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Veklury® (remdesivir) Storage and Stability of Lyophilized Powder

This document is in response to your request for extended storage and stability information of Veklury® (remdesivir [RDV]) for injection 100 mg lyophilized powder and does not intend to offer an opinion regarding the clinical relevance of these data or the advisability of storing or administering any drug in a manner inconsistent with its approved labeling. Veklury® (RDV) should be stored according to the product label.

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

Formulation Description

RDV for injection contains 100 mg of RDV as a sterile, preservative-free lyophilized white to off-white to yellow powder in a single-dose clear glass vial. It requires reconstitution and then further dilution prior to administration by IV infusion. The inactive ingredients are 3 g betadex sulfobutyl ether sodium and may include hydrochloric acid and/or sodium hydroxide for pH adjustment.[1]

The color does not affect product stability.[2]

Storage and Handling[1]

Store RDV for injection, 100 mg vials below 30°C (below 86°F) until required for use.

Storage of Prepared Dosages[1]

After reconstitution, use vials immediately to prepare diluted solution. Dilute the reconstituted solution in 0.9% sodium chloride injection, USP within the same day as administration. The diluted RDV solution in the infusion bags can be stored up to 24 hours at room temperature (20°C to 25°C [68–77°F]) prior to administration or 48 hours at refrigerated temperature (2°C to 8°C [36–46°F]).

For infusion with syringe for pediatric patients (birth to <18 years of age) weighing 1.5 kg to <40 kg, the prepared diluted solution should be used immediately.

IMPORTANT: This product contains no preservative. Any unused portion of a single-dose RDV vial should be discarded after a diluted solution is prepared.

Additional Storage and Handling Recommendations[2]

Do not use vials beyond expiration date.

Alternative Storage and Stability Information[2]

The table below summarizes available data from in-house studies regarding the storage of RDV lyophilized powder in varying conditions above and below the recommended temperatures. The “acceptable duration” refers to the stability of RDV lyophilized powder in the specified packaging and storage condition, but it does not endorse alternative packaging or use beyond the expiration date stated on the original packaging.

Table 1. Summary of Extended Stability Data for RDV Lyophilized Powder[2]

Storage Condition	Package Type	Acceptable Duration
40°C (104°F)/75% relative humidity	Original vial	6 months
60°C (140°F)	Original vial	1 month

An excursion study showed that original vials of RDV lyophilized powder could be exposed to temperatures from -20°C to 14°C (-4°F to 57.2°F) for an acceptable duration of <1 month.

References

1. Veklury. Gilead Sciences Inc. Veklury® (remdesivir) for injection, for intravenous use. U.S. Prescribing Information. Foster City, CA.
2. 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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