Azonam®

Aztreonam

Presentation

Azonam® 1g IM/IV injection: Each vial contains Aztreonam 1 gm as Aztreonam for Injection (Sterile) USP.

Description

Aztreonam is a synthetic bactericidal monobactam antibiotic. It inhibits bacterial cell wall synthesis by blocking peptidoglycan crosslinking. The inhibition of bacterial cell wall synthesis occurs due to a high affinity of Aztreonam for penicillin binding protein 3 (PBP3). By binding to PBP3, Aztreonam inhibits the third and last stage of bacterial cell wall synthesis. Cell lysis is then mediated by bacterial cell wall autolytic enzymes such as autolysins. It is possible that Aztreonam interferes with an autolysin inhibitor.

Indications

Aztreonam is indicated for the treatment of the following infections caused by susceptible Gram-negative microorganisms:

- Urinary Tract Infections (complicated and uncomplicated), including pyelonephritis and cystitis (initial and recurrent) caused by *Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa, Enterobacter cloacae, Klebsiella oxytoca,* Citrobacter species and *Serratia marcescens*.
- Lower Respiratory Tract Infections, including pneumonia and bronchitis caused by *Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, Haemophilus influenzae, Proteus mirabilis,* Enterobacter species and *Serratia marcescens.*
- Septicemia caused by *Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, Proteus mirabilis, Serratia marcescens* and Enterobacter species.
- Skin and Skin-Structure Infections, including those associated with postoperative wounds, ulcers and burns caused by *Escherichia coli, Proteus mirabilis, Serratia marcescens,* Enterobacter species*, Pseudomonas aeruginosa, Klebsiella pneumoniae* and Citrobacter species.
- Intra-abdominal Infections, including peritonitis caused by *Escherichia coli,* Klebsiella species including *K. pneumoniae,* Enterobacter species including *E. cloacae, Pseudomonas aeruginosa, Citrobacter species* including *C. freundii* and Serratia species including *S. marcescens.*
- Gynecologic Infections, including endometritis and pelvic cellulitis caused by *Escherichia coli, Klebsiella pneumoniae,* Enterobacter species including *E. cloacae* and *Proteus mirabilis*.

Aztreonam is indicated for adjunctive therapy to surgery in the management of infections caused by susceptible organisms.

Dosage and administration

Patients	Type of Infection	Dose	Frequency (hrs)
Adult	Urinary tract infections	500 mg or 1 g	8 or 12
	Moderately severe systemic infections	1 g or 2 g	8 or 12
	Severe systemic or life-threatening infections	2 g	6 or 8
Pediatric	Mild to moderate infections	30 mg/kg	8
	Moderate to severe infections (2 years or older)	50 mg/kg	6 or 8

Maximum recommended dose for adult is 8 g per day.
Maximum recommended dose for pediatric patient is 120 mg/kg/day.

Pediatric use

Dosage information is not yet available for new born less than one week.

Renal impairment in adult patients

The dosage of Aztreonam should be halved in patients with estimated creatinine clearances between 10 mL/min/1.73 m^2 and 30 mL/min/1.73 m^2 after an initial loading dose of 1 g or 2 g. When only the serum creatinine concentration is available, the following formula (based on sex, weight, and age of the patient) may be used to approximate the creatinine clearance (Clcr):-

$$\text{Males: Clcr} = \frac{\text{weight (kg)} \times (140\text{-age})}{72 \times \text{serum creatinine (mg/dL)}}$$

Females: Clcr = 0.85 × above value

In patients with severe renal failure (creatinine clearance less than 10 mL/min/1.73 m^2), the usual dose of 500 mg, 1 g or 2 g should be given initially. The maintenance dose should be one-fourth of the usual initial dose given at the usual fixed interval of 6, 8 or 12 hours. For serious or life-threatening infections, in addition to the maintenance doses, one-eighth of the initial dose should be given after each hemodialysis session.

Side effect

Local reactions such as phlebitis/thrombophlebitis following IV administration and discomfort/swelling at the injection site following IM administration may occur. Systemic reactions like diarrhea, nausea and/or vomiting, and rash may occur. Other side effects include anaphylaxis, angioedema, bronchospasm, pancytopenia, neutropenia, thrombocytopenia, anemia, eosinophilia, leukocytosis, thrombocytosis, abdominal cramps, dermatitis, urticaria, pruritus, hypotension, flushing, seizure, weakness, headache, fever, malaise may occur.

Drug interaction

Concomitant administration of probenecid or furosemide and Aztreonam causes clinically insignificant increases in the serum levels of Aztreonam.

Use in pregnancy and lactation

Aztreonam is a Pregnancy Category B drug. There are no adequate and well-controlled studies in pregnant women. Aztreonam is excreted in human milk in concentrations less than 1%; consideration should be given to temporary discontinuation of nursing.

Contraindication

This preparation is contraindicated in patients with known hypersensitivity to Aztreonam or any other component in the formulation.

Precaution

In patients with impaired hepatic or renal function, appropriate monitoring is recommended during therapy.

Direction for reconstitution

Rout	Injection/ Infusion	1 gm
IV	Bolus injection	6 to 10 mL
	Infusion	3 mL*
IM	Injection	3 mL

*Intravenous infusion: The reconstituted solution must be further diluted with an appropriate infusion solution to final concentration less than 2% w/v (at least 50 ml solution per gram of Aztreonam).
Appropriate infusion solution may be 0.9% Sodium Chloride Injection BP, 5% Glucose Intravenous Infusion BP, 5% or 10% Mannitol Intravenous Infusion BP.

Administration

Intravenous administration
Bolus injection: The dose should be slowly injected directly into a vein, or the tubing of a suitable administration set, over a period of 3 to 5 minutes.
Infusion: Infusion should be completed within a 20 to 60 minutes period.
Intramuscular administration
The dose should be given by deep injection into a large muscle mass. Aztreonam is well tolerated and should not be admixed with any local anesthetic agent.

Pharmaceutical precaution

Aztreonam solutions for IV infusion at concentrations not exceeding 2% w/v must be used within 48 hours following constitution if kept at controlled room temperature (15°-30 °C) or within 7 days if refrigerated (2°- 8 °C).

Commercial pack

Azonam®1g IM/IV injection: Each box contains 1 vial of Aztreonam 1 gm, one ampoule of 10 ml water for injection BP and a sterile disposable syringe (10 ml).

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