

LEVETIRACETAM

AHFS 28:12.92

Products — Levetiracetam is available as a 100-mg/mL concentrate for injection in 5-mL single-use vials. (2833) The concentrate must be diluted before administration. (2833)

Levetiracetam is also available as a single-use, ready-to-use solution for intravenous infusion containing 500 mg, 1 g, or 1.5 g levetiracetam in 100 mL sodium chloride in dual-port plastic bags. (2834)

Both the concentrate and the ready-to-use formulations contain water for injection and sodium chloride. (2833; 2834)

pH — Levetiracetam concentrate and ready-to-use solutions for infusion have a pH adjusted to approximately 5.5 with glacial acetic acid and sodium acetate trihydrate. (2833; 2834)

Osmolality — The osmolality of levetiracetam 100-mg/mL concentrate for injection was determined to be approximately 950 mOsm/kg. (2835) Following dilution of 500 mg of the concentrate in 100 mL of sodium chloride 0.9%, the osmolality of levetiracetam was determined to be approximately 430 mOsm/kg. (2835)

Sodium Content — Ready-to-use solutions of levetiracetam 500 mg, 1 g, and 1.5 g in 100 mL of sodium chloride injection contain 820, 750, and 540 mg of sodium, respectively. (2834)

Trade Name(s) — Keppra.

Administration — Single-use vials contain levetiracetam concentrate that is administered by intravenous infusion after dilution in 100 mL of a compatible diluent. (2833) Single-use, ready-to-use solutions of levetiracetam should not be further diluted prior to intravenous infusion. (2834)

Levetiracetam is administered by intravenous infusion over 15 minutes. (2833; 2834)

Stability — Levetiracetam concentrate and diluted solutions should be clear and colorless. (2833; 2834) Intact vials of levetiracetam concentrate and ready-to-use bags of levetiracetam in solution in their unopened aluminum overwrap should be stored at controlled room temperature. (2833; 2834) Discolored products or products containing particulate matter should not be used. (2833; 2834) Ready-to-use levetiracetam infusion bags should be used promptly once the aluminum overwrap has been removed. (2834)

The unused contents of an opened vial or a partially used infusion bag should be discarded. (2833; 2834) The diluted contents of a vial of levetiracetam concentrate should be used within 24 hours. (2835)

Compatibility Information

Solution Compatibility

Levetiracetam						
<i>Solution</i>	<i>Mfr</i>	<i>Mfr</i>	<i>Conc/L</i>	<i>Remarks</i>	<i>Ref</i>	<i>C/I</i>
Dextrose 5%	^a	UCB	5 and 40 g	Physically compatible and chemically stable for 24 hours at controlled room temperature	2833; 2835	C
Ringer's injection lactated	^a	UCB	1 and 8 g	Physically compatible and chemically stable for 24 hours at controlled room temperature	2833; 2835	C
Sodium chloride 0.9%	^a	UCB	5 and 40 g	Physically compatible and chemically stable for 24 hours at controlled room temperature	2833; 2835	C

^aTested in PVC containers.

Additive Compatibility

Levetiracetam								
<i>Drug</i>	<i>Mfr</i>	<i>Conc/L</i>	<i>Mfr</i>	<i>Conc/L</i>	<i>Test Soln</i>	<i>Remarks</i>	<i>Ref</i>	<i>C/I</i>
Diazepam	200 mg	UCB	5 and 40 g		D5W, NS ^a	Physically compatible and chemically stable for 24 hr at controlled room temperature	2833; 2835	C
	40 mg	UCB	1 and 8 g		LR ^a	Physically compatible and chemically stable for 24 hr at controlled room temperature	2833; 2835	C

Additive Compatibility (Cont.)**Levetiracetam**

<i>Drug</i>	<i>Mfr</i>	<i>Conc/L</i>	<i>Mfr</i>	<i>Conc/L</i>	<i>Test Soln</i>	<i>Remarks</i>	<i>Ref</i>	<i>C/I</i>
Lorazepam		40 mg	UCB	5 and 40 g	D5W, NS ^a	Physically compatible and chemically stable for 24 hr at controlled room temperature	2833; 2835	C
		8 mg	UCB	1 and 8 g	LR ^a	Physically compatible and chemically stable for 24 hr at controlled room temperature	2833; 2835	C
Valproate sodium		12 g	UCB	5 and 40 g	D5W, NS ^a	Physically compatible and chemically stable for 24 hr at controlled room temperature	2833; 2835	C
		2.4 g	UCB	1 and 8 g	LR ^a	Physically compatible and chemically stable for 24 hr at controlled room temperature	2833; 2835	C

^aTested in PVC containers.