

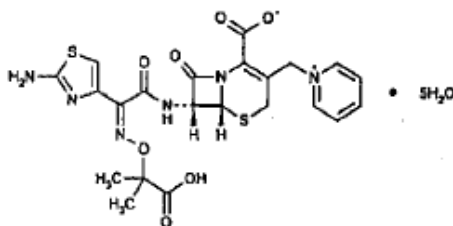
# PRODUCT INFORMATION

## CEFTAZIDIME ASPEN

powder for injection

### NAME OF THE MEDICINE

Non-Proprietary Name: Ceftazidime (as pentahydrate)  
Chemical Name: (6R,7R)-7-[[[(2Z)-2-(2-aminothiazol-4-yl)-2-[(1-carboxyl-1-methylethoxy)imino]acetyl]amino]-8-oxo-3-[(1-pyridinio)methyl]-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate pentahydrate  
Chemical Structure:



CAS: 78439-06-2

MW: 637.0

### DESCRIPTION

Ceftazidime is a cephalosporin antibiotic for use by injection only. CEFTAZIDIME ASPEN powder for injection is a white or almost white crystalline powder of ceftazidime pentahydrate (sterile and buffered with sodium carbonate) equivalent to 1 g or 2 g ceftazidime (on dried and sodium carbonate free basis). On the addition of water for injections, CEFTAZIDIME ASPEN powder for injection dissolves with effervescence to produce a solution for injection. CEFTAZIDIME ASPEN powder for injection contains approximately 50.5 mg (2.2 mEq) of sodium per gram of ceftazidime. For laboratory tests associated with ceftazidime administration, ceftazidime pentahydrate should be used.

### PHARMACOLOGY

#### 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* spp (other), *Klebsiella pneumoniae*, *Klebsiella* spp (other), *Proteus mirabilis*, *P vulgaris*, *Morganella morganii* (formerly *P morganii*), *P rettgeri*, *Providencia* spp, *Escherichia coli*, *Enterobacter* spp, *Citrobacter* spp, *Serratia* spp, *Acinetobacter* spp, *Neisseria gonorrhoeae*, *N meningitidis*, *Haemophilus influenzae* (including ampicillin resistant strains).

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

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

*In vitro*, the activities of ceftazidime and aminoglycoside antibiotics in combination have been shown to be at least additive and 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. Clinical and Laboratory Standards Institute [CLSI formerly NCCLS]). Standardised susceptibility test procedures require the use of the 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 ASPEN is intended for parenteral use only.

In humans, after a single intramuscular administration of 500 mg and 1 g, mean peak serum levels of 18 mg/L and 37 mg/L respectively are achieved at 1 hour, falling to 8 mg/L and 2 mg/L (500 mg) and 20 mg/L and 5 mg/L (1 g) at four hours and eight hours respectively for the two doses.

Five minutes after an intravenous bolus injection of 500 mg, 1 g and 2 g, mean serum levels are respectively 46 mg/L, 87 mg/L and 170 mg/L, falling to 17 mg/L and 6 mg/L (500 mg), 32 mg/L and 10 mg/L (1 g) and 85 mg/L and 15 mg/L (2 g) 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 (1.2-2.9 hours). This may be prolonged to 20-35 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%.

#### Mean peak serum concentrations of Ceftazidime following IV administrations

ceftazidime IV dose	Serum concentrations (mg/L)	
	1 hour	4 hour
500 mg	17	6
1 g	32	10
2 g	85	15

#### Mean peak serum concentrations of Ceftazidime following IM administrations

ceftazidime IM dose	Serum concentrations (mg/L)		
	1 hour	4 hour	8 hour
500 mg	18	8	2
1 g	37	20	5

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 80-90% 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 occurs readily. 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:** For example, septicaemia (including neonatal sepsis), bacteraemia; patients in intensive care units with specific problems, e.g. infected burns.

**Respiratory tract:** For example, pneumonia, bronchopneumonia, infected pleurisy, infected bronchiectasis and bronchitis.

**Severe ear, nose and throat infections:** For example, otitis media, mastoiditis.

**Urinary tract:** For example, acute and chronic pyelonephritis, pyelitis, cystitis, urethritis (bacterial only); infections associated with bladder and renal stones.

**Skin and soft tissue:** For example, erysipelas, abscesses, cellulitis, infected burns and wounds, mastitis.

**Gastrointestinal and abdominal:** For example, intra-abdominal abscesses, enterocolitis.

**Bone and joint:** For example, osteitis, osteomyelitis, septic arthritis, infected bursitis.

## CONTRAINDICATIONS

CEFTAZIDIME ASPEN powder for injection is contraindicated in patients with 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. If an allergic reaction to ceftazidime occurs, discontinue the drug. Serious hypersensitivity reactions may require adrenaline, hydrocortisone, antihistamine or other emergency measures.

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

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.

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 or brain abscess, is not advised at present.

