Zidicef®
Ceftazidime

Presentation
Zidicef® 250 mg IM/IV Injection: Each vial contains sterile Ceftazidime USP equivalent to 250 mg Anhydrous Ceftazidime.

Zidicef® 500 mg IM/IV Injection: Each vial contains sterile Ceftazidime USP equivalent to 500 mg Anhydrous Ceftazidime.

Zidicef® 1 g IM/IV Injection: Each vial contains sterile Ceftazidime USP equivalent to 1 g Anhydrous Ceftazidime.

Description
Ceftazidime is a semi-synthetic broad-spectrum, beta-lactam antibiotic for parenteral administration. Ceftazidime is a dry, white to off-white powder supplied in vials. It is a bactericidal Cephalosporin antibiotic active against a wide range of gram-positive and gram-negative bacteria. It is highly stable to most clinically important beta-lactamases, plasmid or chromosomal enzymes, which are produced by both gram-positive and gram-negative bacteria.

Indications
It is indicated for the treatment of single infections and for mixed infections caused by two or more susceptible organisms. The more common indications are as follows *Severe infections in general:* Septicemia, bacteremia, peritonitis, meningitis, infections in immunosuppressed patients with hematological or solid malignancies and in patients with 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 infections:* 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. *Gynecologic infections:* Endometritis, pelvic cellulitis and other infections of the female genital tract Gastrointestinal, billary and abdominal infections: Cholangitis, cholecystitis, emphysema of gall bladder, intra-abdominal abscesses, peritonitis, diverticulitis, ceterocolitis, post-partum pelvic inflammatory conditions. Ceftazidime, because of its broad antibacterial spectrum, may be used alone as first choice of drug. When appropriate, however, it may be used safely in combination with an Aminoglycoside or other beta-lactum antibiotic, for example in the presence of severe neutropenia, or with an antibiotic active against anaerobes when the presence of *Bacteroides fragilis* is suspected.

Dosage and Administrations
Dosage:
Adults: Average dose: 500 mg IV/IM, 8 - 12 hourly; Total daily dose: 1 - 6 g *Infants (>2 months) & children:* 30-100 mg/kg/day (Bid); maximum 150 mg/kg/day. *Neonates up to 2 months of age:* 25-60 mg/kg/day (Bid). In case of meningitis or immunocompromised patients, IV route is recommended for children. More specific doses are - *Uncomplicated & complicated UTI* - 250-500 mg every 8-12 hours. Bone and *joint infections* - 2 g every 12 hours. *Pneumonia* - 500 mg - 1 g every 8 hours. *Intra abdominal infections* - 2 g every 8 hours, *Serious gynecologic infections* - 2 g every 8 hours. *Meningitis* - 2 g every 8 hours. *Surgical prophylaxis:* 1 g at induction of anaesthesia in prostatic surgery, repeated if necessary when cather is removed.

Administration:
Zidicef® 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, Zidicef® 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, Zidicef® should be reconstituted with WFI as directed and should be injected slowly into the vein over a period of 3 to 5 minutes.

Instructions 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 dissolves, generating pressure within the vial. The solution will become clear within 1 to 2 minutes.
3. Invert the vial, insert needle into it 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.

Preparation of solution :

Strength	Route of administration	WFI to be added (ml)
250 mg	IM	1.0
	IV	2.5
500 mg	IM	1.5
	IV	5.0
1 g	IM	3.0
	IV	10.0

Side Effects
Adverse reactions are infrequent and may include the following :
Local : Phlebitis or thrombophlebitis with IV administration; pain and/or inflammation after IM injection. *Hypersensitivity:* Maculopapular or urticarial rash, fever, pruritus, and very rarely angioedema and anaphylaxis (bronchospasm and/or hypotension). *Gastrointestinal:* Diarrhoea, 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 : *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 Ceftazidime has not been appropriately reduced.

Contraindications
Ceftazidime is contraindicated in patients who have shown hypersensitivity to Ceftazidime or the Cephalosporin group of antibiotics.

Drug Interaction
The admixture of beta-lactam antibacterials (Penicillins and Cephalosporins) and 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
Cephalosporin antibiotics at high dose should be given with caution to patients receiving concurrent treatment with nephrotoxic drugs, e.g. Aminoglycoside antibiotics or potent diuretics, such as, Furosemide. Avoid intramuscular injection with Lidocaine in patients hypersensitive to Lidocaine, or repeated injections in patients with hepatic dysfunction. Consider dosage modification in patients with renal impairment. There is no experimental evidence of embryopathic or teratogenic effect attributable to Ceftazidime but like other drugs it should be administered with caution during the early months of pregnancy. Ceftazidime is excreted in milk in less concentration.

Overdosage
Ceftazidime overdosage reactions have included - seizure activity, encephalopathy, asterixis, neuromuscular excitability, and coma. Patients who receive an acute overdosage should be carefully observed and given supportive treatment. In the presence of renal insufficiency, aemodialysis or peritoneal dialysis may aid in the removal of Ceftazidime from the body.

Pharmaceutical Precautions
Store in cool dry place protected from light. Keep out of reach of children.

Commercial Packs
Zidicef® 250 mg IM/IV Injection: Each combipack contains 1 vial of sterile Ceftazidime USP equivalent to 250 mg Anhydrous Ceftazidime and 1 ampoule of 5 ml Water for Injection.

Zidicef® 500 mg IM/IV Injection: Each combipack contains 1 vial of sterile Ceftazidime USP equivalent to 500 mg Anhydrous Ceftazidime and 1 ampoule of 5 ml Water for Injection.

Zidicef® 1 g IM/IV Injection: Each combipack contains 1 vial of sterile Ceftazidime USP equivalent to 1 g Anhydrous Ceftazidime and 1 ampoule of 10 ml Water for Injection.

Manufactured by :

POPULAR

POPULAR PHARMACEUTICALS LTD.
TONGI, GAZIPUR, BANGLADESH