Ceftazidime

Zeptrigen®

℞

500 mg and 1 g Powder for Injection
Intramuscular/Intravenous

Antibacterial (Cephalosporin)

FORMULATIONS

Each vial contains:

Ceftazidime (as pentahydrate)..... 500 mg or 1 g

PRODUCT DESCRIPTION

Ceftazidime (Zeptrigen®) is a sterile white to cream-colored, crystalline powder in a colorless vial. When reconstituted, the powder dissolves completely into a clear to yellowish solution.

Ceftazidime is a dry-powdered mixture of ceftazidime (as pentahydrate) and sodium carbonate. In this formulation, sodium carbonate (115.19 mg per gram of ceftazidime) has been admixed to facilitate dissolution. The total sodium content of the mixture is approximately 50 mg per gram of ceftazidime.

PHARMACODYNAMICS

Ceftazidime is a semi-synthetic, third-generation cephalosporin which exerts its bactericidal activity by interfering with the bacterial cell wall synthesis. It binds to specific penicillin-binding proteins responsible for the synthesis of peptidoglycan, a heteropolymeric structure that gives the cell wall its mechanical stability. The final stage of peptidoglycan synthesis involves completion of the cross-linking of the terminal glycine residue of the pentaglycine bridge to the fourth residue of the pentapeptide. The transpeptidase enzyme that catalyzes this step is inhibited by cephalosporins. As a result the bacterial cell wall is weakened, the cell swells and then ruptures.

ANTIMICROBIAL SPECTRUM OF ACTIVITY

Ceftazidime is active against the following microorganisms, both *in vitro* and in clinical infections:

Aerobic Gram-positive	*Staphylococcus aureus,* including penicillinase- and non-penicillinase-producing strains *Streptococcus agalactiae* (group B streptococci) *Streptococcus pneumoniae* *Streptococcus pyogenes* (group A beta-hemolytic streptococci)
Aerobic Gram-negative	*Citrobacter* spp., including *Citrobacter freundii* and *Citrobacter diversus* *Enterobacter* spp., including *Enterobacter cloacae* and *Enterobacter aerogenes* *Escherichia coli* *Haemophilus influenzae,* including ampicillin-resistant strains *Klebsiella* spp. (including *Klebsiella pneumoniae*) *Neisseria meningitidis* *Proteus mirabilis* *Proteus vulgaris* *Pseudomonas* spp. (including *Pseudomonas aeruginosa*) *Serratia* spp.
Anaerobes	*Bacteroides* spp. (Note: Many strains of *Bacteroides fragilis* are resistant)

Ceftazidime has been shown to be active *in vitro* against most strains of the following organisms; however, the clinical significance of these data is unknown: *Acinetobacter* spp., *Clostridium* spp. (excluding *Clostridium difficile*), *Haemophilus parainfluenzae, Morganella morganii* (formerly *Proteus morganii), Neisseria gonorrhoeae, Peptococcus* spp., *Peptostreptococcus* spp., *Providencia* spp., (including *Providencia rettgeri*), *Salmonella* spp., *Shigella* spp., *Staphylococcus epidermidis,* and *Yersinia enterocolitica.*

Ceftazidime is not active *in vitro* against methicillin-resistant staphylococci, *Streptococcus faecalis* and many other enterococci, *Listeria monocytogenes, Campylobacter* spp., or *Clostridium difficile.*

The prevalence of acquired resistance may vary geographically and with time for selected species and local information on resistance is desirable particularly when treating severe infections. It is suggested to carry out sensitivity tests.

PHARMACOKINETICS

Ceftazidime is not absorbed from the gastrointestinal (GI) tract and must be administered parenterally.

After intramuscular (IM) administration of 500 mg and 1 g doses of ceftazidime in healthy adults, mean peak serum concentrations (C_{max}) were 17 and 29 to 39 mcg/mL, respectively, about 1 hour after the dose. Serum concentrations remained above 4 mcg/mL for 6 and 8 hours after IM administration of 500 mg and 1 g doses, respectively.