Prescribing ceftazidime in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Inducible type I beta-lactamase resistance has been noted with some organisms (eg *Enterobacter* spp., *Pseudomonas* spp., and *Serratia* spp.). As with other extended-spectrum beta-lactam antibiotics, resistance can develop during therapy, leading to clinical failure in some cases. When treating infections caused by these organisms, periodic susceptibility testing should be performed when clinically appropriate. If patients fail to respond to monotherapy, an aminoglycoside or similar agent should be considered.

Cephalosporins may be associated with a fall in prothrombin activity. Those at risk include patients with renal and hepatic impairment, or poor nutritional state, as well as patients receiving a protracted course of antimicrobial therapy. Prothrombin time should be monitored in patients at risk and exogenous vitamin K administered as indicated.

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

Distal necrosis can occur after inadvertent intra-arterial administration of ceftazidime.

Vials of CEFTAZIDIME ASPEN powder for 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).

### **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).

## **Impaired Hepatic Function**

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

Repeated use of lignocaine 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.

## **Use in Pregnancy (Category B1)**

The safety of CEFTAZIDIME ASPEN 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.

## **Paediatric Use**

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

## **Interactions with Other Medicines**

Aminoglycoside antibiotics and / or diuretics: Nephrotoxicity has been reported following concomitant administration of cephalosporins with aminoglycoside antibiotics or potent diuretics such as furosemide. 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 aminoglycosidic antibiotics. Nephrotoxicity and ototoxicity were not noted when ceftazidime was given alone in clinical trials.

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

Chloramphenicol: Chloramphenicol has been shown to be antagonistic to beta-lactam antibiotics, including ceftazidime, based on in vitro studies and time kill curves with enteric gram-negative bacilli. Due to the possibility of antagonism in vivo, particularly when bacterial activity is desired, this drug combination should be avoided.

## **Effect on 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.

The administration of ceftazidime may result in a false-positive reaction for glucose in the urine when using CLINITEST<sup>®</sup> tablets, Benedict's solution, or Fehling's solution. It is recommended that glucose tests based on enzymatic glucose oxidase reactions (such as CINISTIX<sup>®</sup>) be used.

## ADVERSE REACTIONS

Clinical trial experience has shown that ceftazidime is generally well tolerated. Adverse reactions are infrequent and include the following.

**Local:** Phlebitis or thrombophlebitis with intravenous administration; pain and/or inflammation after intramuscular injection.

**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.

**Gastrointestinal:** Diarrhoea, nausea, vomiting, abdominal pain and very rarely oral thrush or colitis. Pseudomembranous colitis has been reported.

**Central Nervous System:** Headache, dizziness, paraesthesia and bad taste. There have been reports of neurological sequelae including tremor, myoclonia, convulsions, encephalopathy and coma occurring in patients with renal impairment in whom the dose of ceftazidime has not been appropriately reduced.

**Genitourinary:** Candidiasis, vaginitis.

**Renal:** Transient elevations of blood urea, serum urea and/or serum creatinine have been observed occasionally.

**Hepatic:** Elevations in one or more of the hepatic enzymes, AST, ALT, LDH, GGT and alkaline phosphatase, may occur.

**Haematological:** Eosinophilia, positive Coombs test, thrombocytosis; very rarely, transient leucopenia, haemolytic anaemia, neutropenia, thrombocytopenia and lymphocytosis have been seen.

**Other:** Hot flushes, superficial desquamation around injection site.

## DOSAGE AND ADMINISTRATION

**Note:** Vials of CEFTAZIDIME ASPEN powder for 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, and the age, weight and renal function of the patient.

CEFTAZIDIME ASPEN powder for injection is for use in one patient only. Discard any remaining contents.

### Adults

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

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

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

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

Individual doses exceeding 1 g should be administered intravenously.

## Children

**Over 12 months:** The usual dosage range for children aged over 12 months is 25-100 mg/kg/day (up to a maximum of 6 g/day), given as two or three divided doses. The maximum daily dosage (6 g) 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:** 25-100 mg/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 50 mL/minute. In patients with suspected renal insufficiency, an initial loading dose of ceftazidime 1 g 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 1: Recommended maintenance doses of ceftazidime in renal insufficiency**

<b>Creatinine Clearance (mL/min)</b>	<b>Approx Serum Creatinine* (micromole/L)</b>	<b>Recommended Unit Dose of Ceftazidime (g)</b>	<b>Frequency of Dosing (hours)</b>
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 6 g 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 40 mg/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)

$$\text{Men: } \frac{\text{Bodyweight (kg)} \times (140 - \text{age in years})}{72 \times \text{serum creatinine}} \times 0.0885$$

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, 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, or added to intraperitoneal dialysis fluids.

