Veklury® (remdesivir) Use in Breastfeeding

This document is in response to your request for information regarding the use of Veklury® (remdesivir [RDV]) for the treatment of COVID-19 in women who are breastfeeding.

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]

Use in Specific Populations: Lactation

Risk summary

A published case report describes the presence of RDV and active metabolite GS-441524 in human milk. Available data (n=11) from pharmacovigilance reports do not indicate adverse effects on breastfed infants from exposure to RDV and its metabolite through breast milk. There are no available data on the effects of RDV on milk production. In animal studies, RDV and metabolites have been detected in the nursing pups of mothers given RDV, likely due to the presence of RDV in milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for RDV and any potential adverse effects on the breastfed child from RDV or from the underlying maternal condition. Breastfeeding individuals with COVID-19 should follow practices according to clinical guidelines to avoid exposing the infant to COVID-19.

Data

RDV and its metabolites were detected in the plasma of nursing rat pups, likely due to the presence of RDV and/or its metabolites in milk, following daily IV administration of RDV to pregnant rats from Gestation Day 6 to Lactation Day 20. Exposures in nursing pups were approximately 1% that of maternal exposure on Lactation Day 10. The concentration of RDV in animal milk does not necessarily predict the concentration of drug in human milk.

Available Data on RDV Use During Breastfeeding

Clinical Trial Data

Currently, there are no clinical trial data available on the use of RDV for the treatment of COVID-19 in women who are breastfeeding.

Maternal Drug Levels

RDV and GS-441524 concentrations in breast milk

There are limitations in the interpretation of case reports. Case reports cannot be generalized. Unlike controlled clinical trials, causality cannot be inferred based on uncontrolled observational data. In addition, incidence or prevalence cannot be estimated due to the lack of a representative population sample. Other limitations of case reports include the retrospective design and publication bias.[2]

Case series[3]

Between March and May 2020, 17 breast milk samples from 4 hospitalized patients with COVID-19 who received RDV (200 mg IV loading dose on Day 1 followed by 100 mg IV maintenance doses) were analyzed for concentrations of RDV and its active metabolite, GS-441524. Thirteen of 17 samples were collected between 4 hours and 61 days after RDV administration. In all 17 samples (100%), RDV concentrations were <lower limit of quantification (LLOQ; 100 ng/mL; relative infant dose [RID] <1%). GS-441524 concentrations were <LLOQ in 11 of 17 samples (65%), with the highest observed concentration of 168 ng/mL (RID, <5%) in 1 of the remaining 6 samples.

Case report[4]

A 28-year-old patient was diagnosed with COVID-19 2 days after she delivered her infant in a hospital in Japan; breastfeeding was interrupted, the infant was quarantined, and the patient initiated a course of RDV (200 mg on Day 1 and 100 mg doses once daily on Days 2–5). The patient continued to pump her breast milk, and, on Day 5, breast milk samples were taken before RDV administration and at 1, 3, 6, and 24 hours after the end of administration. RDV concentrations in the breast milk samples were <LLOQ (0.5 ng/mL) in 3 of the 4 samples; the remaining sample was taken 1 hour before RDV administration on Day 5 and had an RDV concentration of 1.29 ng/mL (RID=0.007%). The concentrations of GS-441524 in breast milk samples on Day 5 were 13.5 ng/mL before RDV administration and 64.34 ng/mL 24 hours after RDV administration (RID=1.55%).

Infant Drug Levels

Currently, there are no data available on RDV levels in infants who are breastfeeding.

Effects in Breastfed Infants and Effects on Lactation and Breastfeeding

A literature search was conducted in Ovid MEDLINE and Embase databases for studies published up to 23 June 2025 using the search terms Veklury, remdesivir, GS-5734, GS-441524, breastfeeding, breast milk, lactation, nursing, and related search terms. No relevant citations were found.

Ongoing Study

PK and safety of commonly used drugs in lactating women and breastfed infants[5]

A prospective, observational study (NCT03511118) will evaluate the amounts of selected drugs, including RDV, in the breast milk and blood of lactating women and in the blood of breastfed infants. The study began on October 4, 2018, has an estimated enrollment of 1600 participants, and has an estimated study completion date of July 31, 2027.

References

1. Veklury, Gilead Sciences Inc. Veklury® (RDV) for injection, for intravenous use. VEKLURY® (RDV) injection, for intravenous use. U.S. Prescribing Information. Foster City, CA.
2. Nissen T, Wynn R. The Clinical Case Report: A Review of Its Merits and Limitations. *BMC Res Notes.* 2014;7:264. https://www.ncbi.nlm.nih.gov/pubmed/24758689
3. Bertrand K, Sepulveda Y, Spiegel BJ, et al. Concentrations of remdesivir and GS-441524 in human milk from lactating individuals diagnosed with COVID-19. *Pediatric Research.* 2024.
4. Wada YS, Saito J, Hashii Y, et al. Remdesivir and Human Milk: A Case Study. *J Hum Lact.* 2022;38(2):248-251.
5. ClinicalTrials.gov. Pharmacokinetics and Safety of Commonly Used Drugs in Lactating Women and Breastfed Infants. ClinicalTrials.gov Identifier: NCT03511118. Available at: https://clinicaltrials.gov/ct2/show/NCT03511118. Accessed: 25 June 2025. Last Updated: 17 December. 2024.

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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