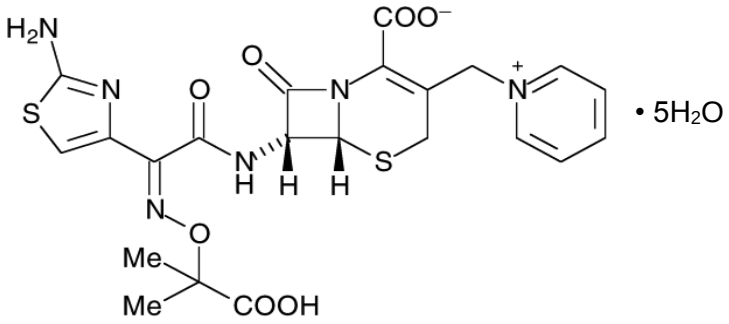
PRODUCT INFORMATION

CEFTAZIDIME SANDOZ® 1/2g POWDER FOR INJECTION

NAME OF THE MEDICINE

Active ingredient: Ceftazidime (as ceftazidime pentahydrate)

Chemical structure:



Chemical name: *(6R,7R)-7*-[[(*Z*)-2-(2-aminothiazol-4-yl)-2-[(1-carboxy-1-methylethoxy)imino]acetyl]amino]-8-oxo-3-[(1-pyridinio)methyl]-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate pentahydrate.

Molecular formula: $C_{22}H_{22}N_6O_7S_2 \cdot 5H_2O$

Molecular weight: 636.6

CAS: 72558-82-8

DESCRIPTION

Inactive ingredient: *S*odium carbonate anhydrous
Total sodium content of the mixture is approximately 54mg/g.

Ceftazidime Sandoz® is a cephalosphorin antibiotic containing ceftazidime pentahydrate, a white to faintly yellow crystalline powder, soluble in acid and alkali solution; slightly soluble in water and in methanol; practically insoluble in acetone and in alcohol. On addition of water for injections, Ceftazidime Sandoz® dissolves with effervescence to produce a solution for use by injection only.

For laboratory tests associated with ceftazidime administration, ceftazidime pentahydrate should be used.

PHARMACOLOGY

Actions

Microbiology

Ceftazidime is bactericidal in action, exerting its effect on target cell wall proteins and causing inhibition of cell wall synthesis. It 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). Ceftazidime has been shown to have *in vitro* activity against the following organisms:

Gram-negative organisms. Pseudomonas aeruginosa, Pseudomonas sp. (other), *Klebsiella pneumoniae*, Klebsiella sp. (other), *Proteus mirabilis*, *P. vulgaris*, *Morganella morganii* (formerly *P. morganii*), *P. rettgeri*, Providencia sp., *Escherichia coli*, Enterobacter sp., Citrobacter sp., Serratia sp., Acinetobacter sp., *Neisseria gonorrhoeae*, *N. meningitidis*, *Haemophilus influenzae* (including ampicillin resistant strains).

Gram-positive organisms. Staphylococcus aureus (methicillin sensitive strains), *Staph. epidermidis* (methicillin sensitive strains), Micrococcus sp., *Streptococcus pyogenes*, Streptococcus group B, *Strep. pneumoniae*, Streptococcus sp. (excluding *Strep. faecalis*).

Ceftazidime is not active *in vitro* against methicillin resistant Staphylococci, *Streptococcus faecalis* and many other Enterococci, *Listeria monocytogenes*, Campylobacter sp. or *Clostridium difficile*.

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 tests

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.

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. 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.

Pharmacokinetics
Absorption of ceftazidime after oral administration is negligible, therefore Ceftazidime Sandoz® is intended for parenteral use only.

