

NLM Citation: Drugs and Lactation Database (LactMed®) [Internet]. Bethesda (MD): National Institute of Child Health and Human Development; 2006-. Simeprevir. [Updated 2023 Sep 15]. **Bookshelf URL:** https://www.ncbi.nlm.nih.gov/books/



Simeprevir

Revised: September 15, 2023.

CASRN: 923604-59-5

Drug Levels and Effects

Summary of Use during Lactation

Simeprevir has been removed from the US market. It has not been studied in nursing mothers being treated for hepatitis C infection. Because it is greater than 99.9% bound to maternal plasma proteins, amounts in breastmilk are likely to be very low. Some sources recommend against breastfeeding when simeprevir is used with ribavirin.

Hepatitis C is not transmitted through breastmilk and breastmilk has been shown to inactivate hepatitis C virus (HCV).[1-4] However, the Centers for Disease Control recommends that mothers with HCV infection should consider abstaining from breastfeeding if their nipples are cracked or bleeding. It is not clear if this warning would apply to mothers who are being treated for hepatitis C.

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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Infants born to mothers with HCV infection should be tested for HCV infection; because maternal antibody is present for the first 18 months of life and before the infant mounts an immunologic response, nucleic acid testing is recommended.[1,4]

Drug Levels

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

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

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

(Hepatitis C) Interferon Alfa, Interferon Alfacon-1, Peginterferon Alfa

References

- 1. Cottrell EB, Chou R, Wasson N, et al. Reducing risk for mother-to-infant transmission of hepatitis C virus: A systematic review for the U.S. Preventive Services Task Force. Ann Intern Med 2013;158:109-13. PubMed PMID: 23437438.
- 2. Pfaender S, Heyden J, Friesland M, et al. Inactivation of hepatitis C virus infectivity by human breast milk. J Infect Dis 2013;208:1943-52. PubMed PMID: 24068703.
- 3. Tovo PA, Calitri C, Scolfaro C, et al. Vertically acquired hepatitis C virus infection: Correlates of transmission and disease progression. World J Gastroenterol 2016;22:1382-92. PubMed PMID: 26819507.
- 4. Workowski KA, Bachmann LH, Chan PA, et al. Sexually transmitted infections treatment guidelines, 2021. MMWR Recomm Rep 2021;70:1-187.

Substance Identification

Substance Name

Simeprevir

CAS Registry Number

923604-59-5

Drug Class

Breast Feeding

Lactation

Milk, Human

Antiviral Agents

Protease Inhibitors