Summary of product characteristics

1. Name of the medicinal product:

Cefidime vial

2. Qualitative and quantitative composition:

Ceftazidime (as pentahydrate buffered with sodium carbonate)….0.25, 0.5, 1, or 2 g

For the full list of excipients, see section 6.1.

3. Pharmaceutical form:

Off white powder.
After reconstitution: clear straw yellow solution free from particles.

4. Clinical particulars:

4.1. Therapeutic indications:

Cefidime is indicated for the treatment of the infections listed below in adults and children including neonates (from birth):

- Nosocomial pneumonia.
- Broncho-pulmonary infections in cystic fibrosis.
- Bacterial meningitis.
- Chronic suppurative otitis media.
- Malignant otitis externa.
- Complicated urinary tract infections.
- Complicated skin and soft tissue infections.
- Complicated intra-abdominal infections.
- Bone and joint infections.
- Peritonitis associated with dialysis in patients on CAPD.

Treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above.
Ceftazidime may be used in the management of neutropenic patients with fever that is suspected to be due to a bacterial infection.
Cefidime may be used in the peri-operative prophylaxis of urinary tract infections in patients undergoing transurethral resection of the prostate (TURP).
The selection of **Cefidime** should take into account its antibacterial spectrum, which is mainly restricted to aerobic Gram negative bacteria.
Cefidime should be co-administered with other antibacterial agents whenever the possible range of causive bacteria would not fall within its spectrum of activity.
Consideration should be given to official guidelines on the appropriate use of antibacterial agents.

4.2. Posology and method of administration: Posology:

Table 1:

Adults and Children ≥ 40 kg:

Intermittent Administration	
Infection	**Dose to be administered**
Broncho-pulmonary infections in cystic fibrosis	100 to 150 mg/kg/day every 8 hours; maximum 9 g/day.[1]
Febrile neutropenia	2 g every 8 hours.
Nosocomial pneumonia	
Bacterial meningitis	
Bacteraemia*	
Bone and joint infections	1-2 g every 8 hours.
Complicated skin and soft tissue infections	
Complicated intra-abdominal infections	
Peritonitis associated with dialysis in patients on CAPD	
Complicated urinary tract infections	1-2 g every 8 h or 12 hours.
Per-operative prophylaxis for transurethral resection of prostate (TURP)	1 g at induction of anaesthesia, and a second dose at catheter removal.
Chronic suppurative otitis media	1-2 g every 8 hours.
Malignant otitis externa	
Continuous Infusion	
Infection	**Dose to be administered**
Febrile neutropenia	Loading dose of 2 g followed by a continuous infusion of 4-6 g every 24 hours.[1]
Nosocomial pneumonia	
Broncho-pulmonary infections in cystic fibrosis	
Bacterial meningitis	
Bacteraemia*	
Bone and joint infections	
Complicated skin and soft tissue infections	
Complicated intra-abdominal infections	
Peritonitis associated with dialysis in patients on CAPD	
[1]In adults with normal renal function 9 g/day has been used without adverse effects. *When associated with, or suspected to be associated with, any of the infections listed in therapeutic indication section.	

Table 2:
Children < 40 kg:

Infants, Toddlers > 2 months and Children < 40 kg	**Infection**	**Usual dose**
Intermittent Administration		
	Complicated urinary tract infections	100-150 mg/kg/day in three divided doses; maximum 6 g/day.
	Chronic suppurative otitis media	
	Malignant otitis externa	
	Neutropenic children	150 mg/kg/day in three divided doses; maximum 6 g/day.
	Broncho-pulmonary infections in cystic fibrosis	
	Bacterial meningitis	
	Bacteraemia*	
	Bone and joint infections	100-150 mg/kg/day in three divided doses; maximum 6 g/day.
	Complicated skin and soft tissue infections	
	Complicated intra-abdominal infections	
	Peritonitis associated with dialysis in patients on CAPD	
Continuous Infusion		
	Febrile neutropenia	Loading dose of 60-100 mg/kg followed by a continuous infusion 100-200 mg/kg/day; maximum 6 g/day.
	Nosocomial pneumonia	
	Broncho-pulmonary infections in cystic fibrosis	
	Bacterial meningitis	
	Bacteraemia*	
	Bone and joint infections	
	Complicated skin and soft tissue infections	
	Complicated intra-abdominal infections	
	Peritonitis associated with dialysis in patients with CAPD	

Neonates and Infants ≤ 2 months	**Infection**	**Usual dose**
Intermittent Administration		
	Most infections	25-60 mg/kg/day in two divided doses.[1]
[1]In neonates and infants ≤ 2 months, the serum half life of ceftazidime can be three to four times that in adults. *Where associated with, or suspected to be associated with, any of the infections listed in therapeutic indication section.		