In humans, after a single intramuscular administration of 500mg and 1g, mean peak serum levels of 18 and 37mg/L respectively are achieved at 1 hour, falling to 8 and 2mg/L and 20 and 5mg/L at four and eight hours respectively for the two doses. Five minutes after an intravenous bolus injection of 500mg, 1g and 2g, mean serum levels are respectively 46, 87 and 170mg/L, falling to 17 and 6mg/L, 32 and 10mg/L and 85 and 15mg/L at one and four hours respectively with the three doses. 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. The serum protein binding of ceftazidime is low at about 10%.

Ceftazidime is not metabolised in the body 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.

The mean maximum concentrations of ceftazidime in bone, heart, bile, sputum, aqueous humour and synovial, pleural and peritoneal fluids were in excess of the *in vitro* minimum inhibitory levels for susceptible organisms (see *Susceptibility tests*). Transplacental transfer of the antibiotic readily occurs. Ceftazidime penetrates the intact blood-brain barrier poorly and low levels are achieved in the cerebrospinal fluid (CSF).

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.

INDICATIONS

Treatment of single and mixed infections caused by susceptible aerobic organisms with suspected or documented resistance to other antimicrobials, but not to ceftazidime; as an alternative to aminoglycosides in pseudomonal infection in patients in whom aminoglycoside toxicity is a cause for concern and other antipseudomonal antibiotics cannot be used.

Indications include the following:

- *Severe infections in general (e.g.* septicaemia including neonatal sepsis, bacteraemia; in patients in intensive care units with specific problems, e.g. infected burns).
- *Respiratory tract (e.g.* pneumonia, bronchopneumonia, infected pleurisy, infected bronchiectasis and bronchitis).
- *Severe ear, nose and throat infections (e.g.* otitis media, mastoiditis).
- *Urinary tract (e.g.* acute and chronic pyelonephritis, pyelitis, cystitis, urethritis - bacterial only; infections associated with bladder and renal stones).
- *Skin and soft tissue (e.g.* erysipelas, abscesses, cellulitis, infected burns and wounds, mastitis).
- *Gastrointestinal and abdominal (e.g.* intra-abdominal abscesses, enterocolitis).
- *Bone and joint (e.g.* osteitis, osteomyelitis, septic arthritis, infected bursitis).

CONTRAINDICATIONS

Hypersensitivity to cephalosporins or a major allergy to penicillin (anaphylaxis, angioneurotic oedema, urticaria).

Lignocaine should not be used as a diluent for intramuscular injection in patients who are hypersensitive to lignocaine.

PRECAUTIONS

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. Ceftazidime should be given only with special caution to patients with mild type I or immediate hypersensitivity reactions to penicillin or other beta-lactams. If an allergic reaction to ceftazidime occurs, discontinue the drug. Serious hypersensitivity reactions may require adrenaline, hydrocortisone, antihistamine or other emergency measures.

Antibiotic-associated pseudomembranous colitis has been reported with many antibiotics including ceftazidime. A toxin produced by *Clostridium difficile* appears to be the primary cause. The severity of the colitis may range from mild to life-threatening. It is important to consider this diagnosis in patients who develop diarrhoea or colitis in association with antibiotic use (this may occur up to several weeks after cessation of antibiotic therapy). Mild cases usually respond to drug discontinuation alone. However, in moderate to severe cases appropriate therapy with a suitable oral antibacterial agent effective against *Cl. difficile* should be considered. Fluids, electrolytes and protein replacement should be provided when indicated. If prolonged or significant diarrhoea occurs or the patient experiences abdominal cramps, treatment should be discontinued immediately and the patient investigated further.

Drugs that delay peristalsis, e.g. opiates and diphenoxylate with atropine (e.g. Lomotil), may prolong and/or worsen the condition and should not be used.

Cl. difficile infection rarely manifests as diarrhoea in neonates.

Peak concentrations of ceftazidime in the CSF are considerably lower than those in the plasma. Its use in the treatment of infections of the central nervous system, e.g. meningitis, brain abscess, is not advised at present.

