

Veklury[®] (remdesivir)

Compatibility With Alternative Diluents

This document is in response to your request for information regarding the compatibility of Veklury[®] (remdesivir [RDV]) with alternative diluents.

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The full indication, important safety information, and boxed warnings are available at: www.gilead.com/-/media/files/pdfs/medicines/covid-19/veklury/veklury_pi.

Reconstitution With Alternative Diluents¹

Only use SWFI to reconstitute RDV for Injection, 100 mg (lyophilized powder).¹

Please refer to your local label for full dose preparation instructions.

- Reconstitution with D5W and NS resulted in hypertonic drug solutions with higher osmolality compared with reconstitution with SWFI (Table 1).²
- Use SWFI for reconstitution to minimize osmolality of the drug product solution before it is further diluted.²

Table 1. Osmolality of the Reconstituted Solution²

Formulation	RDV Dose	Reconstitution Diluent	Osmolality ^a
Veklury for Injection, 100 mg (lyophilized powder)	100 mg	19 mL SWFI	483 mOsm/kg
		19 mL NS	780 mOsm/kg
		19 mL D5W	819 mOsm/kg

^aAverage ± standard deviation of osmolality from 3 measurements using freezing point osmometer.

Reconstitution When SWFI is Unavailable

RDV for Injection, 100 mg is recommended to be reconstituted with SWFI prior to further dilution into NS.¹

If the preferred reconstitution diluent SWFI is unavailable for reconstitution, NS may be used to reconstitute RDV.²

- If NS is used to reconstitute RDV, then the subsequent dilution should only be done using 250 mL of NS.²
- The recommended dilution volume with NS is 250 mL, because dilution of the 200 mg loading dose into 100 mL of NS results in osmolality >400 mOsm/kg, which may affect tolerability (Table 2).²

Table 2. Osmolality of the Final Solution²

Formulation	Reconstitution Diluent	Dilution Diluent	RDV Dose	Final Infusion Volume ^{a,b}	Osmolality
Veklury for Injection, 100 mg (lyophilized powder)	SWFI	NS	100 mg	100 mL	317.5 mOsm/kg
				250 mL	299 mOsm/kg
			200mg	100 mL	351.7 mOsm/kg
				250 mL	314.2 mOsm/kg
	NS	NS	100 mg	100 mL	378 mOsm/kg
				250 mL	327.3 mOsm/kg
200mg	NS	100 mL	100 mL	468.3 mOsm/kg	
			250 mL	361 mOsm/kg	

^aThe final diluted volume is per the recommended preparation instructions for adults.

^bThe proportionate amount of infusion fluid was removed from the IV bag prior to addition of dose volume to maintain the overall solution volume of 100 mL or 250 mL.

Dilution With Alternative Diluents

Dilute the reconstituted RDV solution using NS¹ or D5W.² Please refer to your local label for full dose preparation instructions.

- Based on an internal Gilead study, RDV may be diluted with D5W.²
- The type of infusion fluid (NS or D5W) did not have an impact on osmolality for the same dilution ratios (Table 3).²

Table 3. Osmolality of the Final Solution²

Formulation	RDV Dose	Reconstitution Diluent	Dilution Diluent	Final Infusion Volume ^{a,b}	Osmolality ^c
Veklury for Injection, 100 mg (lyophilized powder)	100 mg	19 mL SWFI	NS	100 mL	318 mOsm/kg
			D5W	100 mL	310 mOsm/kg
			NS	250 mL	299 mOsm/kg
			D5W	250 mL	299 mOsm/kg
	200 mg	19 mL SWFI	NS	100 mL	352 mOsm/kg
			D5W	100 mL	354 mOsm/kg
			NS	250 mL	314 mOsm/kg
			D5W	250 mL	301 mOsm/kg

^aThe final diluted volume is per the recommended preparation instructions for adults.

^bThe proportionate amount of infusion fluid was removed from the IV bag prior to addition of dose volume to maintain the overall solution volume of 100 mL or 250 mL.

^cOverall average osmolality from measurements using freezing point osmometer.

There are no data on the compatibility of RDV with Lactated Ringer's solution for dilution.

Infusion With Other IV Solutions or Medications

Do not administer the prepared diluted solution simultaneously with any other medication. The compatibility of RDV with IV solutions and medications other than NS is not known.¹

References

1. Enclosed. Gilead Sciences Inc. Veklury® (remdesivir) for injection, for intravenous use. VEKLURY® (remdesivir) injection, for intravenous use. U.S. Prescribing Information. Foster City, CA.
 2. Gilead Sciences Inc. Data on File.
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Abbreviations

D5W=dextrose 5% in water
NS=0.9% normal saline

RDV=remdesivir

SWFI=sterile water for
injection

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Veklury US Prescribing Information available at:

www.gilead.com/-/media/files/pdfs/medicines/covid-19/veklury/veklury_pi.

Follow Up

For any additional questions, please contact Gilead Medical Information at:

☎ 1-866-MEDI-GSI (1-866-633-4474) or 🌐 www.askgileadmedical.com

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Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or

🌐 www.gilead.com/utility/contact/report-an-adverse-event

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉ MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or 🌐 www.accessdata.fda.gov/scripts/medwatch

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