DORTUM

250mg, 500mg
FOR I.V. & I.M. USE

(Ceftazidime)

For Injection U.S.P.

QUALITATIVE AND QUANTITATIVE COMPOSITION QUALITATIVE
DORTUM for Injection 250mg U.S.P.:
Each vial contains:
Ceftazidime (as pentahydrate with sodium carbonate).....250mg
DORTUM for Injection 500mg U.S.P.:
Each vial contains:
Ceftazidime (as pentahydrate with sodium carbonate).....500mg

DESCRIPTION
Ceftazidime is a semisynthetic, broad-spectrum, beta-lactam antibacterial drug for parenteral administration.

CLINICAL PHARMACOLOGY
Therapeutic indications:
Nosocomial pneumonia
Broncho-pulmonary infections in cystic fibrosis Bacterial meningitis
Chronic suppurative otitis media Malignant otitis externa Complicated urinary tract infections
Complicated skin and soft tissue infections Complicated intra-abdominal infections Bone and joint infections
Peritonitis associated with dialysis in patients on CAPD.
Bacteremia (Inhibits the cell wall synthesis)

Ceftazidime may be used in the management of neutropenic patients with fever that is suspected to be due to a bacterial infection. Ceftazidime may be used in the preoperative prophylaxis of urinary tract infections for patients undergoing transurethral resection of the prostate (TURP).

MECHANISM OF ACTION:
Pharmacokinetics: Absorption: After intramuscular administration of 500 mg and 1 g of ceftazidime, peak plasma levels of 18 and 37 mg/l, respectively, are achieved rapidly. Five minutes after intravenous bolus injection of 500 mg, 1 g or 2 g, plasma levels are 46, 87 and 170 mg respectively. Distribution: The serum protein binding is low at about 10%. Concentrations in excess of the MIC for common pathogens can be achieved in tissues such as bone, heart, bile, sputum, aqueous humour, synovial, pleural and peritoneal fluids. Ceftazidime crosses the placenta readily, and is excreted in the breast milk. Penetration of the intact blood-brain barrier is poor, resulting in low levels of ceftazidime in the CSF in the absence of inflammation. However, concentrations of 4 to 20 mg/l or more are achieved in the CSF when the meninges are inflamed. Biotransformation: Ceftazidime is not metabolised. Elimination: After parenteral administration plasma levels decrease with a half-life of about 2 h. Ceftazidime is excreted unchanged into the urine; approximately 80 to 90% of the dose is recovered in the urine within 24 h. Less than 1% is excreted via the bile. Special patient populations Renal impairment: Elimination of ceftazidime is decreased in patients with impaired renal function and the dose should be reduced. Hepatic impairment: The presence of mild to moderate hepatic dysfunction had no effect on the pharmacokinetics of ceftazidime. Elderly: The reduced clearance observed in elderly patients. The mean elimination half-life ranged from 3.5 to 4 hours following single or 7 days repeat BID dosing of 2 g IV bolus injections in elderly patients 80 years or older. Paediatric population: The half-life of ceftazidime is prolonged in preterm and term neonates by 4.5 to 7.5 hours after doses of 25 to 30 mg/kg. However, by the age of 2 months the half-life is within the range for adults.

CONTRAINDICATIONS:
Ceftazidime is contraindicated in patients with known hypersensitivity to ceftazidime or other cephalosporin antibiotics.

USE IN SPECIFIC POPULATION:
Pregnancy category B: There is no experimental evidence of embryopathic or teratogenic effects, it should be administered with caution during the early months of pregnancy and in early infancy. Lactation: Ceftazidime is excreted in human milk in low concentrations.

SPECIAL WARNINGS AND PRECAUTIONS: Hypersensitivity reactions: Careful inquiry should be made for a history of hypersensitivity reactions to ceftazidime, cephalosporin's, penicillin's or other drugs. If an allergic reaction to ceftazidime occurs, discontinue the drug. Renal function: Cephalosporin antibiotics at high dosage should be given with caution to patients receiving. concurrent treatment with nephrotoxic drugs, Reproductive system disorders: Candidiasis, vaginitis.