Resistance to initially susceptible *Enterobacter* species and *Serratia* spp. can develop during treatment with ceftazidime. When clinically appropriate during therapy of such infections, periodic susceptibility testing should be considered.

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

Vials of Ceftazidime Sandoz® injection, as supplied, are under reduced pressure; a positive pressure is produced on reconstitution due to the release of carbon dioxide. See *Dosage and Administration* for recommended techniques of reconstitution.

Ceftazidime should be prescribed with caution to individuals with a history of gastrointestinal disease, particularly colitis.

Impaired renal function.
Ceftazidime has shown some evidence of renal toxicity in animals. Clinical studies have shown only transient elevations in serum urea and serum creatinine. It is excreted almost entirely by glomerular filtration and its half-life is prolonged in patients with impaired renal function. In such patients, dosage adjustment may be required in order to avoid the clinical consequences of elevated antibiotic levels. Neurological sequelae have occasionally been reported when the dose has not been reduced appropriately (see *Dosage and Administration*). Elevated levels of ceftazidime in patients with renal insufficiency can lead to seizures, encephalopathy, asterixis, neuromuscular excitability and myoclonia. Continued dosage should be determined by degree of renal impairment, severity of infection and susceptibility of the causative organism.

Impaired hepatic function.
Transient rises in hepatic enzymes have been noted in some patients given Ceftazidime Sandoz®, so careful monitoring of hepatic function is advised when any dysfunction exists.

Repeated use of lignocaine hydrochloride as a diluent for intramuscular use should be avoided in patients with severe liver disease or decreased hepatic blood flow, due to the possibility of lignocaine toxicity resulting from decreased metabolism and consequent accumulation.

Carcinogenesis, Mutagenesis, Impairment of Fertility.
Long term studies in animals have not been performed to evaluate carcinogenic potential. However, a mouse Micronucleus test and Ames test were both negative for mutagenic effects.

Use in pregnancy (Category B1).
Category B1: Drugs 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.

The safety of Ceftazidime Sandoz® in pregnancy has not been established, although animal studies have not produced evidence of embryopathic or teratogenic effects attributable to ceftazidime. Therefore, it may be administered during known or suspected pregnancy only if, in the opinion of the treating doctor, the expected benefits outweigh the possible risks.

Use in lactation.
Ceftazidime is excreted in human breast milk in low concentrations, therefore, it is not recommended for breastfeeding mothers unless the expected benefits to the mother greatly outweigh any potential risk to the infant.

Use in children.
Ceftazidime is effective in the treatment of neonatal infections caused by susceptible organisms.

Interactions with other medicines.
Chloramphenicol is antagonistic *in vitro* to 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. There is some evidence in the literature that concurrent use of two beta-lactam antibiotics may exhibit antagonism.

Nephrotoxicity has been reported following concomitant administration of cephalosporins with aminoglycoside antibiotics or potent diuretics such as frusemide. Renal function should be carefully monitored, especially if higher dosages of the aminoglycosides are to be administered or if therapy is prolonged, because of the potential nephrotoxicity and ototoxicity of aminoglycoside antibiotics. Nephrotoxicity and ototoxicity were not noted when ceftazidime was given alone in clinical trials.

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

Laboratory tests.
The development of a positive Coombs' test associated with the use of ceftazidime in about 5% of patients may interfere with the cross matching of blood.

Ceftazidime does not interfere with enzyme based tests for glycosuria. Slight interference with copper reduction methods (Benedict's, Fehling's, Clinitest) may be observed. Ceftazidime does not interfere in the alkaline picrate assay for creatinine.

ADVERSE EFFECTS

Data from large clinical trials 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.

The following convention has been used for the classification of frequency:

very common ≥1/10
common ≥1/100 to <1/10
uncommon ≥1/1,000 to <1/100
rare ≥1/10,000 to <1/1,000
very rare <1/10,000.

Infections and infestations

Uncommon: Candidiasis (including vaginitis and oral thrush).

