

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

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

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 prednisone. Based on the PK profile of each active ingredient within SOF/VEL and prednisone, a PK interaction would be predicted. Prednisone is a moderate CYP3A4 inducer which may decrease the concentration of VEL, however, the clinical significance of this interaction is not known. For more information about prednisone, please refer to its product labeling.^{1,2}

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 prednisone.

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

The safety and efficacy of SOF/VEL ± RBV was evaluated in four phase 3 studies, ASTRAL-1, ASTRAL-2, ASTRAL-3, and ASTRAL-4 in TN and TE GT 1-6 monoinfected participants.¹ In these trials, a prednisone equivalent of > 10 mg/day for 2 weeks was prohibited from 28 days prior to baseline through the end of treatment. Participants with chronic use of prednisone > 10 mg/day were also excluded from these trials.³⁻⁵

Additionally, a literature search was conducted in Ovid MEDLINE and Embase databases for studies published between 1946 and August 6, 2026 using search terms that included Epclusa, sofosbuvir, velpatasvir, prednisone, 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. Par Pharmaceutical. PredniSONE Tablets, USP. US Prescribing Information. Chestnut Ridge, NY.
3. Feld JJ, Jacobson IM, Hezode C, et al. Sofosbuvir and Velpatasvir for HCV Genotype 1, 2, 4, 5, and 6 Infection. N Engl J Med. Nov 16 2015;373(27):2599-2607.
4. Foster GR, Afdhal N, Roberts SK, et al. Sofosbuvir and Velpatasvir for HCV Genotype 2 and 3 Infection. N Engl J Med. 17 Nov 2015;373(27):2608-2617.
5. Curry MP, O'Leary JG, Bzowej N, et al. Sofosbuvir and Velpatasvir for HCV in Patients with Decompensated Cirrhosis. N Engl J Med. Nov 16 2015.

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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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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