

Ceftazidime Sandoz

Ceftazidime Ph Eur, powder for injection, 250 mg, 500 mg, 1 g and 2 g (as ceftazidime)

Presentation

Ceftazidime Sandoz powder for injection is a white to cream coloured powder aseptically filled into single dose glass vials.

Ceftazidime Sandoz 250 mg contains in a 15 ml vial, sterile ceftazidime pentahydrate equivalent to ceftazidime 250 mg.

Ceftazidime Sandoz 500 mg contains in a 15 ml vial, sterile ceftazidime pentahydrate equivalent to ceftazidime 500 mg.

Ceftazidime Sandoz 1 g contains in 20 ml or 50 ml vials, sterile ceftazidime pentahydrate equivalent to ceftazidime 1 g.

Ceftazidime Sandoz 2 g contains in 50 ml or 100 ml vials, sterile ceftazidime pentahydrate equivalent to ceftazidime 2 g.

Uses

Actions

Pharmacotherapeutic group

J01DD02 – Third generation cephalosporins, ceftazidime.

Mechanism of action

Beta-lactam antibiotic.

Pharmacodynamic effects

Inhibition of bacterial cell wall synthesis.

Antibiotic class

Third generation cephalosporin.

Antibiotic nature and mode of action

Ceftazidime is bactericidal in action, exerting its effect on target cell wall proteins and causing inhibition of cell wall synthesis. A wide range of pathogenic strains and isolates are susceptible *in vitro* including strains resistant to gentamicin and other aminoglycosides. Ceftazidime is stable to most beta-lactamases produced by Gram-positive and Gram-negative organisms and consequently is active against many ampicillin and cephalothin resistant strains (but not methicillin resistant strains).

In vitro, the activities of ceftazidime and aminoglycoside antibiotics in combination have been shown to be at least additive; there is evidence of synergy in some strains tested. This property may be important in the treatment of febrile neutropenic patients.

Susceptibility data

Dilution or diffusion techniques – either quantitative (MIC) or breakpoint, should be used following a regularly updated, recognised and standardised method (e.g. NCCLS). Standardised susceptibility test procedures require the use of laboratory control microorganisms to control the technical aspects of the laboratory procedures. For laboratory tests associated with ceftazidime administration, ceftazidime pentahydrate should be used.

A report of "Susceptible" indicates that the pathogen is likely to be inhibited if the antimicrobial compound in the blood reaches the concentrations usually achievable. A report of "Intermediate" indicates that the result should be considered equivocal, and if the microorganism is not fully

susceptible to alternative, clinically feasible drugs, the test should be repeated. This category implies possible clinical applicability in body sites where the drug is physiologically concentrated or in situations where high dosage of drug can be used. This category also provides a buffer zone, which prevents small uncontrolled technical factors from causing major discrepancies in interpretation.

Ceftazidime has been shown to have *in vitro* activity against the following organisms.

Gram-negative: *Pseudomonas aeruginosa*; *Pseudomonas* spp. (including *Pseudomonas pseudomallei*); *Escherichia coli*; *Klebsiella* spp. (including *Klebsiella pneumoniae*); *Proteus mirabilis*; *Proteus vulgaris*; *Morganella morganii* (formerly *Proteus morganii*); *Proteus rettgeri*; *Providencia* spp.; *Enterobacter* spp.; *Citrobacter* spp.; *Serratia* spp.; *Salmonella* spp.; *Shigella* spp.; *Yersinia enterocolitica*; *Pasteurella multocida*; *Acinetobacter* spp.; *Neisseria gonorrhoeae*; *Neisseria meningitidis*; *Haemophilus influenzae* (including ampicillin resistant strains); *Haemophilus parainfluenzae* (including ampicillin resistant strains).

Gram-positive: *Staphylococcus aureus* (methicillin-sensitive strains); *Staphylococcus epidermidis* (methicillin-sensitive strains); *Micrococcus* spp.; *Streptococcus pyogenes* (Group A beta-haemolytic streptococci); *Streptococcus* Group B (*Streptococcus agalactiae*); *Streptococcus pneumoniae*; *Streptococcus mitis*; *Streptococcus* spp. (excluding *Enterococcus* (*Streptococcus*) *faecalis*).

