Cefiderocol Sulfate Tosylate

AHFS 8:12.06.28

Products

Cefiderocol sulfate tosylate is available as a lyophilized powder in single-dose vials containing the equivalent of 1 g of cefiderocol.3531 Each vial also contains sucrose 900 mg, sodium chloride 216 mg, and sodium hydroxide to adjust the pH.3531

The contents of each 1-g vial of cefiderocol should be reconstituted with 10 mL of sodium chloride 0.9% or dextrose 5% and the vial should be shaken gently to dissolve the powder.³⁵³¹ Vials should be allowed to stand until any foam that has been generated on the surface has disappeared (usually about 2 minutes).3531 The reconstituted solution must be diluted prior to infusion.3531

The manufacturer's instructions for preparing various doses of cefiderocol from the reconstituted solution are as follows:3531

For a 2-g dose, withdraw the entire contents of 2 vials (i.e., approximately 11.2 mL per vial).

For a 1.5-g dose, withdraw the entire contents of 1 vial (i.e., approximately 11.2 mL) and 5.6 mL from a second vial.

For a 1-g dose, withdraw the entire contents of 1 vial (i.e., approximately 11.2 mL).

For a 0.75-g dose, withdraw 8.4 mL from 1 vial.

All doses should then be added to a 100-mL infusion bag containing sodium chloride 0.9% or dextrose 5%.3531 3544

pН

The pH of the resulting solution that forms when 1 g of cefiderocol is dissolved in 10 mL of water is within the range of 5.2 to 5.8.3531

Equivalency

Cefiderocol sulfate tosylate 1.6 g is equivalent to 1 g of cefiderocol.3531

Sodium Content

Each 1-g vial of cefiderocol contains approximately 176 mg of sodium.3531

Trade Name(s)

Fetroja

Administration

Cefiderocol sulfate tosylate is administered by intravenous infusion over 3 hours following reconstitution and further dilution.3531

Stability

Cefiderocol sulfate tosylate is a white to off-white powder that forms a clear, colorless solution upon reconstitution and dilution.3531 Intact vials of cefiderocol sulfate tosylate should be stored at 2 to 8°C in the original carton until time of use to protect from light.³⁵³¹

After reconstitution with an appropriate diluent as instructed, the drug may be stored for up to 1 hour at room temperature. 3531 Following dilution, the drug is stable for 6 hours at room temperature.3531 The diluted solution for infusion also may be refrigerated at 2 to 8°C for up to 24 hours when protected from light; administration should be completed within 6 hours at room temperature following refrigerated storage. 3531

Compatibility Information

Solution Compatibility

Cefiderocol sulfate tosylate

Test Soln Name	Mfr	Mfr	Conc/L or %	Remarks	Refs	C/I
Dextrose 5%		SHI		Stable for up to 6 hr at room temperature or up to 24 hr at 2 to 8°C protected from light; following refrigerated storage, complete administration within 6 hr at room temperature	3531	С
Sodium chloride 0.9%		SHI		Stable for up to 6 hr at room temperature or up to 24 hr at 2 to 8°C protected from light; following refrigerated storage, complete administration within 6 hr at room temperature	3531	С

Y-Site Injection Compatibility (1:1 Mixture)

Cefiderocol sulfate tosylate

Test Drug	Mfr	Conc	Mfr	Conc	Remarks	Refs	C/I
Acyclovir sodium	AUB	7 mg/mL ^c	SHI	20 mg/mL ^c	Visually incompatible upon mixing	3662	I
Albumin human	ост	250 mg/mL	SHI	20 mg/mL ^c	Results of subvisual tests indicate high turbidity with or without particulate matter	3662, 3670	I
Amikacin sulfate	SGT	5 mg/mL ^a	SHI	20 mg/mL ^a	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Amikacin sulfate	SGT	5 mg/mL ^b	SHI	20 mg/mL ^b	Results of subvisual tests indicate high counts of particles ≥2 and ≥10 µm when cefiderocol is added to amikacin; not observed when order of mixing was reversed	3662	?
Aminophylline	HOS	1 mg/mL ^a	SHI	20 mg/mL ^a	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Aminophylline	HOS	1 mg/mL ^b	SHI	20 mg/mL ^b	Results of subvisual tests indicate high counts of particles ≥2 and ≥10 µm	3662	I
Amiodarone HCl	ww	4 mg/mL ^c	SHI	20 mg/mL ^c	Visually incompatible upon mixing	3662	I
Amphotericin B	XGN	1 mg/mL ^c	SHI	20 mg/mL ^c	Visually incompatible upon mixing	3662	I
Anidulafungin	RR	0.77 mg/mL ^c	SHI	20 mg/mL ^c	Blue haze observed due to Tyndall effects of colloidal-size micelles scattering blue light; turbidity decreased upon mixing	3662	?
Azithromycin	ATX	2 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Aztreonam	BMS	20 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Bumetanide	ww	0.25 mg/mL	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662, 3670	С
Calcium gluconate	FRK	20 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Caspofungin acetate	GLA	0.5 mg/mL ^c	SHI	20 mg/mL ^c	Visually incompatible upon mixing	3662	Ι
Cefazolin sodium	HOS	20 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Cefepime HCl	QI	40 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Ceftaroline fosamil	FOR	12 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Ceftazidime– avibactam sodium	GSK	40 mg/mL ^{c d}	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662, 3670	С
Ceftolozane sulfate- tazobactam sodium	SPA	10 mg/mL ^{c e}	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662, 3670	С
Ciprofloxacin	CLA	2 mg/mL ¹	SHI	20 mg/mL ^a	Results of subvisual tests indicate increased turbidity	3662, 3670	1
Ciprofloxacin	CLA	2 mg/mL ¹	SHI	20 mg/mL ^b	Physically compatible for up to 4 hr at 21 to 25°C	3662, 3670	С
Cisatracurium besylate	ABV	0.4 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Clindamycin phosphate	SGT	10 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Colistimethate sodium	XE	4.5 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Daptomycin	GLA	20 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Dexamethasone sodium phosphate	FRK	1 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С