After intravenous (IV) administration of 500 mg and 1 g doses of ceftazidime over 3 to 5 minutes in healthy men, average serum concentrations at 0.25, 0.5, 1, 2, 4, 6, and 8 hours after dosing were 34.1, 24.5, 17.1, 11.2, 5.6, 2.1-2.4, and 0.9 to1.3 mcg/mL, respectively, after the 500 mg dose and 59.9 to 83.3, 45.3 to 60.9, 32.1 to 40.9, 22.9 to 23.2, 9.7, 4.4 to 5.3, and 1.9 to 3.2 mcg/mL, respectively, after the 1 g dose.

After IV infusion of 500 mg and 1 g doses of ceftazidime over 20 to 30 minutes in healthy men, C_{max} of 42 and 69 mcg/mL, respectively, were achieved. Infusion of a single 2 g dose over 20 to 30 minutes in healthy adults resulted in C_{max} of 159 to185.5 mcg/mL and average serum concentrations of 87.9, 65.2 to 70.6, 38.7, 16.7 to 16.9, and 7.7 mcg/mL at 0.5, 1, 2, 4, and 6 hours, respectively, after completion of the infusion.

Ceftazidime is widely distributed into body tissues and fluids including the gallbladder, bone, bile, skeletal muscle, prostatic tissue, endometrium, myometrium, heart, skin, adipose tissue, aqueous humor, and sputum, and pleural, peritoneal, synovial, ascitic, lymphatic, and blister fluids. It is generally distributed into bile, but biliary concentrations of the drug after IM or IV administration may be lower than concurrent serum concentrations.

Ceftazidime generally diffuses into cerebrospinal fluid (CSF) after IV administration, although CSF concentrations of the drug are higher in patients with inflamed meninges than in those with uninflamed meninges.

Ceftazidime crosses the placenta and is distributed into amniotic fluid. The drug is also distributed into milk. In lactating women with endometritis who received 2 g of ceftazidime IV every 8 hours, mean concentrations of the drug in milk obtained during days 2 to 4 of treatment were 3.8 mcg/mL immediately prior to a dose and 5.2 and 4.5 mcg/mL at 1 and 3 hours, respectively, after a dose.

About 5 to 24% of ceftazidime is bound to serum proteins. The degree of protein binding is independent of drug concentration.

Plasma ceftazidime concentrations decline in a biphasic manner. The distribution half-life ($t_{1/2\alpha}$) and elimination half-life ($t_{1/2\beta}$) in adults with normal renal and hepatic function are 0.1 to 0.6 and 1.4 to 2 hours, respectively.

Ceftazidime is not metabolized and is excreted unchanged mainly by the kidneys, almost exclusively by glomerular filtration. After IM or IV administration of a single 500 mg or 1 g dose of ceftazidime in adults with normal renal function, 80 to 90% of the dose is excreted unchanged in urine within 24 hours; about 50% of the dose is excreted within 2 hours after the dose.

The mean serum clearance of ceftazidime in healthy adults is 98 to 122 mL/min.

The serum half-life of ceftazidime is longer in neonates than in older children and adults, but does not appear to be related to gestational age or birth weight.

Serum concentrations of ceftazidime are higher and serum half-life is prolonged in patients with renal impairment. The $t_{1/2\beta}$ of ceftazidime in patients with creatinine clearances (CL_{CR}) of 39 to 73 mL/min, 13 to 27 mL/min, < 10 mL/min were 3 to 4.6, 9.4 to 10.3, and 11.9 to 35 hours, respectively.

The serum half-life of ceftazidime is only slightly prolonged in patients with hepatic impairment and generally, drug accumulation does not occur in these patients unless renal function is also impaired.

Ceftazidime is removed by hemodialysis and peritoneal dialysis.

