GILEAD | Medical Information

Veklury® (remdesivir) Dosing in Adults Weighing <40 kg

This document is in response to your request for information regarding Veklury® (remdesivir [RDV]) and dosing in adults weighing <40 kg.

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]

RDV is indicated for the treatment of COVID-19 in adults and pediatric patients (birth to <18 years of age weighing ≥1.5 kg) who are:

- Hospitalized, or
- Not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death.

The recommended dosage for adults and pediatric patients weighing ≥40 kg is a single loading dose of RDV 200 mg on Day 1 via intravenous infusion followed by once-daily maintenance doses of RDV 100 mg from Day 2 via intravenous infusion.

Hospitalized patients

The treatment course of RDV should be initiated as soon as possible after diagnosis of symptomatic COVID-19 has been made.

- The recommended total treatment duration for hospitalized patients requiring IMV and/or ECMO is 10 days.
- The recommended treatment duration for hospitalized patients not requiring IMV and/or ECMO is 5 days. If a patient does not demonstrate clinical improvement, treatment may be extended for up to 5 additional days for a total treatment duration of up to 10 days.

Non-hospitalized patients

The treatment course of RDV should be initiated as soon as possible after diagnosis of symptomatic COVID-19 has been made and within 7 days of symptom onset.

- The recommended total treatment duration for non-hospitalized patients diagnosed with mild-to moderate COVID-19 who are at high risk for progression to severe COVID-19, including hospitalization or death, is 3 days.

Available Data

The ACTT-2 study that evaluated RDV + baricitinib for the treatment of COVID-19 enrolled adult participants weighing <40 kg. The range of weights among participants in the RDV + baricitinib group was 38.6 kg to 213.6 kg and in the RDV + placebo group was 33.0 kg to 219.8 kg. RDV was administered as a 200 mg loading dose via IV infusion on Day 1, followed by RDV 100 mg/day via IV infusion for up to 9 days for the duration of hospitalization (total course: up to 10 days). A subanalysis of safety and efficacy by weight was not conducted.[2,3]

In studies of RDV in participants with Ebola, adults with low body weight received the full RDV dose for adults with no dose adjustments. Participants who were randomized to receive RDV weighed 47.8 kg (±17.7 kg) and received RDV 200 mg loading dose on day 1, followed by a daily maintenance dose of 100 mg RDV starting on day 2 and continuing for the total assigned treatment duration of 11 to 15 days.[4]

Please note that RDV is not indicated for the treatment of Ebola.

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. Kalil AC, Patterson TF, Mehta AK, et al. Baricitinib plus Remdesivir for Hospitalized Adults with Covid-19. *N Eng J Med.* 2021;384(9).
3. Kalil AC, Patterson TF, Mehta AK, et al. Baricitinib plus Remdesivir for Hospitalized Adults with Covid-19 [Supplementary Appendix]. *N Eng J Med.* 2020.
4. Mulangu S, Dodd LE, Davey RT, Jr., et al. A Randomized, Controlled Trial of Ebola Virus Disease Therapeutics. *N Engl J Med.* 2019;381(24):2293-2303. https://www.ncbi.nlm.nih.gov/pubmed/31774950

Abbreviations

ACTT=Adaptive COVID-19 Treatment Trial
COVID=coronavirus disease 2019
ECMO=extracorporeal membrane oxygenation
IMV= invasive mechanical ventilation
RDV=remdesivir

Product Label

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