Y-Site Injection Compatibility (1:1 Mixture) (Cont.)

Test Drug	Mfr	Conc	Mfr	Conc	Remarks	Refs	C/I
Dexmedetomidine HCl	AUB	4 mcg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Digoxin	SZ	250 mcg/mL	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662, 3670	С
Diltiazem HCl	AKN	5 mg/mL	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662, 3670	С
Diphenhydramine HCl	ww	50 mg/mL	SHI	20 mg/mL ^c	Visually incompatible upon mixing	3662, 3670	I
Dobutamine HCl	HOS	4 mg/mL ^c	SHI	20 mg/mL ^c	Visually incompatible upon mixing	3662	I
Doxycycline hyclate	FRK	1 mg/mL ^c	SHI	20 mg/mL ^c	Visually incompatible upon mixing	3662	I
Epinephrine ^k	SIN	16 mcg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Ertapenem sodium	PAR	20 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Esomeprazole sodium	MYL	0.8 mg/mL ^c	SHI	20 mg/mL ^c	Visually incompatible upon mixing	3662	I
Famotidine	ww	4 mg/mL ^c	SHI	20 mg/mL ^c	Visually incompatible upon mixing	3662	I
Fentanyl citrate	HOS	50 mcg/mL	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662, 3670	С
Fluconazole	HOS	2 mg/mL ¹	SHI	20 mg/mL ^c	Results of subvisual tests indicate increased counts of particles <5 µm; counts of particles ≥10 and ≥25 µm within limits. No significant changes in turbidity	3662	?
Furosemide	ВА	3 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Gentamicin sulfate	FRK	5 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Heparin sodium	HOS	1000 units/mL	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Hydrocortisone sodium succinate	PF	1 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Hydromorphone HCl	AKN	1 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Imipenem-cilastatin sodium	FRK	5 mg/mL ^{c f}	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662, 3670	С
Insulin, regular	LI	1 unit/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Iron dextran	ALL	25 mg/mL ^c	SHI	20 mg/mL ^c	Opaque dark red solution; turbidity decreased upon mixing	3662	?
Iron sucrose	AMR	20 mg/mL	SHI	20 mg/mL ^c	Opaque dark red solution with significant turbidity	3662, 3670	I
Labetalol HCl	AVG	5 mg/mL	SHI	20 mg/mL ^c	Visually incompatible upon mixing	3662, 3670	I
Levofloxacin	AUR	5 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Lidocaine HCl	HIK	8 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Linezolid	FRK	2 mg/mL ^l	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662, 3670	С
Lorazepam	HOS	1 mg/mL ^c	SHI	20 mg/mL ^c	Results of subvisual tests indicate lightly hazy to hazy solutions with or without increased turbidity and a high count of particles ≥2 µm	3662	I
Magnesium sulfate	FRK	100 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С

Y-Site Injection Compatibility (1:1 Mixture) (Cont.)