Paediatric population:
The safety and efficacy of **Cefidime** administered as continuous infusion to neonates and infants ≤ 2 months has not been established.

Elderly:
In view of the age-related reduced clearance of **Cefidime** in elderly patients, the daily dose should not normally exceed 3 g in those over 80 years of age.

Hepatic impairment:
Available data do not indicate the need for dose adjustment in mild or moderate liver function impairment. There are no study data in patients with severe hepatic impairment. Close clinical monitoring for safety and efficacy is advised.

Renal impairment:
Cefidime 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 creatinine clearance:

Table 3: Recommended maintenance doses of Cefidime in renal impairment – Intermittent Infusion
Adults and Children ≥ 40 kg:

Creatinine clearance (ml/min)	**Approx. serum creatinine µmol/l (mg/dl)**	**Recommended unit dose of Cefidime (g)**	**Frequency of dosing (hourly)**
50-31	150-200 (1.7-2.3)	1	12
30-16	200-350	1	24

	(2.3-4.0)		
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 children, the creatinine clearance should be adjusted for body surface area or lean body mass.

Children < 40 kg:

Creatinine clearance (ml/min)**	**Approx. serum creatinine* µmol/l (mg/dl)**	**Recommended individual dose mg/kg body weight**	**Frequency of dosing (hourly)**
50-31	150-200 (1.7-2.3)	25	12
30-16	200-350 (2.3-4.0)	25	24
15-6	350-500 (4.0-5.6)	12.5	24
< 5	> 500 (> 5.6)	12.5	48

*The serum creatinine values are guideline values that may not indicate exactly the same degree of reduction for all patients with reduced renal function.
** Estimated based on body surface area, or measured.
Close clinical monitoring for safety and efficacy is advised.

Table 4: Recommended maintenance doses of Cefidime in renal impairment – continuous infusion

Adults and Children ≥ 40 kg:

Creatinine clearance (ml/min)	**Approx. Serum creatinine µmol/l (mg/dl)**	**Frequency of dosing (hourly)**
50-31	150-200 (1.7-2.3)	Loading dose of 2 g, followed by 1-3 g/24 hours.
30-16	200-350 (2.3-4.0)	Loading dose of 2 g followed by 1 g/24 hours.
≤ 15	> 350 (> 4.0)	Not evaluated.

Caution is advised in dose selection. Close clinical monitoring for safety and efficacy is advised.

Children < 40 kg:
The safety and effectiveness of **Cefidime** administered as continuous infusion in renally impaired children < 40 kg has not been established, Close clinical monitoring for safety and efficacy is advised.
If continuous infusion is used in children with renal impairment, 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 **Cefidime** recommended in the tables 5 & 6 should be repeated.

Peritoneal dialysis:
Cefidime may be used in peritoneal dialysis and continuous ambulatory peritoneal dialysis (CAPD).
In addition to intravenous use, **Cefidime** can be incorporated into the dialysis fluid (usually 125-250 mg for 2 litres of dialysis solution).
For patients with renal failure on continuous arterio-venous 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 dose recommended under renal impairment.
For patients on veno-venous haemofiltration and veno-venous haemodialysis, follow the dosage recommendations in tables 5 & 6 below.

Table 5: Continuous veno-venous haemofiltration dose guidelines:

Residual renal function (creatinine clearance ml/min)	**Maintenance dose (mg) for an ultrafiltration rate (ml/min) of[1]:**			
	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
[1]Maintenance dose to be administered every 12 hours.				