Anaerobic strains: *Peptococcus* spp.; *Peptostreptococcus* spp.; *Streptococcus* spp.; *Propionibacterium* spp.; *Clostridium perfringens*; *Fusobacterium* spp.; *Bacteroides* spp (many strains of *Bacteroides fragilis* resistant).

Resistance

A report of "Resistant" indicates that the pathogen is not likely to be inhibited if the antimicrobial compound in the blood reaches the concentrations usually achievable, other therapy should be selected. Note: the prevalence of resistance may vary geographically for selected species and local information on resistance is desirable, particularly when treating severe infections.

Ceftazidime is not active *in vitro* against the following organisms: methicillin-resistant staphylococci; *Enterococcus* (*Streptococcus*) *faecalis* and many other enterococci; *Clostridium difficile*; *Listeria monocytogenes*; *Campylobacter* spp.

Clinically relevant MIC ranges

Ceftazidime has high intrinsic activity *in vitro* and acts within a narrow MIC range for most genera with minimal changes in MIC at varied inoculum levels.

Pharmacokinetics

The pharmacokinetics of ceftazidime are similar whether it is administered by a single or by repeat dosage. Concurrent oral administration of probenecid did not affect the serum levels or urinary recoveries of ceftazidime. The pharmacokinetics of ceftazidime were not affected when administered intramuscularly with 0.5% lignocaine.

Absorption

Absorption of ceftazidime after oral administration is negligible, therefore Ceftazidime Sandoz is intended for parenteral use only. In humans, after a single IM administration of 500 mg and 1 g, mean peak serum levels of 18 and 37 mg/l respectively are achieved at 1 hour, falling to 8 and 2 mg/l and 20 and 5 mg/l at four and eight hours respectively for the two doses. Five minutes after an IV bolus injection of 500 mg, 1 g and 2 g, mean serum levels are respectively 46, 87 and 170 mg/l, falling to 17 and 6 mg/l, 32 and 10 mg/l and 85 and 15 mg/l at one and four hours respectively with the three doses.

Distribution

Therapeutically effective concentrations are still present in the serum 8 to 12 hours after either IV or IM administration. 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, therapeutic levels of 4 to 20 mg/l or more are achieved in the CSF when the meninges are inflamed.

Biotransformation

Ceftazidime is not metabolised *in vivo* and is excreted unchanged in the active form into the urine by glomerular filtration. In the presence of normal renal function approximately 80 to 90% of the dose is recovered in the urine within 24 hours. Less than 1% is excreted via the bile.

Elimination

The serum half-life in adults with normal renal function is about 1.8 hours (1.2 to 2.9 hours). This may be prolonged to 20 to 35 hours in anuric patients. In neonates, the serum half-life of ceftazidime can be three to four times greater than that measured in adults. Elimination of ceftazidime is decreased in patients with impaired renal function and the dose should be reduced (refer to Dosage and administration - renal impairment).

Indications

Treatment of single or multiple infections caused by susceptible organisms. May be used alone as first choice medicine before the results of sensitivity tests are available. May be used in combination with an aminoglycoside or most other beta-lactam antibiotics. May be used with an antibiotic against anaerobes when the presence of *Bacteroides fragilis* is suspected.

Indications include: severe infections e.g. septicaemia, bacteraemia, peritonitis, meningitis; infections in immunosuppressed patients; infections in patients in intensive care, e.g. infected burns; respiratory tract infections including lung infections in cystic fibrosis; ear, nose and throat infections; urinary tract infections; skin and soft tissue infections; gastrointestinal, biliary and abdominal infections; bone and joint infections; infections associated with haemo- and peritoneal dialysis and with continuous ambulatory peritoneal dialysis (CAPD).

Dosage and administration

Dosage

Dosage depends upon the severity, sensitivity, site and type of infection and upon the age and renal function of the patient.

Adults

1 to 6 g daily in two or three divided doses by IV or IM injection. Urinary tract and less severe infections - 500 mg or 1 g every 12 hours. Most infections - 1 g every 8 hours or 2 g every 12 hours. Very severe infections particularly in immunocompromised patients including those with neutropenia - 2 g every 8 or 12 hours, or 3 g every 12 hours. Fibrocystic adults with pseudomonal lung infections 100 to 150 mg/kg/day in three divided doses. In adults with normal renal function 9 g daily has been used without ill effect.

