

OMEPRAZOLE
AHFS: 56:28.36 (Proton-pump Inhibitors)

Products--

Omeprazole infusion is available in vials containing 40 mg of drug as the sodium salt. Also present in the formulation are sodium hydroxide and disodium edetate. Reconstitute the vials with 5 mL from a 100-mL bag or bottle of sodium chloride 0.9% or dextrose 5%. Mix thoroughly, ensuring that all of the omeprazole has dissolved; do not use if any particles remain in the reconstituted solution. The reconstituted solution should be transferred into the infusion bag or bottle making 100 mL of the admixture solution.^{38 115}

Omeprazole injection is also available in vials containing 40 mg of drug as the sodium salt with an accompanying 10-mL ampul of special solvent. Each milliliter of the solvent contains citric acid monohydrate 0.5 mg and polyethylene glycol 400 0.4 g in water for injection. The vial of omeprazole should be reconstituted with 10 mL of the solvent provided in the accompanying ampul in two 5-mL increments withdrawing air pressure back into the syringe between the increments. No other diluent should be used for reconstitution. Rotate and shake the vial to ensure all of the omeprazole has dissolved; do not use if any particles remain in the reconstituted solution.^{38 115}

Sodium Content--

Omeprazole 40 mg provides sodium 2.6 mg.¹¹⁵

Trade Name(s)--

Losec, Mopral, Omeprazen

Administration--

Omeprazole is administered by intravenous infusion and intravenous injection. The drug must not be given by any other route.^{38 115}

After dilution of the omeprazole infusion to 100 mL with sodium chloride 0.9% or dextrose 5%, omeprazole is administered only as a 20- to 30-minute intravenous infusion.^{38 115}

After dilution with the accompanying special diluent, omeprazole injection is administered intravenously over 2.5 to 5 minutes at a maximum rate of 4 mL/min.^{38 115}

Stability--

Intact vials of omeprazole infusion and injection should be stored at room temperature not exceeding 25°C and protected from light. Discoloration of the reconstituted solution may occur if reconstituted incorrectly. Dilution of omeprazole infusion with sodium chloride 0.9% results in a solution that is stable for 12 hours^{38 115}; diluted in dextrose 5% omeprazole is stable for three³⁸ to six¹¹⁵ hours. Other solutions must not be used for dilution of omeprazole infusion. Omeprazole injection reconstituted with the accompanying special diluent is stable for four hours. Do not use the reconstituted solution if particles are present.^{38 115}

Reconstituted omeprazole has been reported to develop an unacceptable discoloration indicating decomposition within six hours at room temperature exposed to light.²⁵⁰⁷

Compatibility Information--

Solution Compatibility--

Omeprazole

Test Soln Name	Test Soln Mfr	Base Drug Mfr	Base Drug Conc/L	Remarks	Refs	Compat
Dextrose 5%	BA	PH	400 mg	Physically compatible. 10% loss occurs in 2.5 days at 22°C in light	2696	C
Sodium chloride 0.9%	BA	PH	400 mg	Physically compatible. 10% loss occurs in 8 days at 22°C in light	2696, 3082	C

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

Omeprazole

Test Drug	Test Drug Mfr	Test Drug Conc	Base Drug Mfr	Base Drug Conc	Remarks	Refs	Compat
Lorazepam	WY	0.33 mg/mL ^b	AST	4 mg/mL	Yellow discoloration forms	1855	I
Midazolam HCl	RC	5 mg/mL	AST	4 mg/mL	Brown color then precipitate	1855	I

Omeprazole

Tigecycline	WY			Stated to be incompatible	2915	I
Vancomycin HCl		10 mg/mL ^a	4 mg/mL	White precipitate forms within 5 min	2173	I

^a Tested in dextrose 5%.

^b Tested in sodium chloride 0.9%.

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References--

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