PRODUCT INFORMATION

CEFTAZIDIME MYLAN

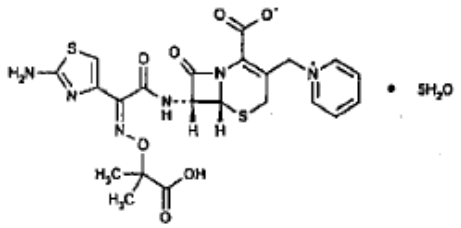
Ceftazidime (as pentahydrate)

NAME OF THE MEDICINE

Active ingredient : 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

Structural formula :



Molecular weight : 637.0

CAS Registry no. : 78439-06-2

DESCRIPTION

Ceftazidine is a cephalosporin antibiotic for use by injection only. CEFTAZIDIME MYLAN 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 MYLAN powder for injection dissolves with effervescence to produce a solution for injection. CEFTAZIDIME MYLAN 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

Pharmacokinetics

Absorption of ceftazidime after oral administration is negligible, therefore CEFTAZIDIME MYLAN 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 IM administration

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

Mean peak serum concentrations of Ceftazidime following IV administration

	Serum concentrations (mg/L)		
Ceftazidime IV dose	5 minutes	1 hour	4 hours
500 mg	46	17	6
1 g	87	32	10
2 g	170	85	15

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.

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:

Quantitative methods that require measurement of zone diameters give the most precise estimate of antibiotic susceptibility. One such procedure has been recommended for use with discs to test susceptibility to ceftazidime.

Reports from the laboratory giving results of the standard single-disc susceptibility test with a 30 mcg ceftazidime disc should be interpreted according to the following criteria:

- Susceptible organisms produce zones of 18 mm or greater, indicating that the test organism is likely to respond to therapy.

- Organisms that produce zones of 15 mm to 17 mm are expected to be susceptible if high dosage is used or if the infection is confined to tissues and fluids (eg, urine) in which high antibiotic levels are attained.

- Resistant organisms produce zones of 14 mm or less, indicating that other therapy should be selected.

Organisms should be tested with the ceftazidime disc, since ceftazidime has been shown by in vitro tests to be active against certain strains found resistant when other beta-lactam discs are used.

Standardised procedures require the use of laboratory control organisms. The 30 mcg ceftazidime disc should give zone diameters between 25 mm and 32 mm for E. coli ATCC 25922. For P. aeruginosa ATCC 27853, the zone diameters should be between 22 mm and 29 mm. For S. aureus ATCC 25923, the zone diameters should be between 16 mm and 20 mm.

In other susceptibility testing procedures, eg, ICS agar dilution or the equivalent, a bacterial isolate may be considered susceptible if the MIC value for ceftazidime is not more than 16 mcg/mL. Organisms are considered resistant to ceftazidime if the MIC is equal to or greater than 64 mcg/mL. Organisms having an MIC value of less than 64 mcg/mL but greater than 16 mcg/mL are expected to be susceptible if high dosage is used or if the infection is confined to tissues and fluids (eg, urine) in which high antibiotic levels are attained.

As with the standard diffusion methods, dilution procedures require the use of laboratory control organisms. Standard ceftazidime powder should give MIC values in the range of 4 mcg/mL and 16 mcg/mL for S. aureus ATCC 25923. For E. coli ATCC 25922, the MIC range should be between 0.125 mcg/mL and 0.5 mcg/mL. For P. aeruginosa ATCC 27853, the MIC range should be between 0.5 mcg/mL and 2 mcg/mL.

Susceptability to ceftazidime will vary with geography and time and local susceptibility data should be consulted where available.

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 infections: For example, pneumonia, bronchopneumonia, infected pleurisy, infected bronchiectasis and bronchitis.

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

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

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

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

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

CONTRAINDICATIONS

CEFTAZIDIME MYLAN 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.

WARNINGSAs 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.

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.

As with other broad spectrum antibiotics, prolonged use may result in the overgrowth of non susceptible organisms (eg. 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.

Concurrent treatment with high doses of cephalosporins and nephrotoxic drugs such as aminoglycosides or potent diuretics (eg. frusemide) 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.

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.

Clostridium 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.

PRECAUTIONS

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.

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

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. There is some evidence in the literature that concurrent use of two beta-lactam antibiotics may exhibit antagonism.

Vials of CEFTAZIDIME MYLAN 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.**Use in Pregnancy (Category B1)**

The safety of CEFTAZIDIME MYLAN 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.

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.

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

Interactions with Other Medicines

Concurrent use of high doses with nephrotoxic drugs may adversely affect renal function (see **Warnings**). In common with other antibiotics, ceftazidime may affect the gut flora, leading to lower oestrogen reabsorption and reduced efficacy of combined oral contraceptives.
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.

ADVERSE REACTIONS

Clinical data has determined 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 Warnings and 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.

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.

DOSAGE AND ADMINISTRATION

Note: Vials of CEFTAZIDIME MYLAN 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 MYLAN 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

Creatinine Clearance (mL/min)	Approx Serum Creatinine* (micromole/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, expecially 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)

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 MYLAN 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 MYLAN powder for injection reconstituted in water for injections are physically and chemically stable for twelve hours if kept below 25ºC or for seven days if refrigerated at 2ºC to 8ºC. When reconstituted in 0.5% Lignocaine Hydrochloride Injection BP, the corresponding times are six hours at below 25ºC or four days under refrigeration (2ºC to 8ºC). Some increase in the colour of prepared solutions of CEFTAZIDIME MYLAN 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 2ºC to 8ºC for a total time not more than 24 hours after reconstitution.

CEFTAZIDIME MYLAN 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 25ºC or seven days if refrigerated (2ºC to 8ºC): 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 2ºC to 8ºC for a total time not more than 24 hours after reconstitution. Sodium bicarbonate injection is not recommended as a diluent.

CEFTAZIDIME MYLAN powder for injection is physically and chemically stable for up to twelve hours below 25ºC or seven days under refrigeration (2ºC to 8ºC) 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 2ºC to 8ºC for a total time not more than 24 hours after reconstitution.

CEFTAZIDIME MYLAN powder for injection is physically and chemically stable for twelve hours below 25ºC or seven days under refrigeration (2ºC to 8ºC) 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 2ºC to 8ºC for a total time not more than 24 hours after reconstitution.

CEFTAZIDIME MYLAN powder for injection (4 mg/mL) is physically and chemically stable for 24 hours when stored below 25ºC or seven days when refrigerated (2ºC to 8ºC, 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 2ºC to 8ºC for a total time not more than 24 hours after reconstitution.

CEFTAZIDIME MYLAN powder for injection (5 mg/mL) is physically and chemically stable for twelve hours when stored below 25ºC or seven days when refrigerated (2ºC to 8ºC, 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 2ºC to 8ºC 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 on 131126 (Australia) for advice on management of overdosage.

PRESENTATION AND STORAGE CONDITIONS

CEFTAZIDIME MYLAN 1g	:	For intramuscular or intravenous injection Powder for injection Vial pack size: 1's and 5's Container: Glass Type I Clear
CEFTAZIDIME MYLAN 2g	:	For intravenous infusion Powder for injection Vial pack size: 1's and 5's Container: Glass Type I Clear

Store below 25ºC. Protect from light.

NAME AND ADDRESS OF THE SPONSOR

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POISON SCHEDULE OF THE MEDICINE

S4 (Prescription Only Medicine)

DATE OF FIRST INCLUSION IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS (THE ARTG)

9 June 2010

DATE OF MOST RECENT AMENDMENT

10/12/2015

Ceftazidime Mylan_pi_Aug15/00