GILEAD | Medical Information

# Epclusa® (sofosbuvir/velpatasvir) Coadministration with lovastatin

This document is in response to your request for information regarding Epclusa® (sofosbuvir/velpatasvir [SOF/VEL]) and coadministration with lovastatin.

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.**

## PK DDI Evaluation

Drug interaction studies have not been conducted between the single-tablet regimen SOF/VEL and lovastatin. Based on the PK profile of each active ingredient within SOF/VEL and lovastatin, a PK interaction cannot be excluded.[1,2] Lovastatin is a substrate of CYP3A4 and OATP1B1. Concentrations may increase due to mild inhibition of OATP1B1 by velpatasvir. Interactions cannot be excluded and close monitoring for statin adverse reactions should be undertaken, and a reduced dose should be considered if required. For more information about lovastatin, please refer to its product labeling.[2]

### SOF/VEL PK[1]

| DDI Mechanism | | SOF | VEL |
|---|---|---|---|
| Drug Transporters | P-gp/BCRP | Substrate | Substrate/Inhibitor |
| | OATP1B1 | N/A | Inhibitor |
| | OATP1B3 | N/A | Inhibitor |
| | OATP2B1 | N/A | Inhibitor |
| Drug Metabolizing Enzymes | CYP1A2 | N/A | N/A |
| | CYP2B6 | N/A | Substrate |
| | CYP2C8 | N/A | Substrate |
| | CYP2C19/19 | N/A | N/A |
| | CYP2D6 | N/A | N/A |
| | CYP3A4 | N/A | Substrate |

## Relevant SOF/VEL Label Information[1]

There is no information in the SOF/VEL product labeling about the coadministration of SOF/VEL and lovastatin.

Clearance of HCV infection with direct acting antivirals may lead to changes in hepatic function, which may impact safe and effective use of concomitant medications. Frequent monitoring of relevant laboratory parameters (INR or blood glucose) and dose adjustments

of certain concomitant medications may be necessary. For more information, please refer to Section 7.3 of the SOF/VEL US Prescribing Information (Established and Potentially Significant Drug Interactions).

## Available Data

There are no Gilead studies evaluating the coadministration of SOF/VEL and lovastatin.

Additionally, a literature search was conducted in Ovid MEDLINE and Embase databases for studies published between 1946 and September 15, 2025 using search terms that included Epclusa, sofosbuvir, velpatasvir, lovastatin, 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. Teva Pharmaceuticals USA, Inc, Lovastatin Tablets, USP, for oral use. US Prescribing Information, Parsippany, NJ.

## Abbreviations

BCRP=breast cancer resistance protein
DDI=drug-drug interaction
OATP=organic anion transporting polypeptide
P-gp=P-glycoprotein
PK=pharmacokinetic(s)
SOF=sofosbuvir
VEL=velpatasvir

# Product Label

For the full indication, important safety information, and Boxed Warning(s), please refer to the Epclusa US Prescribing Information available at:
http://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 Pharmacovigilance and Epidemiology ☎ 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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