Infants and children older than 2 months

30 to 100 mg/kg daily in two or three divided doses. Doses up to 150 mg/kg daily (maximum 6 g daily) in three divided doses may be given to infected immunocompromised or fibrocystic children or children with meningitis.

Neonates aged 0 to 2 months

25 to 60 mg/kg daily in two divided doses. In neonates the serum half life of ceftazidime can be three to four times that in adults.

Use in the elderly

In view of the reduced clearance of ceftazidime in acutely ill elderly patients, the daily dosage should not normally exceed 3 g, especially in those over 80 years of age.

Renal impairment

Ceftazidime is excreted unchanged by the kidneys. Therefore in patients with impaired renal function the dosage should be reduced. An initial loading dose of 1 g should be given. Maintenance doses should be based on GFR.

Recommended maintenance doses of ceftazidime in renal insufficiency

| Creatinine clearance (ml/min) | Approximate serum creatinine in micromol/l (mg/dl) | Recommended unit dose of ceftazidime (g) | Frequency of dosing (hourly) |
|-------------------------------|--|--|------------------------------|
| >50 | <150 (<1.7) | Normal dosage | |
| 50-31 | 150-200 (1.7-2.3) | 1.0 | 12 |
| 30-16 | 200-350 (2.3-4.0) | 1.0 | 24 |
| 15-6 | 350-500 (4.0-5.6) | 0.5 | 24 |
| <5 | >500 (>5.6) | 0.5 | 48 |

In patients with severe infections the unit dose should be increased by 50% or the dosing frequency increased. In such patients the ceftazidime serum levels should be monitored and trough levels should not exceed 40 mg/l.

In children the creatinine clearance should be adjusted for body surface area or lean body mass.

Haemodialysis

The serum half-life during haemodialysis ranges from 3 to 5 hours. Following each haemodialysis period the maintenance dose of ceftazidime recommended in the above table should be repeated.

Peritoneal dialysis

Ceftazidime may be used in peritoneal dialysis and continuous ambulatory peritoneal dialysis (CAPD). In addition to intravenous use, ceftazidime can be incorporated into the dialysis fluid (usually 125 to 250 mg for 2 litres of dialysis solution).

For patients in renal failure on continuous arteriovenous haemodialysis or high-flux haemofiltration in intensive therapy units; 1 g daily either as a single dose or in divided doses. For low-flux haemofiltration follow the dosage recommended under impaired renal function.

For patients on venovenous haemofiltration and venovenous haemodialysis, follow the dosage recommendations in the tables below:

Continuous venovenous haemofiltration dosage guidelines for ceftazidime

| Residual renal function (creatinine clearance in ml/min) | Maintenance dose (mg) administered every 12 h for a ultrafiltration rate (ml/min) of | | | |
|--|--|------|------|-----|
| | 5 | 16.7 | 33.3 | 50 |
| 0 | 250 | 250 | 500 | 500 |
| 5 | 250 | 250 | 500 | 500 |
| 10 | 250 | 500 | 500 | 750 |
| 15 | 250 | 500 | 500 | 750 |
| 20 | 500 | 500 | 500 | 750 |

Ceftazidime dosage guidelines during continuous venovenous haemodialysis

| Residual renal function (creatinine clearance in ml/min) | Maintenance dose (mg) administered every 12 h for a dialysate inflow rate of: | | | | | |
|--|---|-----|------|---------------------------------|-----|------|
| | 1.0 litres/h | | | 2.0 litres/h | | |
| | Ultrafiltration rate (litres/h) | | | Ultrafiltration rate (litres/h) | | |
| | 0.5 | 1.0 | 2.0 | 0.5 | 1.0 | 2.0 |
| 0 | 500 | 500 | 500 | 500 | 500 | 750 |
| 5 | 500 | 500 | 750 | 500 | 500 | 750 |
| 10 | 500 | 500 | 750 | 500 | 750 | 1000 |
| 15 | 500 | 750 | 750 | 750 | 750 | 1000 |
| 20 | 750 | 750 | 1000 | 750 | 750 | 1000 |

Administration

Use Ceftazidime Sandoz injection intravenously or by deep intramuscular injection. Recommended IM injection sites are the upper outer quadrant of the gluteus maximus or lateral part of the thigh.

Ceftazidime solutions may be given directly into the vein or introduced into the tubing of a giving set if the patient is receiving parenteral fluids.

