

Epclusa[®] (sofosbuvir/velpatasvir) Coadministration with Vonoprazan

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

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 vonoprazan. Based on the PK profile of each active ingredient within SOF/VEL and vonoprazan, a PK interaction would be predicted.^{1,2} Coadministration of SOF/VEL with vonoprazan may decrease the concentration of VEL due to a reduction in intragastric acidity by vonoprazan. For more information about vonoprazan, please refer to its product labeling.²

SOF/VEL PK¹

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 Information¹

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

VEL solubility decreases as pH increases. Drugs that increase gastric pH are expected to decrease the concentration of VEL.

- Separate antacid and SOF/VEL administration by 4 h Section 7.3 of the SOF/VEL US Prescribing Information (Established and Potentially Significant Drug Interactions).
- H2RAs may be administered simultaneously with or 12 h apart from SOF/VEL at a dose that does not exceed doses comparable to FAM 40 mg BID.
- Coadministration of SOF/VEL with OME or other PPIs is not recommended. If it is considered medically necessary to coadminister, SOF/VEL should be administered with food and taken 4 h before OME 20 mg. Use with other PPIs has not been studied.

Available Data

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

Additionally, a literature search was conducted in Ovid MEDLINE and Embase databases for studies published between 1946 and May 13, 2025 using search terms that included Epclusa, velpatasvir, sofosbuvir, vonoprazan, 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. Phathom Pharmaceuticals, Inc. Voquezna® (vonoprazan) tablets, for oral use. US Prescribing Information. Buffalo Grove, IL.

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

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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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