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]

pH

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	C
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	C

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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	OCT	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	C
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	C
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	C
Aztreonam	BMS	20 mg/mL[c]	SHI	20 mg/mL[c]	Physically compatible for up to 4 hr at 21 to 25°C	3662	C
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	C
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	C
Caspofungin acetate	GLA	0.5 mg/mL[c]	SHI	20 mg/mL[c]	Visually incompatible upon mixing	3662	I
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	C
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	C
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	C
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	C
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	C
Ciprofloxacin	CLA	2 mg/mL[l]	SHI	20 mg/mL[a]	Results of subvisual tests indicate increased turbidity	3662, 3670	I
Ciprofloxacin	CLA	2 mg/mL[l]	SHI	20 mg/mL[b]	Physically compatible for up to 4 hr at 21 to 25°C	3662, 3670	C
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	C
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	C
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	C
Daptomycin	GLA	20 mg/mL[c]	SHI	20 mg/mL[c]	Physically compatible for up to 4 hr at 21 to 25°C	3662	C
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	C

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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	C
Digoxin	SZ	250 mcg/mL	SHI	20 mg/mL[c]	Physically compatible for up to 4 hr at 21 to 25°C	3662, 3670	C
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	C
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	C
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	C
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	C
Fluconazole	HOS	2 mg/mL[l]	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	BA	3 mg/mL[c]	SHI	20 mg/mL[c]	Physically compatible for up to 4 hr at 21 to 25°C	3662	C
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	C
Heparin sodium	HOS	1000 units/mL	SHI	20 mg/mL[c]	Physically compatible for up to 4 hr at 21 to 25°C	3662	C
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	C
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	C
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	C
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	C
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	C
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	C
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	C
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	C

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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	C
Meropenem	AMB	10 mg/mL[c]	SHI	20 mg/mL[c]	Physically compatible for up to 4 hr at 21 to 25°C	3662	C
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	C
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	C
Metronidazole	HOS	5 mg/mL[l]	SHI	20 mg/mL[c]	Physically compatible for up to 4 hr at 21 to 25°C	3662, 3670	C
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	C
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	C
Milrinone lactate	HIK	0.2 mg/mL[c]	SHI	20 mg/mL[c]	Physically compatible for up to 4 hr at 21 to 25°C	3662	C
Morphine sulfate	HOS	15 mg/mL[a]	SHI	20 mg/mL[a]	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	C
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	C
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	C
Nicardipine HCl	HIK	0.1 mg/mL[c]	SHI	20 mg/mL[c]	Physically compatible for up to 4 hr at 21 to 25°C	3662	C
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	C
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	C
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	C
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	C
Pantoprazole sodium	AUR[i]	0.4 mg/mL[c]	SHI	20 mg/mL[c]	Physically compatible for up to 4 hr at 21 to 25°C	3662	C
Phenylephrine HCl	WW	1 mg/mL[a]	SHI	20 mg/mL[a]	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	C
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/mL[a]	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	C
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	C

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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	C
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	I
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	C
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	C
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	C
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	C
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	C
Tigecycline	LEK	1 mg/mL[c]	SHI	20 mg/mL[c]	Physically compatible for up to 4 hr at 21 to 25°C	3662	C
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	C
Vancomycin HCl	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	C
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	C
Voriconazole	PF	2 mg/mL[c]	SHI	20 mg/mL[c]	Physically compatible for up to 4 hr at 21 to 25°C	3662	C

[a] Tested in dextrose 5%.

[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.

[g] 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.

[i] Test performed using the formulation WITH edetate disodium.

[j] Test performed using the formulation WITHOUT edetate disodium.

[k] Salt not specified.

[l] Tested as the premixed infusion solution.

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