INDICATIONS

For the treatment of the following infections caused by susceptible microorganisms:
- Respiratory tract infections, including ear, nose and throat infections, pneumonia, lung infections in cystic fibrosis
- Skin and skin-structure infections
- Urinary tract infections (UTI), both complicated and uncomplicated
- Bone and joint infections
- Gynecologic infections, including endometritis, pelvic cellulitis, and other infections of the female genital tract
- Intra-abdominal infections, including peritonitis and polymicrobial infections
- Central Nervous System infections, including meningitis
- Bacterial Septicemia
- Dialysis: Infections associated with hemo- and peritoneal dialysis and with continuous ambulatory peritoneal dialysis (CAPD)
- Other severe infections such as:
  - Infections in immunocompromised patients
  - Infections in patients in intensive care, e.g., infected burns

DOSAGE AND ADMINISTRATION

- For intravenous (IV) administration 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. **Intra-arterial administration should be avoided since arteriospasm and distal necrosis can occur.**
- The dosage and route should be determined by the susceptibility of the causative organism, the severity of infection, and the condition and renal function of the patient.
- The IV route is preferred in patients with severe or life-threatening infections, or in patients with lowered resistance resulting from malnutrition, trauma, surgery, diabetes, heart failure, or malignancy, particularly if shock is present or impending.

Usual Adult Dose: 1 g IV or IM every 8 to 12 hours
Maximum Dose: 6 g/day

Recommended Dose for Specific Infections in Adults:

Infections	Unit Dose	Frequency
Uncomplicated UTI	250 mg IV or IM	Every 12 hours
Complicated UTI	500 mg IV or IM	Every 8 to 12 hours
Uncomplicated pneumonia	500 mg to 1 g IV or IM	Every 8 hours
Mild skin and skin structure infections	500 mg to 1 g IV or IM	Every 8 hours
Bone and joint infections	2 g IV	Every 12 hours
Serious gynecologic infections	2 g IV	Every 8 hours
Serious intra-abdominal infections	2 g IV	Every 8 hours
Meningitis	2 g IV	Every 8 hours
Very severe life-threatening infections, especially in immunocompromised patients, including those with neutropenia	2 g IV	Every 8 hours
Lung infections caused by *Pseudomonas* spp. in patients with cystic fibrosis with normal renal function	30 to 50 mg/kg IV (Maximum dose: 6 g/day)	Every 8 hours
• In meningitis, it is recommended that the results of a sensitivity test are known before treatment with ceftazidime 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 in combination with an aminoglycoside or other beta-lactam antibiotic for example, in the presence of severe neutropenia, or with an antibiotic active against anaerobes when the presence of *Bacteroides fragilis* is suspected. • Although clinical improvement has been shown, bacteriologic cures cannot be expected in patients with chronic respiratory disease and cystic fibrosis.		

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

Patients with Renal Impairment: An initial loading dose of 1 g ceftazidime may be given in adults with suspected renal insufficiency ($CL_{CR} \leq 50$ mL/min). Maintenance dosage is based on the patient's CL_{CR} as shown below:

Recommended Maintenance Doses in Adults with Renal Impairment:

CL_{CR} (mL/min)	Recommended Unit Dose of Ceftazidime	Frequency
31 to 50	1 g	Every 12 hours
16 to 30	1 g	Every 24 hours
6 to 15	500 mg	Every 24 hours
< 5	500 mg	Every 48 hours
If the usual adult dose is lower than the recommended dose for patients with renal impairment, the lower dose should be used.		

When only the serum creatinine is available, the following formula may be used to estimate CL_{CR}. The serum creatinine should represent a steady state of renal function:

Men: CL_{CR} (mL/min) = $\frac{\text{Weight (kg) x (140 – age in years)}}{\text{72 x serum creatinine (mg/dL)}}$

Women: 0.85 x value calculated using the above formula

- In patients with severe infections, especially in neutropenics, who would normally receive 6 g of ceftazidime daily were it not for renal insufficiency, the unit dose given in the table above may be increased by 50% or the dosing frequency may be increased appropriately. In such patients it is recommended that ceftazidime serum levels should be monitored and trough levels should not exceed 40 mg/L. Further dosing should be determined by therapeutic monitoring, severity of infection, and susceptibility of the causative organism.
- In patients undergoing hemodialysis, a loading dose of 1 g is recommended, followed by 1 g after each hemodialysis period.
- Ceftazidime can also be used in patients undergoing intraperitoneal dialysis and continuous ambulatory peritoneal dialysis. In such patients, a loading dose of 1 g of ceftazidime may be given, followed by 500 mg every 24 hours.

