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Epclusa® (sofosbuvir/velpatasvir) Coadministration with Dabigatran

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

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 dabigatran. Based on the PK profile of each active ingredients in SOF/VEL and of dabigatran, VEL may increase dabigatran concentrations. The clinical significance of this potential increase is unknown. No effect on SOF/VEL concentrations is expected. Close monitoring is recommended.[1,2] For more information on dabigatran, 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 dabigatran.

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 dabigatran.

Additionally, a literature search was conducted in Ovid MEDLINE and Embase databases for studies published between 1946 and January 14, 2026 using search terms that included Epclusa, sofosbuvir, velpatasvir, dabigatran, and related search terms. The following citations were identified.

- Rosato V, Nevola R, Dallio M, et al. Safety of Sofosbuvir-Based Direct-Acting Antivirals for Hepatitis C Virus Infection and Direct Oral Anticoagulant Co-Administration. *J. Clin. Med*.2024;13(19). doi:10.3390/jcm13195807

References

1. Enclosed. Gilead Sciences Inc, EPCLUSA® (sofosbuvir and velpatasvir) tablets, for oral use. US Prescribing Information. Foster City, CA.
2. Boehringer Ingelheim Pharmaceuticals, Inc. PRADAXA® (dabigatran etexilate) capsules, for oral use. US Prescribing Information. Ridgefield, CT.

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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