Contraindications

Patients with known hypersensitivity to cephalosporin antibiotics, ceftazidime pentahydrate or to any of the excipients.

History of severe hypersensitivity (e.g. anaphylactic reaction) to any other type of beta-lactam antibacterial agent (penicillins, monobactams and carbapenems).

Warnings and precautions

Ceftazidime should not ordinarily be given to those allergic to cephalosporins or to penicillins, especially where an allergic or urticarial reaction has occurred. Before beginning treatment establish whether the patient has a history of hypersensitivity reactions to ceftazidime, cephalosporins, penicillins or other medicines. Special care is indicated in patients who have experienced an allergic reaction to penicillins or other beta-lactams. If an allergic reaction to ceftazidime occurs discontinue the medicine. Serious hypersensitivity reactions may require epinephrine (adrenaline), hydrocortisone, antihistamine or other emergency measures.

Ceftazidime has a limited spectrum of antibacterial activity. It is not suitable for use as a single agent for the treatment of some types of infections unless the pathogen is already documented and known to be susceptible or there is a very high suspicion that the most likely pathogen(s) would be suitable for treatment with ceftazidime. This particularly applies when considering the treatment of patients with bacteraemia and when treating bacterial meningitis, skin and soft tissue infections and bone and joint infections. In addition, ceftazidime is susceptible to hydrolysis by several of the extended spectrum beta lactamases (ESBLs). Therefore information on the prevalence of ESBL producing organisms should be taken into account when selecting ceftazidime for treatment.

Antibacterial agent-associated colitis and pseudo-membranous colitis have been reported with nearly all anti-bacterial agents, including ceftazidime, and may range in severity from mild to life-threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhoea during or subsequent to the administration of ceftazidime. Discontinuation of therapy with ceftazidime and the administration of specific treatment for *Clostridium difficile* should be considered. Medicinal products that inhibit peristalsis should not be given.

Concurrent treatment with high doses of cephalosporins and nephrotoxic medicines such as aminoglycosides or potent diuretics (e.g. furosemide) may adversely affect renal function. Clinical experience has shown that this is not likely to be a problem with ceftazidime at the recommended dose levels. There is no evidence that ceftazidime adversely affects renal function at normal therapeutic doses.

Ceftazidime is eliminated via the kidneys, therefore the dosage should be reduced according to the degree of renal impairment. Neurological sequelae have occasionally been reported when the dose has not been reduced appropriately (refer to Dosage and administration - Renal impairment and Adverse Effects).

As with other broad spectrum antibiotics, prolonged use may result in the overgrowth of non-susceptible organisms (e.g. *Candida*, enterococci) which may require interruption of treatment or appropriate measures. Repeated evaluation of the patient's condition is essential.

As with other extended-spectrum cephalosporins and penicillins, some initially susceptible strains of *Enterobacter* spp. and *Serratia* spp. may develop resistance during ceftazidime therapy. When clinically appropriate during therapy of such infections, periodic susceptibility testing should be considered.

Pregnancy and lactation

Use in pregnancy

Assigned Category B1 by the Australian Drug Evaluation Committee. This category includes medicines which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human foetus having been observed. Studies in animals have not shown evidence of an increased occurrence of foetal damage. There is no experimental evidence of embryopathic or teratogenic effects, but as with all medicines, ceftazidime should be administered with caution during the early months of pregnancy and early infancy.

Use in lactation

Ceftazidime is excreted in human milk in small quantities and should be used with caution in nursing mothers.

Effects on ability to drive and use machines

This medicine is presumed to be safe or unlikely to produce an effect.

Adverse effects

Data from large clinical trials (internal and published) were used to determine the frequency of very common to uncommon undesirable effects. The frequencies assigned to all other undesirable effects were mainly determined using post-marketing data and refer to a reporting rate rather than a true frequency.

Clinical trial data

Common - incidence between 1/100 and 1/10

Blood and lymphatic system disorders

Eosinophilia and thrombocytosis.

Gastrointestinal disorders

Diarrhoea.

General disorders and administration site conditions

Pain and/or inflammation after IM injection.

Hepatobiliary disorders

Transient elevations in one or more of the hepatic enzymes, ALT (SGPT), AST (SOGT), LDH, GGT and alkaline phosphatase.

Investigations

Positive Coombs' test. A positive Coombs' test develops in about 5% of patients and may interfere with blood cross-matching.

