Epclusa® (sofosbuvir/velpatasvir) Coadministration with Vitamins/Supplements

Gilead Sciences, Inc. is providing this document to you, a US Healthcare Professional, in response to your unsolicited request for medical information. Some of the data may be outside of the US FDA-approved Prescribing Information. Gilead Sciences, Inc. does not intend to offer an opinion regarding the clinical relevance of these data or the advisability of administering any drug in a manner inconsistent with its approved labeling.

This letter summarizes available information about Epclusa® (sofosbuvir/velpatasvir [SOF/VEL]) and coadministration with vitamins and/or supplements.

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

Please see available information below from the SOF/VEL label regarding the coadministration of SOF/VEL with antacids and St. John's Wort. Drug interaction studies have not been conducted and there are no recommendations for the coadministration of SOF/VEL and any additional supplements, including vitamins.

SOF/VEL PK[1]

DDI Mechanism		SOF	VEL
Drug Transporters	P-gp/BCRP	Substrate	Substrate/Inhibitor
	OATP1B1	NA	Inhibitor
	OATP1B3	NA	Inhibitor
	OATP2B1	NA	Inhibitor
Drug Metabolizing Enzymes	CYP1A2	NA	NA
	CYP2B6	NA	Substrate
	CYP2C8	NA	Substrate
	CYP2C9/19	NA	NA
	CYP2D6	NA	NA
	CYP3A4	NA	Substrate

Relevant SOF/VEL Label Information[1]

The coadministration of SOF/VEL and St. John's Wort is not recommended due to the potential decrease in SOF and VEL concentrations by St. John's Wort.

Antacids (e.g. aluminum and magnesium hydroxide) and SOF/VEL administration should be separated by 4 hours.

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 Epclusa US Prescribing Information (Established and Potentially Significant Drug Interactions).

Reference

1. Enclosed. Gilead Sciences Inc, EPCLUSA® (sofosbuvir and velpatasvir) tablets, for oral use. US Prescribing Information. Foster City, CA

Abbreviations

BCRP=breast cancer resistance protein
CYP=cytochrome
DDI=drug-drug interaction
INR=international normalized ratio
NA=not applicable
OATP=organic anion transporting polypeptide
P-gp=p-glycoprotein
PK=pharmacokinetic
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 🖱 http://www.askgileadmedical.com/

Adverse Event Reporting

Please report all adverse events to:

Gilead Pharmacovigilance and Epidemiology ☎ 1-800-445-3235, option 3

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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