**Reconstitution:** CEFTAZIDIME ASPEN may be reconstituted with water for injections or, for intramuscular injection, with 0.5% 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)
1 g – intramuscular	3 mL	260
1 g – intravenous bolus	10.0 mL	90
2 g – intravenous bolus	10.0 mL	170
2 g – intravenous infusion	50.0 mL*	40

\* Note: addition should be in two 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.

**1 g intramuscular/intravenous and 2 g 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; they may be disregarded.

**2 g 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 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 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 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.

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.

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

Product is for single use in one patient only. Discard any residue.

Solutions of CEFTAZIDIME ASPEN powder for injection reconstituted in water for injections are physically and chemically stable for twelve hours if kept below 25°C or for seven days if refrigerated at 2°C to 8°C. When reconstituted in 0.5% Lignocaine Hydrochloride Injection BP, the corresponding times are six hours at below 25°C or four days under refrigeration (2°C to 8°C). Some increase in the colour of prepared solutions of CEFTAZIDIME ASPEN for injection may occur on storage. To reduce microbiological hazard, the reconstituted solution should be diluted as soon as practicable after

reconstitution and administered as soon as practicable after dilution. If storage is necessary, hold at 2°C to 8°C for a total time not more than 24 hours after reconstitution.

CEFTAZIDIME ASPEN is compatible with the intravenous fluids shown below. Solutions at concentrations between 1 mg/mL and 40 mg/mL in these infusion fluids are physically and chemically stable for up to twelve hours below 25°C or seven days if refrigerated (2°C to 8°C): 0.9% Sodium Chloride Injection BP, M/6 Sodium Lactate Injection BP, M/6 Compound Sodium Lactate Injection BP (Hartmann's solution), 5% Dextrose Injection BP, Dextran 40 Injection BP 10% in 0.9% Sodium Chloride Injection BP, Dextran 40 Injection BP 10% in 5% Dextrose Injection BP, Dextran 70 Injection BP 6% in 0.9% Sodium Chloride Injection BP, Dextran 70 Injection BP 6% in 5% Dextrose Injection BP. To reduce microbiological hazard, the reconstituted solution should be diluted as soon as practicable after reconstitution and administered as soon as practicable after dilution. If storage is necessary, hold at 2°C to 8°C for a total time not more than 24 hours after reconstitution. Sodium bicarbonate injection is not recommended as a diluent.

CEFTAZIDIME ASPEN powder for injection is physically and chemically stable for up to twelve hours below 25°C or seven days under refrigeration (2°C to 8°C) at concentrations between 0.05 mg/mL and 0.25 mg/mL in Intraperitoneal Dialysis Fluid (Lactate) BPC 1973. To reduce microbiological hazard, the reconstituted solution should be diluted as soon as practicable after reconstitution and administered as soon as practicable after dilution. If storage is necessary, hold at 2°C to 8°C for a total time not more than 24 hours after reconstitution.

CEFTAZIDIME ASPEN powder for injection is physically and chemically stable for twelve hours below 25°C or seven days under refrigeration (2°C 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. To reduce microbiological hazard, the reconstituted solution should be diluted as soon as practicable after reconstitution and administered as soon as practicable after dilution. If storage is necessary, hold at 2°C to 8°C for a total time not more than 24 hours after reconstitution.

CEFTAZIDIME ASPEN powder for injection (4 mg/mL) is physically and chemically stable for 24 hours when stored below 25°C or seven days when refrigerated (2°C to 8°C, do not freeze) when admixed with cloxacillin. To reduce microbiological hazard, the reconstituted solution should be diluted as soon as practicable after reconstitution and administered as soon as practicable after dilution. If storage is necessary, hold at 2°C to 8°C for a total time not more than 24 hours after reconstitution.

CEFTAZIDIME ASPEN powder for injection (5 mg/mL) is physically and chemically stable for twelve hours when stored below 25°C or seven days when refrigerated (2°C to 8°C, do not freeze) when admixed with metronidazole. To reduce microbiological hazard, the reconstituted solution should be diluted as soon as practicable after reconstitution and administered as soon as practicable after dilution. If storage is necessary, hold at 2°C to 8°C for a total time not more than 24 hours after reconstitution.

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 administrations of these two agents.

Protect from light.

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**

### **Symptoms**

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

### **Treatment**

Ceftazidime can be removed by haemodialysis.

Contact the Poisons Information Centre for advice on management of overdose.

## **PRESENTATION AND STORAGE CONDITIONS**

CEFTAZIDIME ASPEN powder for injection 1 g (for IM or IV use) or 2 g (for IV use).

Available in packs of 1 and 5\* vials.

Store below 25°C. Protect from light.

(\* not currently distributed in Australia)

## **POISON SCHEDULE**

Schedule 4: Prescription Only Medicine

## **NAME AND ADDRESS OF SPONSOR**

Aspen Pharmacare Australia Pty Limited  
34-36 Chandos St  
St Leonards NSW 2065

**Date of TGA approval:** 9 June 2010

Date of most recent amendment: 13 July 2010