Patients with Hepatic Impairment: No dosage adjustment is necessary.

Usual Pediatric Dosage:

Neonates (0 to 4 weeks old): 30 mg/kg body weight IV every 12 hours

Infants and children (1 month to 12 years old): 30 to 50 mg/kg body weight IV every 8 hours.
Maximum dose: 6 g/day

- The higher dose (i.e., 50 mg/kg body weight every 8 hours) should be reserved for immuno-compromised pediatric patients or pediatric patients with cystic fibrosis or meningitis.
- In pediatric patients, the CL_{CR} should be adjusted for body surface area or lean body mass, and the dosing frequency reduced in cases of renal insufficiency as for adults.

Duration of Treatment:

- Usual duration of treatment is 7 to 14 days.
- For most infections, treatment generally should be continued for at least 48 hours after the patient becomes asymptomatic or evidence of bacterial eradication has been obtained, but in complicated infections longer therapy may be required.
- For streptococcal infections, treatment should be continued for at least 10 days.
- Antibiotic treatment in patient with meningitis caused by Gram-negative bacilli generally should be continued for at least 3 weeks. In neonates with meningitis, it is recommended that antibiotic treatment be continued for 2 weeks beyond the first sterile CSF culture or at least 3 weeks, whichever is longer.

Or, as prescribed by a physician.

Directions for Use, Compatibility and Stability:

To reconstitute, dissolve ceftazidime powder for injection in Sterile Water for Injection according to the following table. Reconstituted solutions are stable for 6 hours if stored at 30°C or for 72 hours at 2°C to 8°C.

Ceftazidime Vial	Volume of Sterile Water for Injection to be added (mL)	Concentration (mg/mL)
Intramuscular		
500mg	1.5	250
1 g	3	250
Intravenous		
500mg	5	90
1 g	10	90

Ceftazidime 500 mg injection (at concentration of 10 mg/mL) and ceftazidime 1 g injection (at concentration of 20 mg/mL) are stable for 6 hours at 30°C or for 72 hours at 2 to 8°C in the following IV solutions:

- 0.9% Sodium Chloride Solution
- 5% Dextrose Solution
- Lactated Ringer's Solution

Incompatibilities:

- Ceftazidime is less stable in Sodium Bicarbonate injection than other IV fluids. It is not recommended as a diluent.
- Ceftazidime and aminoglycosides should not be mixed in the same giving set or syringe.
- Precipitation has been reported when vancomycin was added to ceftazidime in solution. It is recommended that giving sets and IV lines are flushed between administration of these two agents.

- *Prior to administration, parenteral drug products should be inspected visually for particulate matter and discoloration whenever solution and container permit.*
- *Shake the reconstituted solution before use.*
- *Observe strict aseptic technique when drawing up the contents of the vial. If contaminated, it has the potential to become a source of infection to patients.*

CONTRAINDICATION

Known hypersensitivity to cephalosporins, or any component of the product.

WARNINGS AND PRECAUTIONS

- ***Hypersensitivity Reactions:*** **Careful inquiry should be made concerning previous hypersensitivity to cephalosporins, penicillins or other drugs before initiating therapy with ceftazidime. If ceftazidime is to be given to penicillin-sensitive patients, caution should be exercised since cross-hypersensitivity among beta-lactam antibiotics has been clearly documented and may occur in up to 10% of patients with a history of penicillin allergy. If an allergic reaction to ceftazidime occurs, discontinue treatment with the drug.**

  Serious acute hypersensitivity reactions may require treatment with epinephrine and other emergency measures including oxygen, IV fluids, IV antihistamines, corticosteroids, pressor amines, and airway management as clinically indicated.