Table 6: Continuous veno-venous haemodialysis dose guidelines:

Residual renal function (creatinine clearance in ml/min)	**Maintenance dose (mg) for a dialysate in flow rate of 1:**					
	1.0 litre/hour			2.0 litre/hour		
	Ultrafiltration rate (litre/hour)			Ultrafiltration rate (litre/hour)		
	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
[1]Maintenance dose to be administered every 12 hours.						

Method of administration:
The dose depends on the severity, susceptibility, site and type of infection and on the age and renal function of the patient.
Cefidime should be administered by intravenous injection or infusion, or by deep intramuscular injection. Recommended intramuscular injection sites are the upper outer quadrant of the gluteus maximus or lateral part of the thigh. **Cefidime** solutions may be given directly into the vein or introduced into the tubing of a giving set if the patient is receiving parenteral fluids. The standard recommended route of administration is by intravenous intermittent injection or intravenous continuous infusion. Intramuscular administration should only be considered when the intravenous route is not possible or less appropriate for the patient.

4.3. Contraindications:

Hypersensitivity to the active substance, to other cephalosporins or to any of the excipients.

Previous immediate and/or severe hypersensitivity reaction to a penicillin or to any other beta-lactam medicinal products.

4.4. Special warnings and precautions for use:

Special caution is required to determine any other type of previous hypersensitivity reactions to penicillin or to other beta-lactam medicinal products because patients hypersensitive to these medicines may be hypersensitive to **Cefidime** as well (cross- allergy).
As with all beta-lactam antibacterial agents, serious and occasionally fatal hypersensitivity reactions have been reported. In case of severe hypersensitivity reactions, treatment with **Cefidime** must be discontinued immediately and adequate emergency measures must be initiated.
Before beginning treatment, it should be established whether the patient has a history of severe hypersensitivity reactions to ceftazidime, to other cephalosporins or to any other type of beta-lactam agent. Caution should be used if ceftazidime is given to patients with a history of non-severe hypersensitivity to other beta-lactam agents.
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 medicinal products such as aminoglycosides or potent diuretics (e.g. furosemide) may adversely affect renal function.
Ceftazidime is eliminated via the kidneys, therefore the dose of **Cefidime** should be reduced according to the degree of renal impairment. Patients with renal impairment should be closely monitored for both safety and efficacy. Neurological sequelae have occasionally been reported when the dose has not been reduced in patients with renal impairment.
Prolonged use may result in the overgrowth of non-susceptible organisms (e.g. Enterococci, fungi) which may require interruption of treatment or other appropriate measures. Repeated evaluation of the patient's condition is essential.
Ceftazidime does not interfere with enzyme-based tests for glycosuria, but slight interference (false-positive) may occur with copper reduction methods (Benedict's, Fehling's, Clinitest).
Ceftazidime does not interfere in the alkaline picrate assay for creatinine.
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.

Important information about one of the ingredients of Cefidime:
Cefidime contains sodium; this should be considered for patients who are on a controlled sodium diet.

4.5. Interaction with other medicinal products:

Interaction studies have only been conducted with probenecid and furosemide.
Concurrent use of high doses with nephrotoxic medicinal products may adversely affect renal function.
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.

4.6. Fertility, pregnancy and lactation:

Pregnancy:

There are limited amounts of data from the use of ceftazidime in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development.

Cefidime should be prescribed to pregnant women only if the benefit outweighs the risk.

Lactation:

Ceftazidime is excreted in human milk in small quantities but at therapeutic doses of ceftazidime, no effects on the breast-fed infant are anticipated. **Cefidime** can be used during breast-feeding.

4.7. Effects on ability to drive and use machines:

No studies on the effects on the ability to drive and use machines have been performed. However, undesirable effects may occur (e.g. dizziness), which may influence the ability to drive and use machines.

4.8. Undesirable effects:

The most common adverse reactions are eosinphilia, thrombocytosis, phlebitis or thrombophlebitis with intravenous administration, diarrhoea, transient increases in hepatic enzymes, maculopapular or uticarcial rash, pain and/or inflammation following intramuscular injection and positive Coomb's test.

