Veklury® (remdesivir) Shaking or Agitating

This document is in response to your request for information regarding shaking or agitating Veklury® (remdesivir [RDV]).

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]

Dosage and Administration

Dosage preparation and administration

Reconstitution instructions

Remove the required number of single-dose vial(s) from storage. After reconstituting RDV lyophilized powder with Sterile Water for Injection, do the following:

- Immediately shake the vial for 30 seconds.
- Allow the contents of the vial to settle for 2 to 3 minutes. A clear, colorless to yellow solution, free of visible particles, should result.
- If the contents of the vial are not completely dissolved, shake the vial again for 30 seconds and allow the contents to settle for 2 to 3 minutes. Repeat this procedure as necessary until the contents of the vial are completely dissolved. Discard the vial if the contents are not completely dissolved.

Dilution instructions for adults and pediatric patients weighing ≥40 kg

After dilution of the reconstituted RDV lyophilized powder with 0.9% sodium chloride, gently invert the bag 20 times to mix the solution in the bag. Do not shake.

Dilution instructions for pediatric patients (birth to <18 years of age) weighing 1.5 kg to <40 kg

Infusion with IV bag or syringe: Gently invert the bag or syringe 20 times to mix the solution in the bag. Do not shake.

Available Data on Shaking or Agitating RDV

No Gilead studies have been conducted with vigorous shaking or vibration of RDV vials or IV bags that contain diluted solution of RDV.

No Gilead studies have been conducted with transporting RDV vials or IV bags that contain diluted solution of RDV via pneumatic tube system.

Reference

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

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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