Test Drug	Mfr	Conc	Mfr	Conc	Remarks	Refs	C/I
Mannitol	HOS	20% ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Meropenem	AMB	10 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Meropenem– vaborbactam	FAC	8 mg/mL ^{c g}	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662, 3670	С
Methylprednisolone acetate	PF	20 mg/mL ^c	SHI	20 mg/mL ^c	Visually incompatible upon mixing	3662	I
Metoclopramide HCl	HOS	0.2 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Metronidazole	HOS	5 mg/mL ¹	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662, 3670	С
Micafungin sodium	ASP	4 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Midazolam HCl	HOS	2 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Milrinone lactate	нік	0.2 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Morphine sulfate	HOS	15 mg/mL²	SHI	20 mg/mLª	Results of subvisual tests indicate high counts of particles ≥25 and ≥50 µm when cefiderocol is added to morphine; not observed when order of mixing was reversed	3662	?
Morphine sulfate	HOS	15 mg/mL ^b	SHI	20 mg/mL ^b	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Multivitamins	SZ	0.02 mL/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Mycophenolate mofetil HCl	GEN	6 mg/mL ^c	SHI	20 mg/mL ^c	Visually incompatible upon mixing	3662	I
Naloxone HCl	MYL	0.04 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Nicardipine HCl	нік	0.1 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Nitroglycerin	AMR	0.4 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Norepinephrine bitartrate	TE	0.128 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Octreotide acetate	TE	4 mcg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Ondansetron HCl	HOS	0.16 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Pantoprazole sodium	AURi	0.4 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Phenylephrine HCl	ww	1 mg/mL²	SHI	20 mg/mLª	Results of subvisual tests indicate high counts of particles ≥ 2 , ≥ 10 , ≥ 25 , and ≥ 50 µm when phenylephrine is added to cefiderocol; not observed when order of mixing was reversed	3662	?
Phenylephrine HCl	ww	1 mg/mL ^b	SHI	20 mg/mL ^b	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Phenytoin sodium	ww	10 mg/mL ^c	SHI	20 mg/mL ^c	Visually incompatible upon mixing	3662	I
Polymyxin B sulfate	XE	1250 units/ mL ^a	SHI	20 mg/mL²	Results of subvisual tests indicate high turbidity	3662	I
Polymyxin B sulfate	XE	1250 units/ mL ^a	SHI	20 mg/mL ^b	Slight haze forms and gas bubbles evolve	3662	I
Posaconazole	MSD	2 mg/mL ^c	SHI	20 mg/mL ^c	Visually incompatible upon mixing	3662	I
Potassium chloride	HOS	0.1 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Potassium phosphates	HOS	0.3 mmol/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С

Y-Site Injection Compatibility (1:1 Mixture) (Cont.)

Test Drug	Mfr	Conc	Mfr	Conc	Remarks	Refs	C/I
Propofol	SGT ^j	10 mg/mL	SHI	20 mg/mL ^c	Visually incompatible upon mixing	3662, 3670	I
Ranitidine HCl	CDL	2.5 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Rocuronium bromide	XGN	5 mg/mL ^c	SHI	20 mg/mL ^c	Visually incompatible upon mixing	3662	I
Sodium bicarbonate	HOS	1 mEq/mL	SHI	20 mg/mL ^a	Results of subvisual tests indicate a high count of particles ≥25 µm when sodium bicarbonate is added to cefiderocol; not observed when order of mixing was reversed	3662, 3670	1
Sodium bicarbonate	HOS	1 mEq/mL	SHI	20 mg/mL ^b	Physically compatible for up to 4 hr at 21 to 25°C	3662, 3670	С
Sodium nitroprusside	HOS	0.4 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Sodium phosphates	FRK	0.5 mmol/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Succinylcholine chloride	CDL	2 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Tedizolid phosphate	PNN	0.8 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Tigecycline	LEK	1 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Tobramycin sulfate	FRK	10 mg/mL	SHI	20 mg/mL ^c	Results of subvisual tests indicate the presence of white particles	3662, 3670	I
Trimethoprim– sulfamethoxazole	MYL	1 mg/mL ^{c h}	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662, 3670	С
Vancomycin HCI	GLA	5 mg/mL ^a	SHI	20 mg/mL ^a	Visually incompatible upon mixing	3662	I
Vancomycin HCl	GLA	5 mg/mL ^b	SHI	20 mg/mL ^b	Results of subvisual tests indicate the presence of cloudiness with white particles	3662	I
Vasopressin	PAR	1 unit/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Vecuronium bromide	TE	1 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С
Voriconazole	PF	2 mg/mL ^c	SHI	20 mg/mL ^c	Physically compatible for up to 4 hr at 21 to 25°C	3662	С

^a Tested in dextrose 5%.

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^b Tested in sodium chloride 0.9%

^c Tested in both dextrose 5% and sodium chloride 0.9%.

^d Ceftazidime component. Ceftazidime in a 4:1 fixed-ratio concentration with avibactam.

^e Ceftolozane component. Ceftolozane in a 2:1 fixed-ratio concentration with tazobactam.

^f Imipenem component. Imipenem in a 1:1 fixed-ratio concentration with cilastatin.

⁹ Meropenem component. Meropenem in a 1:1 fixed-ratio concentration with vaborbactam.

^h Trimethoprim component. Trimethoprim in a 1:5 fixed-ratio concentration with sulfamethoxazole.

¹ Test performed using the formulation WITH edetate disodium.

^j Test performed using the formulation WITHOUT edetate disodium.

^k Salt not specified.

¹ Tested as the premixed infusion solution.