Blood and lymphatic system disorders

Common: Eosinophilia and thrombocytosis.

Uncommon: Leucopenia, neutropenia, and thrombocytopenia.

Very rare: Lymphocytosis, haemolytic anaemia, and agranulocytosis.

Immune system disorders

Very rare: Anaphylaxis (including bronchospasm and/or hypotension).

Nervous system disorders

Uncommon: Headache and dizziness

Very rare: 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.

Vascular disorders

Common: Phlebitis or thrombophlebitis with i.v. administration.

Gastrointestinal disorders

Common: Diarrhoea.

Uncommon: Nausea, vomiting, abdominal pain, and colitis.

Very rare: Bad taste.

As with other cephalosporins, colitis may be associated with Clostridium difficile and may present as pseudomembranous colitis (See Precautions).

Hepatobiliary disorders

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

Very rare: Jaundice.

Skin and subcutaneous tissue disorders

Common: Maculopapular or urticarial rash.

Uncommon: Pruritus.

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

Not known: DRESS syndrome[#]

General disorders and administration site conditions

Common: Pain and/or inflammation after i.m. injection.

Uncommon: Fever.

Investigations

Common: Positive Coombs test.

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

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

Other (frequency not known)
Hypersensitivity. Maculopapular or urticarial rash, fever, pruritus; very rarely angioedema and anaphylaxis (including bronchospasm and hypotension), erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis.

Hot flushes, superficial desquamation around injection site.

[#] DRESS syndrome (Drug Reaction/Rash with Eosinophilia and Systemic Symptoms). There have been rare reports where DRESS has been associated with ceftazidime.

DOSAGE AND ADMINISTRATION

Note: Vials of Ceftazidime Sandoz® injection as supplied are under reduced pressure; a positive pressure is produced on reconstitution due to the release of carbon dioxide.

Ceftazidime is to be used by the parenteral route, the dosage depending upon the severity, sensitivity and type of infection, age, weight and renal function of the patient.

Dosage

Adults. The adult dosage range for ceftazidime is 1 to 6g daily, for instance, 500mg, 1g or 2g given every twelve or eight hours by intravenous or intramuscular injection.

In urinary tract infections and in many less serious infections, 500mg or 1g every twelve hours is usually adequate.

In the majority of infections, 1g every eight hours or 2g every twelve hours should be given.

In very severe infections, 2g every eight or twelve hours should be administered.

Individual doses exceeding 1g should be administered intravenously.

Children (over 12 months). The usual dosage range for children aged over 12 months is 25 to 100mg/kg/day (up to a maximum of 6g/day), given as two or three divided doses. The maximum daily dosage (6g) may be given to children with very serious infections, e.g. those who are immunocompromised or who suffer from cystic fibrosis.

Neonates, infants up to 12 months. 25 to 100mg/kg/day in two divided doses. In neonates the serum half-life of ceftazidime can be three to four times greater than that measured in adults.

Use in the elderly. In view of the reduced clearance of ceftazidime in elderly patients, the daily dosage should be adjusted according to renal function.

Impaired renal function. Adults. 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 50mL/minute. In patients with suspected renal insufficiency, an initial loading dose of ceftazidime 1g may be given. An estimate of GFR should be made to determine the appropriate maintenance dose. Recommended maintenance doses are shown in Table 1.

Table I: Recommended maintenance doses of ceftazidime in renal insufficiency

Creatinine clearance (mL/min)	Approx. serum creatinine* (micromol/L)	Recommended unit dose of ceftazidime (g)	Frequency of dosing (hours)
50 – 31	150 – 200	1.0	12
30 – 16	200 – 350	1.0	24
15 – 6	350 – 500	0.5	24
5	500	0.5	48

**These values are guidelines and may not accurately predict renal function in all patients, especially in the elderly in whom the serum creatinine concentration may overestimate renal function.*

In patients with severe infections who would normally receive ceftazidime 6g daily were it not for renal insufficiency, the unit dose given in the table above may be increased by 50% or the dosing frequency increased appropriately. In such patients it is recommended that ceftazidime serum levels should be monitored and trough levels should not exceed 40mg/L.