The following convention has been used for the classification of frequency: Very common ≥1/10

Common ≥1/100 and <1/10

Uncommon ≥1/1,000 and
<1/100 Rare ≥1/10,000 and
<1/1000 Very rare <1/10,000

Unknown (cannot be estimated from the available data).

Infections and infestations:

Uncommon: Candidiasis (including vaginitis and oral thrush).

Blood and lymphatic system disorders:

Common: Eosinophilia, thrombocytosis.
Uncommon: Neutropenia, leucopenia, thrombocytopenia.
Unknown: Agranulocytosis, haemolytic anaemia, lymphocytosis

Immune system disorders:

Unknown: Anaphylaxis (including bronchospasm and/or hypotension).

Nervous system disorders:

Uncommon: Headache, dizziness.
Unknown: Neurological sequelae[1], paraesthesia.

Vascular disorders:

Common: Phlebitis or thrombophlebitis with intravenous administration.

Gastrointestinal disorders:
Common: Diarrhoea.
Uncommon: Antibacterial agent-associated diarrhoea and colitis[2], abdominal pain, nausea, vomiting.
Unknown: Bad taste.
Heptobiliary disorders:
Common: Transient elevations in one or more hepatic enzymes[3]. Unknown: Jaundice.
Skin and subcutaneous tissue disorders:
Common: Maculopapular or urticarial rash.
Uncommon: Pruritus.
Unknown: Toxic epidermal necrolysis, Stevens-Johnson syndrome, Erythema multiforme, angioedema.
Renal and urinary disorders:
Uncommon: Transient elevations of blood urea, blood urea nitrogen and/or serum creatinine.
Very rare: Interstitial nephritis, acute renal failure.
General disorders and administration site conditions:
Common: Pain and/or inflammation after intramuscular injection. Uncommon: Fever.
Investigations:
Common: Positive Coombs test[4].
[1] 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.
[2] Diarrhoea and colitis may be associated with *Clostridium difficile* and may present as pseudomembranous colitis.
[3] ALT (SGPT), AST (SOGT), LHD, GGT, alkaline phosphatase.
[4] A positive Coombs test develops in about 5% of patients and may interfere with blood cross matching.
Reporting suspected adverse reactions
Reporting suspected adverse reactions after Authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org/

4.9. Overdose:
Overdosage can lead to neurological sequelae including encephalopathy, convulsions and coma.
Symptoms of overdose can occur if the dose is not reduced appropriately in patients with renal impairment.
Serum levels of ceftazidime can be reduced by haemodialysis or peritoneal dialysis.

5. Pharmacological properties:

5.1. Pharmacodynamic properties:

Pharmacotherapeutic group: Anti-bacterials for systemic use. Third-generation cephalosporins.

Mechanism of action: Ceftazidime inhibits bacterial cell wall synthesis following attachment to penicillin binding proteins (PBPs). This results in the interruption of cell wall (peptidoglycan) biosynthesis, which leads to bacterial cell lysis and death.

PK/PD relationship:

For cephalosporins, the most important pharmacokinetic-pharmacodynamic index correlating with in vivo efficacy has been shown to be the percentage of the dosing interval that the unbound concentration remains above the minimum inhibitory concentration (MIC) of ceftazidime for individual target species (i.e. %T>MIC).

Mechanism of Resistance:

Bacterial resistance to ceftazidime may be due to one or more of the following mechanisms:

- hydrolysis by beta-lactamases. Ceftazidime may be efficiently hydrolysed by extended-spectrum beta-lactamases (ESBLs), including the SHV family of ESBLs and AmpC enzymes that may be induced or stably derepressed in certain aerobic Gram-negative bacterial species.
- reduced affinity of penicillin-binding proteins for ceftazidime.
- outer membrane impermeability, which restricts access of ceftazidime to penicillin binding proteins in Gram-negative organisms.
- bacterial efflux pumps.

Microbiological Susceptibility:

The prevalence of acquired resistance may vary geographically and with time for selected species and local information on resistance is desirable, particularly when treating severe infections. As necessary, expert advice should be sought when the local prevalence of resistance is such that the utility of ceftazidime in at least some types of infections is questionable.

