Serozid®

Ceftazidime

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

Mode of action
Ceftazidime (**Serozid®**) kills bacteria by interfering in the synthesis of the bacterial cell wall. Ceftazidime binds with high affinity to penicillin-binding proteins in the bacterial cell wall, thus interfering with peptidoglycan synthesis. As a result, the bacterial cell wall is weakened, the cell swells and then rupture.

Composition
Serozid® 250 mg IM/IV Injection: Each vial contains sterile Ceftazidime Pentahydrate USP 320.510 mg equivalent to Ceftazidime 250 mg. **Serozid® 500 mg IM/IV Injection:** Each vial contains sterile Ceftazidime Pentahydrate USP 641.02 mg equivalent to Ceftazidime 500 mg. **Serozid® 1 g IM/IV Injection:** Each vial contains sterile Ceftazidime Pentahydrate USP 1.282 gm equivalent to Ceftazidime 1 gm.

Indications
Severe infections, such as septicaemia, bacteraemia, peritonitis, meningitis and infections in immuno-suppressed patients with haematological or solid malignancies. Lower respiratory tract infections including pneumonia, pleurisy, lung abscess, bronchiectasis and lung infections with cystic fibrosis. Severe infections of the ear, nose, and throat such as otitis media, malignant otitis externa, mastoiditis and sinusitis. Severe urinary tract infections including pyelonephritis, renal abscess and prostitis. Skin and soft tissue infections, including infected burns. Gastrointestinal, biliary and intra-abdominal infections including peritonitis, diverticulitis and pelvic infections. Bone and joint infections. Dialysis: Infections associated with haemo and peritoneal dialysis and with continuous ambulatory peritoneal dialysis (CAPD). Infections in immuno-compromised patients. Concomitant antibiotic therapy.

Dosage & administration
Ceftazidime is to be used by the parenteral route, the dosage depending upon the severity, sensitivity and type of infection and the age, weight and renal function of the patient. *Adults:* The adult dosage range for ceftazidime is 1 to 6 g per day 8 or 12-hourly (IM or IV). In the majority of infections, 1 g 8-hourly or 2 g 12-hourly should be given. In urinary tract infections and in many less serious infections, 500 mg or 1 g 12-hourly is usually adequate. In very severe infections, especially immuno-compromised patients, including those with neutropenia, 2 g 8 or 12-hourly, or 3 g 12-hourly should be administered. When used as a prophylactic agent in prostatic surgery 1 g (from the 1 g vial) should be given at the induction of anaesthesia. A second dose should be considered at the time of catheter removal. *Cystic fibrosis:* In fibrocystic adults with normal renal function who have pseudomonal lung infections, high doses of 100 to 150 mg/kg/day as three divided doses should be used. In adults with normal renal function, 9 g/day has been used. *Infants and children:* The usual dosage range for children aged over 2 months is 30 to 100 mg/kg/day, given as two or three divided doses. Doses upto 150 mg/kg/day (maximum 6 g daily) in three divided doses may be given to infected immuno-compromised or fibrocystic children or children with meningitis. *Neonates and children upto 2 months of age:* A dose of 25 to 60 mg/kg/day given as two divided doses has been proved to be effective. *Dosage in impaired renal function:* Ceftazidime is excreted by the kidneys almost exclusively by glomerular filtration. Therefore, in patients with impaired renal function it is recommended that the dosage of ceftazidime should be reduced to compensate for its slower excretion except in mild impairment, i.e. glomerular filtration rate (GFR) greater than 50 mL/min. *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 250 mg for 2 L of dialysis fluid). *Administration:* Ceftazidime may be given intravenously or by deep intramuscular injection into a large muscle mass such as the upper outer quadrant of the gluteus maximus or lateral part of the thigh.