Skin and subcutaneous tissue disorders

Maculopapular or urticarial rash.

Vascular disorders

Phlebitis or thrombophlebitis with IV administration.

Uncommon - incidence between 1/1000 and 1/100

Blood and lymphatic system disorders

Leucopenia, neutropenia, and thrombocytopenia.

Gastrointestinal disorders

Nausea, vomiting, abdominal pain, and colitis. As with other cephalosporins, colitis may be associated with *Clostridium difficile* and may present as pseudomembranous colitis.

General disorders and administration site conditions

Fever.

Infections and infestations

Candidiasis including vaginitis and oral thrush.

Investigations

As with some other cephalosporins, transient elevations of blood urea, blood urea nitrogen and/or serum creatinine have been observed.

Nervous system disorders

Headache and dizziness.

Skin and subcutaneous tissue disorders

Pruritus.

Post-marketing pharmacovigilance data

Very rare - incidence lower than 1/10,000

Blood and lymphatic system disorders

Lymphocytosis, haemolytic anaemia, and agranulocytosis.

Gastrointestinal disorders

Bad taste.

Hepatobiliary disorders

Jaundice.

Immune system disorders

Anaphylaxis (including bronchospasm and/or hypotension).

Nervous system disorders

Paraesthesia. There have been reports of neurological sequelae including tremor, myoclonia, convulsions, encephalopathy, and coma in patients with renal impairment in whom the dose of ceftazidime has not been appropriately reduced.

Skin and subcutaneous tissue disorders

Angioedema, erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis.

Interactions

Interactions with other medicines

Concurrent use of high doses with nephrotoxic medicines may adversely affect renal function (refer to Warnings and precautions).

Chloramphenicol is antagonistic *in vitro* with ceftazidime and other cephalosporins. The clinical relevance of this finding is unknown, but if concurrent administration of ceftazidime with chloramphenicol is proposed, the possibility of antagonism should be considered.

In common with other antibiotics, ceftazidime may affect the gut flora, leading to lower oestrogen reabsorption and reduced efficacy of combined oral contraceptives.

Effects on laboratory tests

Ceftazidime does not interfere with enzyme-based tests for glycosuria but slight interference may occur with copper (II) reduction methods (Benedict's and Fehling's solutions, Clinitest).

Ceftazidime does not interfere in the alkaline picrate assay for creatinine.

Overdosage

Signs and symptoms

Overdosage can lead to neurological sequelae including encephalopathy, convulsions and coma.

Management

Serum levels of ceftazidime can be reduced by haemodialysis or peritoneal dialysis.

Pharmaceutical precautions

Instructions for use/handling

On addition of water for injections, Ceftazidime Sandoz dissolves with effervescence to produce a solution for use by injection only. Solutions range from light yellow to amber depending on concentration, diluent and storage conditions used. Within the stated recommendations, product potency is not adversely affected by such colour variations.

Solutions of Ceftazidime Sandoz injection reconstituted in water for injections retain satisfactory potency for 24 hours if refrigerated at 2 to 8°C. Ceftazidime Sandoz 1 g injection may be reconstituted for intramuscular administration using 0.5% Lignocaine Hydrochloride Injection BP; the resultant

solutions may be stored for 24 hours under refrigeration (2 to 8°C). Solutions of Ceftazidime Sandoz 1 g injection reconstituted in 1.0% lignocaine solution retain satisfactory potency for 24 hours if refrigerated (2 to 8°C). Some increase in the colour of prepared solutions of ceftazidime for injection may occur on storage. It is, however, advisable to use the reconstituted product as soon as possible.

Ceftazidime Sandoz 2 g injection is compatible with 0.9% sodium chloride, 5% glucose, 5% glucose/0.9% sodium chloride (1:1, v/v) and Ringer's Lactate Solution. Solutions at concentrations of 50 mg/ml in these infusion fluids may be stored for up to 24 hours if refrigerated (2 to 8°C).

Ceftazidime Sandoz 2 g injection may be stored for up to 24 hours under refrigeration (2 to 8°C) at concentrations between 0.05 mg/ml and 0.25 mg/ml in Intra-peritoneal Dialysis Fluid (Lactate) BPC 1973.

