Veklury® (remdesivir) Reconstitution When Sterile Water for Injection (SWFI) is Unavailable

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This document summarizes available information regarding Veklury[®] (remdesivir [RDV]) reconstitution when the preferred reconstitution diluent sterile water for injection (SWFI) is unavailable.

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

Available Data

RDV for injection, 100 mg is recommended to be reconstituted with SWFI prior to further dilution into 0.9% sodium chloride for injection (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 dilution volume is recommended to be 250 mL because dilution of the 200 mg loading dose into 100 mL of NS results in osmolality greater than 400 mOsm/kg which may affect tolerability (<u>Table 1</u>).²

Formulation	Reconstitution Diluent	Dilution Diluent	RDV Dose	Final Infusion Volume ^{a,b}	Osmolality
Veklury for Injection, 100mg (lyophilized powder)	SWFI	NS	100 mg	100 mL	317.5 mOsm/kg
				250 mL	299.0 mOsm/kg
			200mg	100 mL	351.7 mOsm/kg
				250 mL	314.2 mOsm/kg
	NS	NS	100 mg	100 mL	378.0 mOsm/kg
				250 mL	327.3 mOsm/kg
			200mg	100 mL	468.3 mOsm/kg
				250 mL	361.0 mOsm/kg

Table 1. Osmolality of the Final Solution²

^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.

References

- 1. VEKLURY, 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.

Abbreviations

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

Follow up

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FDA MedWatch Program by ﷺ 1-800-FDA-1088 or ⊠MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or ⁴ www.accessdata.fda.gov/scripts/medwatch

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