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Sofosbuvir

Revised: September 15, 2023.

CASRN: 1190307-88-0

Drug Levels and Effects

Summary of Use during Lactation

Sofosbuvir has not been well studied in nursing mothers being treated for hepatitis C infection, although one infant was breastfed for 3 weeks and had no developmental abnormalities. If sofosbuvir alone or in combination with ledipasvir (Harvoni) is required by the mother, it is not a reason to discontinue breastfeeding.[1] Some sources recommend against breastfeeding when sofosbuvir is used with ribavirin.

Hepatitis C is not transmitted through breastmilk and breastmilk has been shown to inactivate hepatitis C virus (HCV).[2-5] 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.[2,5]

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

An infant was breastfed (extent not stated) for 3 weeks postpartum by a mother who took sofosbuvir 400 mg plus ledipasvir 90 mg daily for 12 weeks beginning at 31 weeks of gestation for her chronic hepatitis C infection. The infant was followed for 1 year and found to have normal growth and development.[6]

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

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- 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.
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- 4. 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.
- 5. Workowski KA, Bachmann LH, Chan PA, et al. Sexually transmitted infections treatment guidelines, 2021. MMWR Recomm Rep 2021;70:1-187.
- 6. Zeng QL, Yu ZJ, Lv J, et al. Sofosbuvir-based therapy for late pregnant women and infant with severe chronic hepatitis C: A case series study. J Med Virol 2022;94:4548-53. PubMed PMID: 35595682.

Substance Identification

Substance Name

Sofosbuvir

CAS Registry Number

1190307-88-0

Drug Class

Breast Feeding

Sofosbuvir 3

Lactation

Milk, Human

Antiviral Agents

Nucleotides