Commonly Susceptible Species: Gram-positive aerobes: *Streptococcus pyogenes.*
Streptococcus agalactiae.
Gram-negative aerobes: *Citrobacter koseri.*
Haemophilus influenzae. *Moraxella catarrhalis.*
Neisseria menigitidis.
Pasteurella multocida.
Proteus mirabilis.
Proteus spp (other).
Providencia spp..

Gram-negative aerobes:
Acinetobacter baumannii[+].
Burkholderia cepacia.
Citrobacter freundii.
Enterobacter aerogenes.
Enterobacter cloacae.
Escherichia coli.
Klebsiella pneumoniae.
Klebsiella spp (other).
Pseudomonas aeruginosa.
Serratia spp..
Morganella morganii.
Gram-positive aerobes:
Staphylococcus aureus[£].
Staphylococcus pneumoniae[£&]. *Viridans group streptococcus.* **Gram-positive anaerobes:**
Clostridium perfringens.
Peptostreptococcus spp..
Gram-negative anaerobes *Fusobacterium spp..*
Inherently resistant organisms:
Gram-positive aerobes:
Enterococcus spp. including *Enterococcus faecalis* and *Enterococcus faecium.*
Listeria spp..
Gram-positive anaerobes:
Clostridium difficile.
Gram-negative anaerobes
Bacteroides spp. (many strains of *Bacteroides fragilis* are resistant).
Others:
Chlamydia spp..
Mycoplasma spp..
Legionella spp..
[£] S. aureus that is methicillin susceptible is considered to have inherent low susceptibility to ceftazidime.All methicillin-resistance *S. aureus* are resistant to ceftazidime.
[£&] S.pneumoniae that demonstrate intermediate susceptibility or are resistant to penicillin can be expected to demonstrate at least reduced susceptibility to ceftazidime.
[+] High rates of resistance have been observed in one or more areas/countries/regions within the EU.

5.2. Pharmacokinetic properties:

Absorption:

After intramuscular administration of 500 mg and 1 g of ceftazidime, peak plasma levels of 18 and 37 mg/l respectively are achieved rapidly. Five minutes after intravenous bolus injection of 500 mg, 1 g or 2 g, plasma levels are 46, 87 and 170 mg/l, respectively. The kinetics of ceftazidime are linear within the single dose range of 0.5 to 2 g following intravenous or intramuscular dosing.

Distribution:

The serum protein binding of ceftazidime 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, concentrations of 4 to 20 mg/l or more are achieved in the CSF when the meninges are inflamed.

Biotransformation:

Ceftazidime is not metabolised.

Elimination:

After parenteral administration, plasma levels decrease with a half-life of about 2 h. Ceftazidime is excreted unchanged into the urine by glomerular filtration; approximately 80 to 90 % of the dose is recovered in the urine within 24 h. Less than 1 % is excreted via the bile.

Special patient populations:

Renal impairment:

Elimination of ceftazidime is decreased in patients with impaired renal function and the dose should be reduced.

Hepatic impairment:

The presence of mild to moderate hepatic dysfunction had no effect on the pharmacokinetics of ceftazidime in individuals administered 2 g intravenously every 8 hours for 5 days, provided renal function was not impaired.

Elderly:

The reduced clearance observed in elderly patients was primarily due to age-related decrease in renal clearance of ceftazidime. The mean elimination half-life ranged from 3.5 to 4 hours following single or 7 days repeat BID dosing of 2 g IV bolus injections in elderly patients 80 years or older.

Paediatric population:

The half-life of ceftazidime is prolonged in preterm and term neonates by 4.5 to 7.5 hours after doses of 25 to 30 mg/kg. However, by the age of 2 months, the half-life is within the range for adults.

6. Pharmaceutical particulars:

6.1 List of excipients:

None.

6.2 Incompatibilities:

None Known.

6.3 Shelf life:
2 years.

6.4 Special precautions for storage:
Cefidime 250 mg Vials: Store at a temperature not exceeding 30°C, and to be used directly after reconstitution.
Cefidime 500 mg Vials:
Before reconstitution: Store at a temperature not exceeding 30°C.