- ***Clostridium difficile*-associated diarrhea (CDAD):** This has been reported with the use of nearly all antibacterial agents, including ceftazidime, and may range in severity from mild diarrhea to fatal colitis. It is important to consider this diagnosis in patients who present with diarrhea following administration of antibacterial agents.
- ***Hemolytic Anemia:*** **CEFTAZIDIME SHOULD NOT BE USED IN PATIENTS WITH A HISTORY OF CEPHALOSPORIN-ASSOCIATED HEMOLYTIC ANEMIA SINCE THE RECURRENCE OF HEMOLYSIS IS MUCH MORE SEVERE.**

  An immune-mediated hemolytic anemia has been observed in patients receiving cephalosporin antibiotics, including ceftazidime. Severe cases of hemolytic anemia, including fatalities, have been in both adults and children. If a patient develops anemia anytime during, or within 2 to 3 weeks following the administration of ceftazidime, the diagnosis of a cephalosporin-associated anemia should be considered and the drug discontinued until the etiology is determined.

  Periodic monitoring of signs and symptoms of hemolytic anemia, including measurement of hematological parameters or drug-induced antibody testing, where appropriate, is recommended.
- ***Seizures:*** Several cephalosporins (e.g., ceftazidime, cefuroxime, cefepime), have been associated with the development of seizures, particularly in patients with impaired renal function in whom dosage of the drug was not reduced (see **UNDESIRABLE EFFECTS**). If seizures occur during treatment with ceftazidime, the drug should be discontinued and anticonvulsant therapy initiated as clinically indicated.
- ***Prothrombin Time:*** Cephalosporins may be associated with a fall in prothrombin activity. Patients who are at risk are those with renal or hepatic impairment or poor nutritional state, as well as patients receiving a protracted course of antimicrobial therapy, and patients previously stabilized on anticoagulant therapy. Prothrombin time should be monitored in patients at risk and exogenous Vitamin K administered as indicated.

Other Precautions

- Cephalosporins at high dosage should be given with caution to patients receiving nephrotoxic medicines or potent diuretics, as these combinations are suspected of adversely affecting renal function (see **INTERACTIONS WITH OTHER MEDICAMENTS**).
- Ceftazidime should be used with caution in patients with a history of lower GI disease, particularly colitis.
- Prescribing ceftazidime in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of development of drug-resistant bacteria.
- Inducible type I beta-lactamase resistance has been noted with some organisms (e.g., *Enterobacter* spp., *Pseudomonas* spp. and *Serratia* spp.) may develop resistance during ceftazidime therapy. When ceftazidime is used to treat infections caused by these Gram-negative bacteria, periodic susceptibility testing should be performed when clinically appropriate. If patients fail to respond to monotherapy, an aminoglycoside or similar agent should be considered.
- As with other antibacterial drugs, long term or repeated use may result in overgrowth of non-susceptible organisms, including fungi.

