· children 1 month and older: 90 to 150 mg/kg daily in 3 divided doses (to a maximum daily dose of 3 g) for mild to moderate infections, or 200 to 300 mg/kg daily in 3 divided doses (to a maximum daily dose of 6 g) in severe infections

Administration in renal impairment.

In patients with renal impairment parenteral doses of ceftazidime may need to be reduced. After a loading dose of I g, maintenance doses are based on the creatinine clearance (CC):

· CC 3 1 to 50 mL/minute: 1 g every 12 hours
· CC 16 to 30 mL/minute: 1 g every 24 hours
· CC 6 to 15 mL/minute: 500 mg every 24 hours
· CC less than 5 mL/minute: 500 mg every 48 hours

In severe infections these doses may need to be increased by 50 %. In these patients ceftazidime trough serum concentrations should not exceed 40 micrograms/mL. In patients undergoing peritoneal dialysis a loading dose of 1g may be given followed by 500 mg every 24 hours; ceftazidime sodium may also be added to the dialysis fluid, usually 125 to 250 mg of ceftazidime for 2 litres of dialysis fluid. In patients undergoing haemodialysis a loading dose of 1 g is given and then 1 g after each dialysis period. For critically ill patients undergoing continuous renal replacement therapy, a loading dose of 2 g and the following maintenance doses, given intravenously, have been recommended: 1

· for continuous venovenous haemodialysis (CVVHD) or haemodialfiltration (CVVHD F) : 1 g every 8 hours or 2 g every 12 hours; 2 g every 8 hours may be necessary for very resistant Gram-negative pathogens

· for continuous venovenous haemofiltration (CVVH) : 1 to 2 g every 12 hours Continuous infusion dosing regimens have also been suggested for use in patients undergoing CVVHDF2 and CVVH.3

Intravenous injection & Intravenous Infusion

· Insert the syringe needle through the vial closure and inject 5mL WFI into each 500-mg vial; 10mL WFI into each 1-g or 2-g vial; 15mL WFI into each 3-g vial.
· Remove the needle and shake to dissolve. CO2 is released and a clear solution should develop in about 1-2 minutes.
· Invert the vial and, with syringe plunger fully depressed, insert the needle through the vial closure and withdraw all the solution into the syringe. Ensure that the needle does not enter the head space.
· Expel any small bubbles of CO2 present in the syringe.
· The solution should be clear and light yellow to amber. Inspect visually for particulate matter or discoloration prior to administration and discard if present.
· Given by IV injection over 3-5 minutes.

IV Infusion

· Withdraw the required dose and add to a suitable volume of compatible infusion fluid (usually 100mL NaCl 0.9%). Use a minimum 50mL for a 2-g dose; 100mL for a 3-g dose.
· Given by IV infusion over 20-30 minutes.

Intramuscular injection

· Insert the syringe needle through the vial closure and inject 1.5mL WFI into each 500-mg vial; 3mL WFI into each 1-g vial.
· Remove the needle and shake to dissolve. CO2 is released and a clear solution should develop in about 1-2 minutes.
· Invert the vial and with syringe plunger fully depressed, insert the needle through the vial closure and withdraw all the solution into the syringe. Ensure that the needle does not enter the head space.
· Expel any small bubbles of CO2 present in the syringe.
· Given by IM injection into a large muscle such as the gluteus or the lateral aspect of the thigh. Rotate injection sites for subsequent injections.

Adverse Effects

Immediate: Anaphylaxis and other hypersensitivity reactions have been reported. Injection/infusion-related: Local: Thrombophlebitis following IV injection; pain and/or inflammation after IM injection. Other: Nausea, vomiting, abdominal pain, diarrhoea, urticaria, pruritus.

Nursing Mothers:

Ceftazidime Injection is excreted in human milk in low concentrations. It is not known whether the arginine component of this product is excreted in human milk. Because many drugs are excreted in human milk and because safety of the arginine component of ceftazidime in nursing infants has not been established, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Overdosage:-

General symptomatic and supportive methods, together with specific measures to control any seizures. Ceftazidime can be removed by haemodialysis and haemoperfusion.

Storage: - Store below 25°C Protected from light & Moisture.

Improper Storage may deteriorate the product

Medicine: - Keep out of reach of children.

Presentation: - Each pack contain Ceftazidime for injection IP in a vial and sterile water for injection IP

Manufactured by:

AMERICAN REMEDIES ©
Care & Cure with Research
American Remedies Healthcare Pvt. Ltd.
(An ISO 9001-2015 Certified Company)

ICO: American Remedies LLC, DE, USA
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WHO GMP CERTIFIED

Scan for Batch Certificate

For the use only of a Registered Medical Practitioner of a Hospital or a Laboratory

℞ Ceftazidime for Injection IP

AMERICAN

AZIDIME 1g
Injection

FOR IM/IV USE ONLY

Composition:-

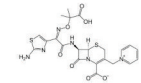
Each Vial Contains:-

Ceftazidime (Sterile)	IP
Eq. to anhydrous Ceftazidime	1000 mg

(A Sterile mixture of Ceftazidime & Sodium carbonate)

Description

Ceftazidime is a semisynthetic, broad-spectrum, beta-lactam antibiotic for parenteral administration. It is as pentahydrate *(7 R)-7 -[(Z)-* 2-(2-arninothiazol-4-yl)-2-(1-carboxy- 1 -methylethoxyimino)- acetainido]-3-(1-pyridinomethyl)-3-cepham-4-carboxylate pentahydrate. The molecular formula is $C_{22}H_{32}N_6O_{12}S_2$, representing a molecular weight of 636.6. It has the following Stricture.