Ceftazidime Sandoz 2 g injection has been found compatible for 24 hours under refrigeration (2 to 8°C) when admixed at 4 mg/ml with potassium chloride 10 mEq/l or 40 mEq/l in 0.9% Sodium Chloride Injection BP, or heparin (10 and 50 units/ml) in 0.9% sodium chloride.

Ceftazidime Sandoz 2 g injection (4 mg/ml) has been found compatible for 24 hours when refrigerated (2 to 8°C, do not freeze) when admixed with cloxacillin.

Ceftazidime Sandoz injection 500 mg, reconstituted with 1.5 ml Water for Injections, may be added to metronidazole infusion (500 mg in 100 ml) and both antibiotics retain their activity. Ceftazidime Sandoz 2 g injection (5 mg/ml) is compatible for 24 hours when refrigerated (2 to 8°C, do not freeze) when admixed with metronidazole.

All vial presentations of Ceftazidime Sandoz injection are packaged 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.

Preparation of solutions for IM or IV bolus injection

Insert syringe needle through vial closure and inject recommended volume of diluent. The vacuum may assist entry of the diluent. Remove syringe needle. Shake to dissolve; carbon dioxide is released and a clear solution obtained in about one to two minutes. Invert the vial. With the syringe plunger fully depressed, insert the needle through 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 which should be expelled from the syringe before injection.

Preparation of solutions for IV infusion in a mini-bag or burette-type set

Ceftazidime Sandoz injection 1 g or 2 g vials may be reconstituted for short intravenous infusion (e.g. up to 30 minutes) using a total of 50 ml of compatible diluent, added in two stages as follows. Insert syringe needle through the vial closure and inject 10 ml 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 is obtained in about one to two minutes. When, and not before, the product has dissolved, insert a gas relief needle through vial closure to relieve internal pressure and, with gas relief in position, add a further 40 ml of diluent. Remove the gas relief needle and syringe needle; shake the vial and set up for infusion use in the normal way. Additional pressure that may develop in the vial especially after storage, should be relieved prior to administration to the patient. Note: to preserve product sterility, it is important that a gas relief needle is *not* inserted through the vial closure before the product has dissolved.

Incompatibilities

Ceftazidime Sandoz injection is compatible with most commonly used intravenous fluids. However, since Ceftazidime Sandoz is less stable in Sodium Bicarbonate Injection than in other intravenous fluids it is not recommended as a diluent.

Ceftazidime and aminoglycosides should not be mixed in the same giving set or syringe.

Precipitation has been reported when vancomycin has been added to ceftazidime in solution. Therefore, it would be prudent to flush giving sets and intravenous lines between administration of these two agents.

Special precautions for storage

Store at or below 25°C. Protect from light and moisture. Store the reconstituted medicine between 2 to 8°C and use within 24 hours. Refrigerate, do not freeze.

Ceftazidime Sandoz contains no antimicrobial agent. To reduce microbiological hazard, use as soon as practicable after dilution. Discard any residue.

Medicine classification

Prescription Medicine.

Package quantities

Single vial packs. Not all pack sizes and/or strengths may be currently marketed.

Further information

Displacement volumes

250 mg vial

Ceftazidime Sandoz injection 250 mg is packaged in a 15 ml vial. Reconstitution with 1 ml diluent results in a final volume of approximately 1.2 ml. Reconstitution with 2.5 ml diluent results in a final volume of approximately 2.8 ml.

500 mg vial

Ceftazidime Sandoz injection 500 mg is packaged in a 15 ml vial. Reconstitution with 1.5 ml diluent results in a final volume of approximately 2.1 ml. Reconstitution with 5 ml diluent results in a final volume of approximately 5.5 ml.

1 g vial

Ceftazidime Sandoz injection 1 g is packaged in 20 ml and 50 ml vials. Reconstitution with 3 ml diluent results in a final volume of approximately 3.8 ml. Reconstitution with 10 ml diluent results in a final volume of approximately 11.0 ml. Reconstitution with 40 ml diluent results in a final volume of approximately 41.0 ml.

2 g vial

Ceftazidime Sandoz injection 2 g is packaged in 50 ml and 100 ml vials. Reconstitution with 10 ml diluent results in a final volume of approximately 11.5 ml. Reconstitution with 40 ml diluent results in a final volume of approximately 42.0 ml.

List of excipients

Sodium carbonate anhydrous. Total sodium content of the mixture is approximately 54 mg/g.

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