GILEAD | Medical Information

Veklury® (remdesivir) Injection Site Reactions

This document is in response to your request for information regarding Veklury® (remdesivir [RDV]) and injection site reactions, including extravasation and infiltration. This response was developed according to principles of evidence-based medicine and contains information from phase 3 clinical trials.

Gilead continually assesses safety data from all sources for unidentified drug reactions and updates the product label information accordingly to reflect the safety profile of RDV. Because case reports of potential adverse reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. For this reason, Gilead does not provide information from post-marketing spontaneous reports.

Gilead Sciences is unable to provide treatment recommendations on injection site reactions, including extravasation and infiltration. We recommend that you use your best clinical judgment in guiding therapy based on patient-specific therapeutic goals. Please follow your hospital or outpatient setting guidelines or protocols for treatment or management of injection site reactions, including extravasation and infiltration.

Some data may be outside of the US FDA-approved prescribing information. In providing this data, Gilead Sciences, Inc. is not making any representation as to its clinical relevance or to the use of any Gilead product(s). For information about the approved conditions of use of any Gilead drug product, please consult the FDA-approved prescribing information.

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

Product Labeling[1]

Clinical Trials Experience

Clinical trials experience in adults with COVID-19

In the summary of adverse reactions rates in hospitalized subjects with severe COVID-19 in study GS-US-540-5773, 1 subject who received RDV reported injection site erythema as an adverse reaction that led to treatment discontinuation.

Emergency use authorization experience in subjects with COVID-19

The following adverse reactions have been identified during use of RDV under Emergency Use Authorization:

- General disorders and administration site conditions: administration site extravasation.

Available Data on RDV Injection Site Reactions

Injection site reactions, including extravasation and infiltration, have not been reported as common or serious adverse events in phase 3 clinical studies of RDV for the treatment of COVID-19 in both hospitalized and non-hospitalized patients.[2-5]

pH of the Final Solution[6]

RDV is typically pH 3.4 to 3.6. Table 1 reflects RDV diluted into saline and the resulting pH value.

Table 1. pH of the Final RDV Solution Reconstituted With SWFI and Diluted in Saline[6]

Formulation	Description	pH Value
Lyophilized	100 mg dose into 100 mL final volume	4
	100 mg dose into 250 mL final volume	4.1
	200 mg dose into 100 mL final volume	3.9
	200 mg dose into 250 mL final volume	4

Abbreviation: SWFI=sterile water for injection.

The precision of the pH meter is ±0.1 pH unit. As all values are within the precision of the instrument, there is no significant difference in pH between any of the solutions listed in Table 1 (4±0.1).

References

1. Veklury, Gilead Sciences Inc. VEKLURY® (remdesivir) for injection, for intravenous use. U. S. Prescribing Information. Foster City, CA.
2. Goldman JD, Lye DCB, Hui DS, et al. Remdesivir for 5 or 10 Days in Patients with Severe Covid-19. *N Eng J Med.* 2020:1-11.
3. Spinner CD, Gottlieb RL, Criner GJ, et al. Effect of Remdesivir vs Standard Care on Clinical Status at 11 Days in Patients With Moderate COVID-19: A Randomized Clinical Trial. *JAMA.* 2020;324(11):1048-1057.
4. Beigel JH, Tomashek KM, Dodd LE, et al. Remdesivir for the Treatment of Covid-19 — Final Report. *N Engl J Med.* 2020;383(19):1813-1826.
5. Gottlieb RL, Vaca CE, Paredes R, et al. Early Remdesivir to Prevent Progression to Severe Covid-19 in Outpatients. *N Eng J Med.* 2022;386(4):305-315.
6. Gilead Sciences Inc. Data on File.

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

Adverse Event Reporting

Please report all adverse events to:

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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