Strength	Route of administration	Amount of diluent to be added (mL)
250 mg	Intramuscular	1.0
	Intravenous	2.5
500 mg	Intramuscular	1.5
	Intravenous	5.0
1 g	Intramuscular	3.0
	Intravenous	10.0

IM administration: For IM administration, Ceftazidime should be constituted with recommended amount of diluents given in the table.
IV administration: For direct intermittent IV administration, constitute Ceftazidime as directed in the table with WFI and slowly inject directly into the vein over a period of 3-5 minutes or give through the tubing of an administration set while the patient is also receiving one of the compatible IV fluid. For IV infusion: Constitute the vial and add an appropriate quantity of the resulting solution to an IV container with a compatible IV fluid.
Instructions for constitution: See the table for addition of volumes. All sizes of vials as supplied are under reduced pressure. As the product dissolves, carbon dioxide is released and a positive pressure develops. For ease of use, it is recommended that the following techniques of reconstitution are adopted. Insert the syringe needle through the vial closure and inject the recommended volume of diluent. The vacuum may assist entry of the diluent. Remove the syringe needle. Shake to dissolve; carbon dioxide is released and a clear solution will be obtained in about 1 to 2 minutes. Invert the vial with the syringe plunger fully depressed, insert the needle through the vial closure and withdraw the total volume of solution into the syringe (the pressure in the vial may aid withdrawal). Ensure that the needle remains within the solution and does not enter the headspace. The withdrawn solution may contain small bubbles of carbon dioxide; they may be disregarded.

Contraindications
Ceftazidime is contraindicated in patients with known hypersensitivity to cephalosporin antibiotics.

Side effects
Clinical trial experience has shown that ceftazidime is generally well tolerated. Adverse reactions are infrequent and include: *Local:* Phlebitis or thrombophlebitis with IV Administration, pain and/or inflammation after IM injection. *Hypersensitivity:* Maculopapular or urticarial rash, fever, pruritus, and very rarely angioedema and anaphylaxis (including bronchospasm and/or hypotension). As with other cephalosporins, there have been rare reports of toxic epidermal necrolysis. *Gastrointestinal:* Diarrhoea, nausea, vomiting, abdominal pain, and very rarely oral thrush or colitis. As with other cephalosporins, colitis may be associated with clostridium difficile and may present as pseudomembranous colitis. Other adverse events which may be related to ceftazidime therapy or of uncertain aetiology include: *Genito-urinary:* Candidiasis, vaginitis; *Central nervous system:* Headache, dizziness, paraesthesia and bad taste.

Use in pregnancy & lactation
There is no experimental evidence of embryopathic or teratogenic effects attributable to ceftazidime but, as with all drugs, it should be administered with caution during the early months of pregnancy and in early infancy. Use in pregnancy requires that the anticipated benefit be weighed against the possible risks. Ceftazidime is excreted into human milk in low concentrations and consequently caution should be exercised when ceftazidime is administered to a nursing mother.

Precautions
Cephalosporin antibiotics at high dosage should be given with caution to patients receiving concurrent treatment with nephrotoxic drugs, e.g. aminoglycoside antibiotics, or potent diuretics such as furosemide, as these combinations are suspected of affecting renal function adversely. 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; however, as for all antibiotics eliminated via the kidneys, it is necessary to reduce the dosage according to the degree of reduction in renal function to avoid the clinical consequences of elevated antibiotic levels.

Drug interactions
Nephrotoxicity has been reported following concomitant administration with aminoglycoside antibiotics or potent diuretics such as furosemide. Chloramphenicol has been shown to be antagonistic to β-lactam antibiotics, including ceftazidime.

Overdosage
Overdosage can lead to neurological sequelae including encephalopathy, convulsions and coma. Serum levels of ceftazidime can be reduced by dialysis.

Storage
Store in a cool (Below 25° C temperature) and dry place protected from light.

Packaging
Serozid® 250 mg IM/IV Injection: Each carton contains 1 vial with 1 ampoule of 5 ml water for injection in blister pack and a 5 ml disposable syringe with baby needle.
Serozid® 500 mg IM/IV Injection: Each carton contains 1 vial with 1 ampoule of 5 ml water for injection in blister pack and a 5 ml disposable syringe.
Serozid® 1 g IM/IV Injection: Each carton contains 1 vial with 1 ampoule of 10 ml water for injection in blister pack and a 10 ml disposable syringe.

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Ideas for healthcare

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