



# Epclusa<sup>®</sup> (sofosbuvir/velpatasvir) Coadministration With BIC/FTC/TAF

This document is in response to your request for information regarding the coadministration of Biktarvy<sup>®</sup> (bictegravir/emtricitabine/tenofovir alafenamide [BIC/FTC/TAF]) with Epclusa<sup>®</sup> (sofosbuvir/velpatasvir [SOF/VEL]).

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](http://www.gilead.com/-/media/files/pdfs/medicines/liver-disease/epclusa/epclusa_pi); [www.gilead.com/-/media/files/pdfs/medicines/hiv/biktarvy/biktarvy\\_pi](http://www.gilead.com/-/media/files/pdfs/medicines/hiv/biktarvy/biktarvy_pi).**

## PK DDI Evaluation

Drug interaction studies have been conducted with SOF/VEL and BIC/FTC/TAF. Based on the PK profile of each active ingredient within SOF/VEL and BIC/FTC/TAF, a PK interaction would not be predicted. For more information about BIC/FTC/TAF, please refer to its product labeling.<sup>1,2</sup>

## SOF/VEL PK

Table 1. SOF/VEL DDI Potential<sup>1</sup>

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
	CYP2C9/19	N/A	N/A
	CYP2D6	N/A	N/A
	CYP3A4	N/A	Substrate

Abbreviations: BCRP=breast cancer resistance protein; OATP=organic anion transporting polypeptide; P-gp=P-glycoprotein.

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## Relevant SOF/VEL Label Information<sup>1</sup>

### Drug Interactions

#### Established and potentially significant drug interactions

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.

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).

#### Drugs without clinically significant interactions with SOF/VEL

Based on drug interaction studies conducted with the components of SOF/VEL (SOF or VEL) or SOF/VEL, no clinically significant drug interactions have been observed or are expected with the following drugs: elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide, or emtricitabine.

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## Relevant BIC/FTC/TAF Label Information<sup>2</sup>

### Drug Interactions

#### Drugs without clinically significant interactions with BIC/FTC/TAF

Based on drug interaction studies conducted with BIC/FTC/TAF or the components of BIC/FTC/TAF, no clinically significant drug interactions have been observed when BIC/FTC/TAF is combined with the following drugs: SOF or SOF/VEL.

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## References

1. Enclosed. Gilead Sciences Inc, EPCLUSA® (sofosbuvir and velpatasvir) tablets, for oral use. US Prescribing Information. Foster City, CA.
2. BIKTARVY, Gilead Sciences Inc. BIKTARVY® (bictegravir, emtricitabine, and tenofovir alafenamide) tablets, for oral use. U.S. Prescribing Information. Foster City, CA.

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## Abbreviations

E/C/F/TAF=elvitegravir/  
cobicistat/emtricitabine/

tenofovir alafenamide  
DDI=drug-drug interaction  
PK=pharmacokinetic(s)

SOF=sofosbuvir  
VEL=velpatasvir

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## Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Epclusa and Biktarvy US Prescribing Information available at:

[www.gilead.com/-/media/files/pdfs/medicines/liver-disease/epclusa/epclusa\\_pi](http://www.gilead.com/-/media/files/pdfs/medicines/liver-disease/epclusa/epclusa_pi);  
[www.gilead.com/-/media/files/pdfs/medicines/hiv/biktarvy/biktarvy\\_pi](http://www.gilead.com/-/media/files/pdfs/medicines/hiv/biktarvy/biktarvy_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](http://www.askgileadmedical.com)

## Adverse Event Reporting

Please report all adverse events to:

Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or

🌐 [www.gilead.com/utility/contact/report-an-adverse-event](http://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](http://www.accessdata.fda.gov/scripts/medwatch)

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