When only serum creatinine is available, the following formula (Cockcroft's equation) may be used to estimate creatinine clearance. The serum creatinine should represent a steady state of renal function.

Calculation of creatinine clearance (mL/minute)

$$\text{Men: } \frac{\text{Bodyweight (kg) x (140 – age in years)}}{\text{72 x serum creatinine (mmol/L)}} \text{ x 0.0885}$$

Women: Multiplication of the result of the above equation by 0.85.

Children. In children the creatinine clearance should be adjusted for body surface area or lean body mass and the dosing frequency reduced in cases of renal insufficiency as for adults.

The serum half-life of ceftazidime during haemodialysis is approximately three hours. The appropriate maintenance dose of ceftazidime should be repeated following each haemodialysis period. Continuous ambulatory peritoneal dialysis (CAPD) removed approximately 10% of the antibiotic when the dwell time was four to six hours.

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.

Reconstitution

Ceftazidime for injection may be reconstituted with water for injections or, for intramuscular injection, with 0.5% or 1% lignocaine. See Table 2 for additive volumes and solution concentrations.

Table 2: Preparation of solution

Vial Size/route	Amount of diluent To be added	Approximate concentration (mg/mL)
1g – intramuscular	3. 0mL	260
1g – intravenous	10.0mL	90
2g – intravenous bolus	10.0mL	170
2g – intravenous infusion	50.0mL*	40

***Note:* Addition should be in 2 stages (see text).**

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:

1g intramuscular/intravenous and 2g intravenous bolus vials. 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.

2g intravenous infusion vial. This vial may be reconstituted for short intravenous infusion (e.g. up to 30 minutes) as follows:

Insert syringe needle through the vial closure and inject 10mL 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 obtained in about one to two minutes. Insert a gas relief needle through vial closure to relieve internal pressure and, with gas relief in position, add a further 40mL 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.

To reduce microbiological hazard, use as soon as practicable after dilution. If storage is necessary hold at 2°-8°C for not more than 24 hours.

Contains no antimicrobial agent. Product is for single use in one patient only. Discard any residue.

Solutions of Ceftazidime Sandoz® 1g and 2g injection reconstituted in water for injections retain satisfactory potency for 24 hours if refrigerated at 2 to 8°C. Ceftazidime Sandoz® 1g 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® 1g 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® 2g injection is compatible with 0.9% sodium chloride, 5% glucose, 5% glucose/0.9% sodium chloride (1:1, V/V) and Ringer Lactate Solution. Solutions at concentrations of 50mg/mL in these infusion fluids may be stored for up to 24 hours if refrigerated (2 to 8°C).

Sodium bicarbonate injection is not recommended as a diluent.

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

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

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

Ceftazidime 2g injection (5mg/mL) is compatible for 24 hours when refrigerated (2 to 8°C, do not freeze) when admixed with metronidazole.

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 the administration of these two agents.

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.

OVERDOSAGE

Contact Poisons Information Centre on 13 11 26 for advice on management of overdose.

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

Treatment. Ceftazidime can be removed by haemodialysis.

PRESENTATION AND STORAGE CONDITIONS

Vial (powder for reconstitution), 1g (for IM or IV use): 1's, 5's* and 10's*;
2g (for IV use): 1's, 5s* and 10's*.

Store powder for reconstitution below 25°C. Protect from light.

*Not currently marketed in Australia

NAME AND ADDRESS OF THE SPONSOR

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Australia
Tel: 1800 634 500

POISON SCHEDULE OF THE MEDICINE

Schedule 4 – Prescription Only Medicine

Date of first inclusion in the Australian Register of Therapeutic Goods (the ARTG): 05/06/2003

Date of most recent amendment: 28/01/2016