chloramphenicol for potential antagonistic action.

STORAGE

Store in a cool (below 30°C), dry place and away from light and children. Reconstituted solutions can be preserved for 18 hours at room temperature (below 25°C) or for 7 days under refrigeration.

PRESENTATION

Cefazid® is supplied as sterile powder in glass vials.

Cefazid® 250 mg IV/IM injection : Pack of 1 vial containing 250 mg powder of ceftazidime USP (as ceftazidime pentahydrate) accompanied by an ampoule of 5 ml WFI.

Cefazid® 500 mg IV/IM Injection : Pack of 1 vial containing 500mg powder of ceftazidime USP (as ceftazidime pentahydrate) accompanied by an ampoule of 5 ml WFI.

Cefazid® 1 gm IV/IM Injection : Pack of 1 vial containing 1 gm powder of ceftazidime USP (as ceftazidime pentahydrate) accompanied by an ampoule of 10 ml WFI.

Cefazid® 2 gm IV for Injection or Infusion : Pack of 1 Vial containing 2 gm powder of ceftazidime USP (as ceftazidime pentahydrate).accompanied by 2 ampoule of 25 ml water for injection USP for IV injection.

® Trade Mark

Manufactured by :
RENATA LIMITED
Rajendrapur, Gazipur, Bangladesh
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