INTERACTIONS WITH OTHER MEDICAMENTS

- **Probenecid:** Concomitant administration of oral probenecid does not affect the pharmacokinetics of ceftazidime, presumably because ceftazidime is excreted principally by glomerular filtration.
- **Nephrotoxic drugs:** Concomitant treatment with high doses of cephalosporins and nephrotoxic medicines such as aminoglycosides or potent diuretics (e.g., furosemide) may result in nephrotoxicity. Renal function should be carefully monitored, especially if higher doses of the aminoglycosides are to be administered or if therapy is prolonged, because of the potential nephrotoxicity and ototoxicity of aminoglycosides. Nephrotoxicity and ototoxicity were not noted when ceftazidime was given alone in clinical trials.
- **Anti-infective agents:** Although the clinical importance is unknown, the following interactions have been observed *in vitro* when ceftazidime is concomitantly used with other anti-infective agents:
  - The antibacterial activity of ceftazidime and an aminoglycoside may be additive or synergistic against some strains of Enterobacteriaceae and *Pseudomonas aeruginosa*
  - Chloramphenicol has been reported to antagonize the bactericidal activity of beta-lactam antibiotics including ceftazidime. Therefore, this combination should be avoided particularly when bactericidal activity is considered important.
  - Use of ceftazidime and another cephalosporin or an extended spectrum penicillin has generally resulted in an effect that was only slightly additive or indifferent against *Pseudomonas aeruginosa.*
  - Ceftazidime and ampicillin has resulted in antagonism against group B streptococci and *Listeria monocytogenes.*
  - The combination of ceftazidime and clindamycin has been reported to be neither synergistic not antagonistic against *Bacteroides fragilis*
  - Ceftazidime and metronidazole may be at least partially synergistic against *Clostridium*, but results against *Bacteroides fragilis* are conflicting.
  - Combination with clavulanic acid is synergistic against some strains of *Bacteroides fragilis* resistant to ceftazidime alone. The combination was not effective against other *Bacteroides* that are not beta-lactamase producers.
- **Oral Contraceptives:** As with other antibiotics, ceftazidime may affect the gut flora, leading to lower estrogen reabsorption and reduced efficacy of combined oral estrogen/progesterone contraceptives. Therefore, alternative non-hormonal methods of contraception are recommended.

Interference with Laboratory Tests:

- A false positive reaction for glucose in the urine may occur with Benedict's solution, Fehling's solution or with Clinitest® tablets, but not with enzyme-based tests such as Clinistix®.
- Positive Coombs' test has been associated with ceftazidime therapy in about 5% of patients which may interfere with the cross-matching of blood.
- Ceftazidime does not interfere in the alkaline picrate assay for creatinine

STATEMENT ON USAGE FOR HIGH RISK GROUPS

Pregnancy: (Pregnancy Category B) Since there are no adequate and well controlled studies using ceftazidime in pregnant women, use in pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation: Ceftazidime is excreted in very low concentrations in human milk and should be used with caution in breastfeeding women.

Elderly: There are no apparent differences in efficacy and safety of ceftazidime between the elderly and younger adults. However, since elderly patients have increased risk of renal impairment, dose adjustment and renal function monitoring may be necessary.

Renal Impairment: Ceftazidime is excreted by the kidneys, almost exclusively by glomerular filtration; therefore, the total daily dosage of ceftazidime should be reduced in patients with renal impairment. Continued dosage should be determined by degree of renal impairment, severity of infection, and susceptibility of the causative organisms.

Since ceftazidime is removed by hemodialysis, a supplemental dose of the drug is generally indicated after each dialysis period.

Hepatic Impairment: No dose adjustment is required for patients with hepatic dysfunction provided renal function is not impaired.

UNDESIRABLE EFFECTS

Ceftazidime is generally well-tolerated. The incidence of adverse reactions associated with ceftazidime use was low in clinical trials. The most common were local reactions after IV injection and allergic and GI reactions. No disulfiram-like reactions were reported.

The following adverse effects (AEs) were considered to be either related to ceftazidime therapy or were of uncertain etiology:

Local Effects: Phlebitis or thrombophlebitis with IV administration, pain and/or inflammation at injection site after IM injection (mild to moderate for about 2 to 5 minutes and subsides within 10-20 minutes); distal necrosis can occur after inadvertent intra-arterial administration of ceftazidime

Dermatologic / Hypersensitivity Reactions: Anaphylaxis (bronchospasm and/or hypotension), angioedema, allergic exanthema, allergic reactions, which, in rare instances, were severe (e.g., cardiopulmonary arrest); erythema multiforme, fever, photosensitivity, pruritus, rash (maculopapular or erythematous), Stevens-Johnson syndrome, toxic epidermal necrolysis, urticaria

GI: Abdominal pain, diarrhea, colitis/pseudomembranous colitis, metallic taste, nausea, vomiting

Nervous System: Dizziness, headache, lethargy, paresthesia; elevated levels of ceftazidime in patients with renal impairment can lead to seizures, convulsions, asterixis, tremor, myoclonia, epilepsy, encephalitis/encephalopathy, neuromuscular excitability, hallucinations and coma.

