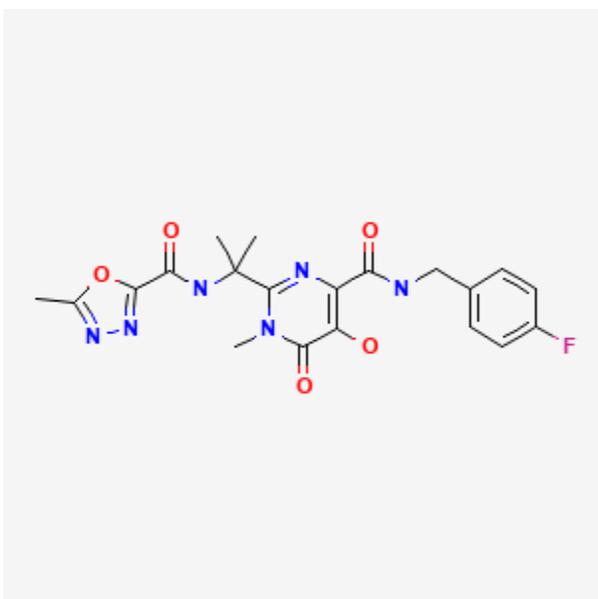




## Raltegravir

Revised: February 15, 2024.

CASRN: 518048-05-0



## Drug Levels and Effects

### Summary of Use during Lactation

Limited information indicates that maternal doses of up to 1200 mg daily of raltegravir produce low levels in milk and would not be expected to cause any adverse effects in breastfed infants. Achieving and maintaining viral suppression with antiretroviral therapy decreases breastfeeding transmission risk to less than 1%, but not zero. Individuals with HIV who are on antiretroviral therapy with a sustained undetectable viral load and who choose to breastfeed should be supported in this decision. If a viral load is not suppressed, banked pasteurized donor milk or formula is recommended.[1,2]

**Disclaimer:** Information presented in this database is not meant as a substitute for professional judgment. You should consult your healthcare provider for breastfeeding advice related to your particular situation. The U.S. government does not warrant or assume any liability or responsibility for the accuracy or completeness of the information on this Site.

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## Drug Levels

*Maternal Levels.* A woman infected with HIV was receiving raltegravir 800 mg, emtricitabine 200 mg and tenofovir disoproxil 245 mg once daily. She exclusively breastfed her infant for 4 months, then partially until 9 months postpartum. Breastmilk samples were taken over 12- to 24-hour periods at 4 and 8 months postpartum. At 4 months postpartum, the average milk concentration over 12 hours was 0.66 mg/L with an estimated daily infant dose of 0.099 mg/kg or 0.8% of the approved daily raltegravir dosage for infants. At 8 months postpartum, a peak milk level of about 6 mg/L occurred at about 6 hours after the dose. The level fell to about 0.3 mg/L at 24 hours after the dose.[3]

Three mothers taking raltegravir 400 mg twice daily provided milk samples at a median of 3.6 hours after a dose. The median drug concentration in milk was 1635 mcg/L, which resulted in an estimated infant dosage of 0.25 mg/kg daily and a relative infant dose of 4.09% of the maternal weight-adjusted dosage. Another 14 mothers taking raltegravir 1200 mg once daily provided milk samples at a median of 13.7 hours after a dose. The median drug concentration in milk was 111 mcg/L (IQR 69-566 mcg/L), which resulted in an estimated infant dosage of 20 mcg/kg daily and a relative infant dose of 0.28% of the maternal weight-adjusted dosage.[4]

*Infant Levels.* A woman infected with HIV was receiving raltegravir 800 mg, emtricitabine 200 mg and tenofovir disoproxil 245 mg once daily. She exclusively breastfed her infant for 4 months, then partially until 9 months postpartum. Single blood samples taken from the infant at 4 hours after a maternal dose at 4 and 8 months postpartum were below the lower limit of quantification (0.01 mg/L) of the assay.[3]

An infant was breastfed by a mother taking raltegravir 400 mg twice daily, although the extent of breastfeeding was not sated. The infant's serum concentrations taken 2 hours after maternal drug intake at 1 month of age was 21 mcg/L. Another 6 infants were breastfed by mothers taking raltegravir 1200 mg once daily, although the extent of breastfeeding was not sated. Infant serum concentrations taken between 11 and 19 hours after maternal drug intake at 1 month of age were undetectable in 5 infants and 14 mcg/L in one.[4]

## Effects in Breastfed Infants

Relevant published information was not found as of the revision date.

## Effects on Lactation and Breastmilk

Relevant published information was not found as of the revision date.

## Alternate Drugs to Consider

Lamivudine, Nelfinavir, Nevirapine, Zidovudine

## References

1. World Health Organization. Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach. 2021. Available at: <https://www.who.int/publications/i/item/9789240031593>
2. Department of Health and Human Services. Recommendations for the use of antiretroviral drugs during pregnancy and interventions to reduce perinatal HIV transmission in the United States. Infant feeding for individuals with HIV in the United States. 2023. Available at: <https://clinicalinfo.hiv.gov/en/guidelines/perinatal/infant-feeding-individuals-hiv-united-states?view=full>
3. Feiterna-Sperling C, Bukkems VE, Teulen MJA, Colbers AP. Low raltegravir transfer into the breastmilk of a woman living with HIV. *Aids* 2020;34:1863-5. PubMed PMID: 32675580.

4. Aebi-Popp K, Kahlert CR, Crisinel PA, et al. Transfer of antiretroviral drugs into breastmilk: A prospective study from the Swiss Mother and Child HIV Cohort Study. *J Antimicrob Chemother* 2022;77:3436-42. PubMed PMID: 36177836.

## Substance Identification

### Substance Name

Raltegravir

### CAS Registry Number

518048-05-0

### Drug Class

Breast Feeding

Lactation

Milk, Human

Anti-Infective Agents

Antiviral Agents

Anti-HIV Agents

Anti-Retroviral Agents

HIV Integrase Inhibitors