Ceftazidime

PHARMACOLOGY

Pharmacokinetics

Ceftazidime is given by injection as the sodium salt or in solution with arginine. Mean peak plasma concentrations of 17 and 39 micrograms/mL have been reported about I hour after intramuscular doses of 0.5 and 1 g of ceftazidime, respectively. Five minutes after intravenous bolus injections of 0.5, 1, and 2 g of ceftazidime, means plasma concentrations of 45, 90, and 1 70 micrograms/mL, respectively, have been reported. The plasma half-life of ceftazidime is about 2 hours, but this is prolonged in patients with renal impairment and in neonates. Clearance may be enhanced in patients with cystic fibrosis. It is about 1 0 % bound to plasma proteins. Ceftazidirne is widely distributed in body tissues and fluids; therapeutic concentrations occur in the CSF when the meninges are inflamed. It crosses the placenta and is distributed into breast milk.

Ceftazidime is passively excreted in bile, although only a small proportion is eliminated by this route. It is mainly excreted by the kidneys, almost exclusively by glomerular filtration; probenecid has little effect on the excretion. About 80 to 90% of a dose appears unchanged in the urine within 24 hours. It is removed by haemodialysis and peritoneal dialysis.

Dosage and Administration

Ceftazidime is a third-generation cephalosporin antibacterial with enhanced activity against Pseudomonas aeruginosa. It is used in the treatment of infections caused by susceptible Gram-positive and Gram-negative bacteria, especially infections due to Pseudomonas spp. They include biliarytract infections, bone and joint infections, respiratory-tract infections, infections in immunocompromised patients (neutropenic patients), skin and skin structure infections, and urinary-tract infections. It is also used for surgical infection prophylaxis. For details of these infections and their treatment,

Ceftazidime is available as the pentahydrate but it is formulated with sodium carbonate, to form the sodium salt in solution, or with arginine. Doses are expressed in terms of anhydrous ceftazidime:. It is given by deep intramuscular injection, slow intravenous injection over 3 to 5 minutes, or intravenous infusion over up to 30 minutes. The usual dose for adults ranges from 1 to 6 g daily in divided doses every 8 or 12 hours. The higher doses are used in severe infections especially in immunocompromised patients. In adults with cystic fibrosis who have pseudomonal lung infections, high doses of 90 to 150 mg/kg daily in 3 divided doses are used; up to 9 g daily has been given to those with normal renal function. Single doses of more than 1 g should be given intravenously.

For surgical infection prophylaxis in patients undergoing prostatic surgery, a dose of 1 g may be given at induction of anaesthesia and repeated if necessary when the catheter is removed. The dose of ceftazidime may need to be reduced in patients with renal impairment, For details of doses in children, Ceftazidime can be used with an aminoglycoside, another beta Jactam such as piperadllin, or vancomycin in patients with severe neutropenia, or, if infection with Bacteroides fragilis is suspected, with an antimicrobial such as clindamydn or metronidazole. The drugs should generally be given separately.

Administration in Children

Ceftazidime may be given to children for the treatment of infections caused by susceptible Gram-positive and Gram-negative bacteria. It is given by deep intramuscular injection, slow intravenous injection over 3 to 5 minutes, or intravenous infusion. The BNFC recommends that neonates and children may be given a dose of 25 mg/kg every 24 hours in neonates less than 7 days old, every 12 hours in those aged 7 to 21 days, and every 8 hours in older neonates and children. The dose may be doubled in severe infection, febrile neutropenia, and meningitis (to a maximum daily dose of 6 g in children 1 month of age and older). For pseudomonal lung infection in cystic fibrosis in patients aged 1 month and older a dose of 50 mg/kg every 8 hours (to a maximum daily dose of 9 g) may be given.

American Academy of Pediatrics 1 suggests the following doses for ceftazidime:

· for neonates aged <S 7 days (irrespective of body weight) : 50 mg/kg every 12 hours
· for neonates aged 8 to 2 8 days and weighing <:; 2 kg: 50 mg/kg every 8 to 12 hours; a dosing interval of 12 hours may be used until 2 weeks of life in extremely low birth-weight neonates (weighing less than 1 kg)
· for neonates aged 8 to 2 8 days and weighing > 2 kg: 50 mg/kg every 8 hours