Hematologic: Transient eosinophilia, leukopenia, neutropenia, and thrombocytopenia; reversible thrombocytosis; rare cases of hemolytic anemia, agranulocytosis, and lymphocytosis; positive Coombs' test without hemolysis

Hepatobiliary: Transient increases in serum concentrations of aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase, lactate dehydrogenase (LDH), and/or gamma-glutamyltransferase; hyperbilirubinemia; hepatitis and/or jaundice

Renal Effects: Transient increases in blood urea, blood urea nitrogen (BUN) and/or serum creatinine concentrations; transient mild to moderate decrease in glomerular filtration; interstitial nephritis; renal failure although a causal relationship to the drug has not been established

Other Adverse Effects (AEs): Blurred vision, flushing, candidiasis (oral thrush), vaginitis; superinfections with organisms resistant to ceftazidime

In addition to the AEs listed above which have been observed in patients treated with ceftazidime, the following AEs have been reported for cephalosporin-class antibiotics:

Hypersensitivity reactions including chills, joint pain or inflammation, arthralgia, edema, facial edema, erythema, genital and anal pruritus, shock, vasodilatation, and exfoliative dermatitis; anaphylaxis including a few fatalities; thrombocythemia, leukocytosis, granulocytosis, monocytosis, lymphocytopenia, basophilia, decreased hemoglobin and/or hematocrit; anemia, aplastic anemia, pancytopenia, epistaxis or hemorrhage, hypoprothrombinemia; colitis, tenesmus, epigastric pain/dyspepsia, decreased appetite/anorexia, glossitis, flatulence, taste alteration, decreased salivation, heartburn; renal dysfunction, toxic nephropathy, hepatic dysfunction including cholestasis; prolonged prothrombin time; false-positive test for urinary glucose; increased or decreased serum glucose concentration; decreased serum albumin and/or total protein; vaginal candidiasis, menstrual irregularities; malaise, fatigue, nightmares, vertigo, hyperactivity, nervousness or anxiety, agitation, sleep disorder/insomnia, somnolence, weakness, hot flushes, alteration in color perception, confusion, and hypertonia; chest pain, pleural effusion, pulmonary infiltrate, dyspnea or respiratory distress, cough, rhinitis

OVERDOSE AND TREATMENT

Ceftazidime overdosage has occurred in patients with renal impairment which can lead to neurological sequelae including encephalopathy, convulsions and coma. Patients who receive an acute overdosage should be carefully monitored and given supportive treatment.

In case of renal insufficiency, serum levels of ceftazidime can be reduced by hemodialysis or peritoneal dialysis.

STORAGE CONDITIONS

- Store ceftazidime powder for injection at temperatures not exceeding 30°C.
- Protect from light.
- Keep the product out of sight and reach of children.

ADVERSE DRUG REACTION REPORTING STATEMENT

For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph and Unilab at (+632) 858-1000 or productsafety@unilab.com.ph. By reporting undesirable effects, you can help provide more information on the safety of this medicine.

AVAILABILITY

Ceftazidime (Zeptrigen®) 500 mg Powder for Injection in vial of 1s and 10s
Ceftazidime (Zeptrigen®) 1 g Powder for Injection in vial of 1s and 10s

CAUTION: Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

DATE OF REVISION: September 20, 2018

DATE OF FIRST AUTHORIZATION: October 2012

Ceftazidime (Zeptrigen®) 500 mg Powder for Injection: DR-XY27652

Ceftazidime (Zeptrigen®) 1 g Powder for Injection:DR-XY27651

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Jl. Lanbau Liobaru RT. 007 RW. 009, Kel.
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