POSOLOGY AND METHOD OF ADMINISTRATION: Adults; Ceftazidime is 1 to 6g per day 8 or 12 hourly via the intramuscular or intravenous route. In urinary tract infections and in many less serious infections, 500mg or 1g 12-hourly is usually adequate. In very severe infections, especially immunocompromised patients, including those with neutropenia, 2g 8 or 12-hourly or 3g 12-hourly should be administered. When used as a prophylactic agent in prostatic surgery, 1g (from the 1g vial) should be given at the induction of anesthesia. A second dose should be considered at the time of catheter removal. Elderly: In view of the reduced clearance of ceftazidime in acutely ill elderly patients, the daily dosage should not normally exceed 3g, especially in those over 80 years of age. Cystic fibrosis: In fibrocystic adults with normal renal function who have pseudomonal lung infections, high doses of 100 to 150mg/kg/day as three divided doses should be used. In adults with normal renal function 9g/day has been used. Infants and children: The usual dosage range for children aged over two months is 30 to 100mg/kg/day, given as two or three divided doses. Doses up to 150mg/kg/day (maximum 6g daily) in three divided doses may be given to infected immunocompromised or fibrocystic children or children with meningitis. Neonates and children up to 2 months of age: Whilst clinical experience is limited, a dose of 25 to 60mg/kg/day given as two divided doses has proved to be effective. In the neonate the serum half-life of ceftazidime can be three to four times that in adults. Dosage in impaired renal function: An initial loading dose of 1g of ceftazidime may be given. For patients in renal failure on continuous arteriovenous haemodialysis or high-flux haemofiltration in intensive therapy units, it is recommended that the dosage should be 1g daily in divided doses. For low-flux hemofiltration it is recommended that the dosage should be that suggested under Dosage in impaired renal function.

Recommended maintenance doses of ceftazidime in renal insufficiency:

Creatinine clearance (ml/min)	Approx. serum creatinine* μmol/l (mg/dl)	Recommended unit dose of ceftazidime (g)	Frequency of dosing (hourly)
50-31	150-200 (1.7-2.3)	1	12
30-16	200-350(2.3-4.0)	1	24
16-6	350-500(4.0-5.6)	0.5	24
<5	>500 (>5.6)	0.5	48

Dosage in peritoneal dialysis: Ceftazidime may also be used in peritoneal dialysis and continuous ambulatory peritoneal dialysis (CAPD). As well as using ceftazidime intravenously, it can be incorporated into the dialysis fluid (usually 125 to 250mg for 2L of dialysis fluid).

METHOD OF ADMINISTRATION: Ceftazidime should be administered by intravenous injection or infusion, or by deep intramuscular injection. Intramuscular administration should only be considered when the intravenous route is not possible or less appropriate for the patient, with 250mg IM add 1mL diluent, with 250mg IV add 2.5ml diluent, with 500mg IM add 1.5mL diluent, with 500IV add 5mL diluent.

Vial size	Route of administration	Amount of Diluent to be added (ml)	Approximate Concentration (mg/ml)
250mg	Intramuscular	1.0	210
250mg	Intravenous	2.5	90
500mg	Intramuscular	1.5	260
500mg	Intravenous	5.0	90

INSTRUCTIONS: Dosage as directed by the physician. Store below 30°C. Protect from light. Keep all medicines out of the reach of children. To be sold on the prescription of registered medical practitioner only.

PRESENTATION:
DORTUM (Ceftazidime) for Injection 250mg U.S.P. as 1 single dose glass vial packed with 1 ampoule of 5mL water for injection with leaflet. DORTUM (Ceftazidime) for Injection 500mg U.S.P. as 1 single dose glass vial packed with 1 ampoule of 5mL water for injection with leaflet.

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