Epclusa® (sofosbuvir/velpatasvir) Use in Males With Partners of Child-Bearing Potential

This document is in response to your request for information regarding the use of Epclusa® (sofosbuvir/velpatasvir [SOF/VEL]) the treatment of HCV infection and the effect of treatment on male fertility.

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/liver-disease/epclusa/epclusa_pi.

Product Labeling[1]

There is no information in the SOF/VEL product labeling regarding the effect of SOF/VEL on human male fertility or on the transmission of SOF/VEL through sperm.

Sofosbuvir: Sofosbuvir had no effects on embryo-fetal viability or on fertility when evaluated in rats. At the highest dose tested, AUC exposure to the predominant circulating metabolite GS-331007 was approximately 4 times the exposure in humans at the recommended human dose.

Velpatasvir: Velpatasvir had no effects on embryo-fetal viability or on fertility when evaluated in rats. At the highest dose tested, velpatasvir exposure was approximately 6 times the exposure in humans at the recommended human dose.

Available Data on the effect of SOF/VEL on Male Fertility

There are no Gilead studies evaluating the effect of SOF/VEL on male fertility. In the phase 3 ASTRAL studies that evaluated the safety and efficacy of SOF/VEL for the treatment of HCV genotype 1-6 infection, all male study participants must have agreed to consistently and correctly use a condom from baseline until 90 days after the last dose of SOF/VEL or 7 months after the last dose of ribavirin. Additionally, if their female partner was of childbearing potential, they must have agreed to use one of the following methods of birth control: IUD with a failure rate of <1% per year, female barrier method (cervical cap or diaphragm with spermicidal agent), tubal sterilization, vasectomy in male partner, implants of levonorgestrel, injectable progesterone, oral contraceptives (either combined or progesterone only), contraceptive vaginal ring, or transdermal contraceptive patch. Consistent and correct use of birth control methods is required from the date of Screening until 7 months after their last dose of ribavirin, or 90 days after last dose of study drug if not taking ribavirin.[2-5]

Male participants must also have agreed to refrain from sperm donation from the date of screening until at least 7 months after the last dose of ribavirin, or 90 days after their last dose of study drug if not taking ribavirin.[2-5]

Additionally, a literature search was conducted in Ovid MEDLINE, BIOSIS Previews, and Embase databases for studies published between 1946 and October 24, 2024, using the search terms of Epclusa, sofosbuvir, velpatasvir, male fertility, sperm, and related search terms. No relevant citations were found.

References

1. Enclosed. Gilead Sciences Inc, EPCLUSA® (sofosbuvir and velpatasvir) tablets, for oral use. US Prescribing Information. Foster City, CA.
2. Feld JJ, Jacobson IM, Hézode C. Protocol For the ASTRAL-1 trial (NCT02201940). Sofosbuvir and Velpatasvir For HCV Genotype 1, 2, 4, 5, and 6 Infection. N Engl J Med. 2014:1-260.
3. Foster GR, Afdhal N, Roberts SK. Protocol for the ASTRAL-2 trial (NCT02220998) and for the ASTRAL-3 trial (NCT02201953). Sofosbuvir and Velpatasvir For HCV Genotype 2 and 3 Infection. N Engl J Med. 2014:1-553.
4. Curry MP, O'Leary JG, Bzowej N. Protocol for the ASTRAL-4 trial (NCT02201901). Sofosbuvir and Velpatasvir for HCV in Patients with Decompensated Cirrhosis. N Engl J Med. 2014:1-314.
5. Wyles D, Bräu N, Kottilil S, et al. Sofosbuvir and Velpatasvir for the Treatment of HCV in Patients Coinfected with HIV-1: an Open-Label, Phase 3 Study [Supplement]. Clin Infect Dis. 2017

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Epclusa US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/liver-disease/epclusa/epclusa_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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