Trizidim®

IM/ IV Injection

Ceftazidime

COMPOSITION

Trizidim® 250 mg IM/IV: Each vial contains sterile Ceftazidime Pentahydrate with sodium carbonate buffer equivalent to Ceftazidime USP 250 mg.

Trizidim® 500 mg IM/IV: Each vial contains sterile Ceftazidime Pentahydrate with sodium carbonate buffer equivalent to Ceftazidime USP 500 mg.

Trizidim® 1 g IM/IV: Each vial contains sterile Ceftazidime Pentahydrate with sodium carbonate buffer equivalent to Ceftazidime USP 1 g.

Water for injection: Each ampoule contains 5 ml or 10 ml sterile water for injection BP for reconstitution.

PHARMACOLOGY

Trizidim® (Ceftazidime) is a bactericidal cephalosporin antibiotic, which is resistant to most beta-lactamases and is active against a wide range of gram-positive and gram-negative bacteria. It is indicated for the treatment of single infections and for mixed infections caused by two or more susceptible organisms.

INDICATIONS

Trizidim® is indicated for the treatment of the following infections caused by susceptible organisms:

- Lower respiratory tract infections
- Skin & skin structure infections
- Urinary tract infections
- Bacterial septicemia
- Bone & joint infections
- Gynecological infections
- Intra-abdominal infections
- Central nervous system infections
- Infections associated with haemo-and peritoneal dialysis and with continuous ambulatory peritoneal dialysis (CAPD)

DOSAGE & ADMINISTRATION

Route of administration: Intravenous & Intramuscular

	Dose	Frequency
Adults		
Usual recommended dosage	**1 g IV or IM**	**8-12 hourly**
Uncomplicated pneumonia	500 mg - 1 g IV or IM	8 hourly
Lung infections caused by Pseudomonas spp. in patients with cystic fibrosis with normal renal function	30-35 mg /kg IV to a maximum of 6 g per day	8 hourly
Mild skin and skin-structure infections	500 mg - 1 g IV or IM	8 hourly
Uncomplicated urinary tract infections	250 mg IV or IM	12 hourly
Complicated urinary tract infections	500 mg IV or IM	12 hourly
Bone & joint infections	2 g IV	8-12 hourly
Very severe life-threatening infections, especially in immunocompromised patients	2 g IV	8 hourly
Meningitis	2 g IV	8 hourly
Serious gynecological and intra-abdominal infections	2 g IV	8 hourly
Neonates (0-4 weeks)	30 mg/kg IV	12 hourly
Infants and children (1 month - 12 years)	30-50 mg/kg IV to maximum of 6 g per day	8 hourly

Dose in dialysis: 1 g loading dose followed by 1 g after each hemodialysis period.

OR AS DIRECTED BY THE PHYSICIAN.

Direction for Reconstitution:

Vial size	Route of administration	Amount of sterile water to be added
250 mg	IM	1 ml
	IV	2.5 ml
500 mg	IM	1.5 ml
	IV	5.0 ml
1 g	IM	3.0 ml
	IV	10 ml

CONTRAINDICATIONS

Ceftazidime is contra-indicated in patients with known hypersensitivity to Cephalosporins or any other ingredients of it.

WARNING & PRECAUTION

As with other beta-lactam antibiotics, before therapy with Ceftazidime is instituted, careful inquiry should be made for a history of hypersensitivity reactions to Ceftazidime, Cephalosporins, penicillins, or other drugs.

There is no experimental evidence of embryopathic or teratogenic effects. Clinical experience with Ceftazidime has shown that this is not likely to be a problem at the recommended dose levels. There is no evidence that Ceftazidime adversely affects renal function at normal therapeutic doses.

SIDE EFFECTS

Common: Local: Phlebitis or thrombophlebitis with IV administration; pain and/or inflammation after IM injection. Gastrointestinal: Diarrhoea, Nausea, Vomiting, Abdominal Pain and very rarely Oral Thrush or Colitis. Hypersensitivity: Urticarial Rash, Fever, Pruritis, and very rarely Angioedema and Anaphylaxis (Bronchospasm and/or Hypotension). Genito-urinary: Candidiasis, Vaginitis. Central Nervous System: Headache, Dizziness and Bad Taste.*Rare:* Side effects my include Colitis, Toxic Nephropathy, Hepatic Dysfunction including Cholestasis, Aplastic Anemia, Hemorrhage.

USE IN PREGNANCY & LACTATION

Ceftazidime is of pregnancy category B. There is no experimental evidence of embryopathic or teratogenic effects attributable to ceftazidime; it should be administered with caution during the early month of pregnancy and early infancy. Nursing Mother: Ceftazidime is excreted in human milk in low concentrations. Caution should be exercised.

USE IN CHILDREN & ADOLESCENTS

Ceftazidime can be given for patients from Zero-day and older.

DRUG INTERACTION

With medicine: Nephrotoxicity has been reported following concomitant administration of Cephalosporins with aminoglycoside antibiotics or potent diuretics such as furosemide.

With food and others: No interactions found.

OVERDOSE

Ceftazidime overdose can cause Muscle Stiffness, Restless Feeling, Confusion, Uncontrolled Movement of the hands, Seizure and Coma.

STORAGE

Unconstituted vials of **Trizidim®** (Ceftazidime) Injection should be stored at a temparature below 25^{0}C. Reconstituted solutions are stable for up to 24 hours if stored between 2^{0}C and 8^{0}C and protected from light & moisture. Reconstituted solutions range from light yellow to amber color.

PACKING

Trizidim® (Ceftazidime) is supplied as sterile powder in glass vials.

Trizidim® 250 mg IM/IV injection: Each box contains 1 vial of Ceftazidime USP 250 mg and one ampoule of 5 ml water for injection in blister pack, a 5 ml disposable syringe, a baby needle & an alcohol pad.

Trizidim® 500 mg IM/IV injection: Each box contains 1 vial of Ceftazidime USP 500 mg and one ampoule of 5 ml water for injection in blister pack, a 5 ml disposable syringe, a baby needle & an alcohol pad.

Trizidim® 1 g IM/IV injection: Each box contains 1 vial of Ceftazidime USP 1 g and one ampoule of 10 ml water for injection in blister pack, a 10 ml disposable syringe & an alcohol pad.

Keep all medicines out of reach of children.

*** Further information is available on request.**

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Manulaclured by:
The ACME Laboratories Ltd.
Dhulivita, Dhamrai, Dhaka, Bangladesh
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