After reconstitution: Store at a temperature 2° - 8°C for 24 hours.
Cefidime 1 gm Vials:
Before reconstitution: Store at a temperature not exceeding 30°C. After reconstitution: Store at a temperature 2° - 8°C for 24 hours. **Cefidime 2 gm Vials**:
Before reconstitution: Store at a temperature not exceeding 30°C. After reconstitution: Store at a temperature 2° - 8°C for 24 hours.

6.5 Nature and contents of container:
Cefidime 250 mg Vials: Carton box containing 1 colourless glass (type I) vial with grey rubber stopper- AL cap + 1 solvent ampoule of sterile water for injection and inner leaflet.
Cefidime 500 mg Vials: Carton box containing one transparent (Type I) glass vial with bromobutyl rubber stopper sealed with aluminum and coverd with plastic (HOPE) (flip up tear) cap containing 647.12 mg powder + transparent (Type I) glass ampoule of solvent (water for injection) containing 5 ml + insert leaflet.
Cefidime 1 gm Vials: Carton box containing 1 vial each + 1 solvent ampoule of sterile water for injection.

Cefidime 2 gm Vials: Carton box containing 1 vial each + 1 solvent ampoules of sterile water for injection**.**

6.6 Special precautions for disposal and other handling:
All sizes of vials of **Cefidime** are supplied under reduced pressure. As the product dissolves, carbon dioxide is released and a positive pressure develops. Small bubbles of carbon dioxide in the constituted solution may be ignored.

Instructions for constitution:
See table for addition volumes and solution concentrations, which may be useful when fractional doses are required.

Vial size		**Amount of Diluent to be added (ml)**	**Approximate Concentration (mg/ml)**
250 mg	Intramuscular	1.0	210
250 mg	Intravenous	2.5	90

500 mg 500 mg	Intramuscular Intravenous	1.5 5.0	260 90
1 g 1 g	Intramuscular Intravenous Intravenous infusion	3.0 10.0 50 ml*	260 90 20
2 g 2 g	Intravenous bolus Intravenous Infusion	10.0 50.0*	170 40

*Note: Addition should be in two stages.

Solutions range in colour from light yellow to amber depending on concentration, diluents and storage conditions used. Within the stated recommendations, product potency is not adversely affected by such colour variations.

Cefidime at concentrations between 1 mg/ml and 40 mg/ml is compatible with:

- Sodium chloride 9 mg/ml (0.9%) solution for injection.
- M/6 sodium lactate injection.
- Compound sodium lactate injection (Hartmann's solution).
- 5% dextrose injection
- 0.225% Sodium chloride and 5% Dextrose injection.
- 0.45% Sodium chloride and 5% Dextrose injection.
- 0.9% Sodium chloride and 5% Dextrose injection.
- 0.18% Sodium chloride and 4% Dextrose injection.
- 10% Dextrose injection.
- Dextran 40 injection 10% in 0.9% Sodium chloride injection.
- Dextran 40 injection 10% in 5% Dextrose injection.
- Dextran 70 injection 6% in 0.9% Sodium chloride injection.
- Dextran 70 injection 6% in 5% Dextrose injection.

Cefidime at concentrations between 0.05 mg/ml and 0.25 mg/ml is compatible with Intra-peritoneal Dialysis Fluid (Lactate).

Cefidime may be constituted for intramuscular use with 0.5% or 1% Lidocaine Hydrochloride Injection.

Preparation of solution for bolus injection:

1. Insert the syringe needle through the vial closure and inject the recommended volume of diluent. The vacuum may assist entry of the diluent. Remove the syringe needle.
2. Shake to dissolve: carbon dioxide is released and a clear solution will be obtained in about 1 to 2 minutes.
3. Invert the vial. With the syringe plunger fully depressed, insert the needle through the vial closure and withdraw the total volume of solution into the syringe (the pressure in the vial may aid withdrawal). Ensure that the needle remains within the solution and does not enter the head space. The withdrawn solution may contain small bubbles of carbon dioxide; they may be disregarded.

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. **Cefidime** is compatible with the most commonly used intravenous fluids.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorization holder:
EIPICO

8. Marketing authorisation number(s)
H2025/CTD11085/23505

9. Date of first registration/ renewal of the registration
2025 March 06

10. Date of revision of the text

22/08/2026