

Biktarvy[®] (BIC/FTC/TAF)

Coadministration with Phenytoin

This document is in response to your request for information regarding Biktarvy[®] (bictegravir/emtricitabine/tenofovir alafenamide [BIC/FTC/TAF]) and coadministration with phenytoin.

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/hiv/biktarvy/biktarvy_pi
www.gilead.com/-/media/files/pdfs/medicines/hiv/descovy/descovy_pi.

PK DDI Evaluation

Based on the PK profile of each active ingredient within BIC/FTC/TAF and phenytoin, a PK interaction would be predicted.^{1,2} Coadministration of BIC/FTC/TAF and phenytoin is expected to decrease the concentration of BIC and of TAF. Coadministration with alternative anticonvulsants should be considered.² For more information about phenytoin, please refer to its product labeling.¹

BIC/FTC/TAF PK^{2,3}

DDI Mechanism		BIC	FTC	TAF
Drug Transporters	OCT2	Inhibitor	N/A	N/A
	MATE1	Inhibitor	N/A	N/A
	P-gp/BCRP	N/A	N/A	Substrate
	OATP1B1	N/A	N/A	Substrate
	OATP1B3	N/A	N/A	Substrate
Drug Metabolizing Enzymes	CYP3A	Substrate ^a	N/A	Minor Substrate
	UGT1A1	Substrate ^a	N/A	N/A

^aA drug that is a strong inducer of CYP3A and also an inducer of UGT1A1 can substantially decrease the plasma concentrations of BIC. Similarly, the use of BIC/FTC/TAF with a drug that is a strong inhibitor of CYP3A and also an inhibitor of UGT1A1 may significantly increase the plasma concentrations of BIC.²

Available Data

There are no Gilead studies evaluating the coadministration of BIC/FTC/TAF and phenytoin.

Additionally, a literature search was conducted in Ovid MEDLINE, BIOSIS Previews, and Embase databases for studies published between 1946 and December 6, 2024 using search terms that included Biktarvy, bictegravir, emtricitabine, tenofovir alafenamide, phenytoin, and related search terms. No relevant citations were found.

References

1. Parke-Davis, Division of Pfizer Inc. Dilantin® (extended phenytoin sodium capsules), for oral use. U.S. Prescribing Information. New York, NY. Revised March 2022.
 2. Enclosed, Gilead Sciences Inc. BIKTARVY® (bictegravir, emtricitabine, and tenofovir alafenamide) tablets, for oral use. U.S. Prescribing Information. Foster City, CA.
 3. Enclosed. Gilead Sciences Inc, DESCovy® (emtricitabine and tenofovir alafenamide) tablets, for oral use. U.S. Prescribing Information. Foster City, CA.
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Abbreviations

BCRP=breast cancer
resistance protein

BIC=bictegravir

DDI=drug-drug interaction

FTC=emtricitabine

MATE=multidrug and toxin

extrusion protein

OATP=organic anion
transporting polypeptide

OCT=organic cation

transporter

P-gp=P-glycoprotein

PK=pharmacokinetic(s)

TAF=tenofovir alafenamide

UGT=uridine 5'-diphospho-
glucourosyltransferase

Product Label

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

www.gilead.com/-/media/files/pdfs/medicines/hiv/biktarvy/biktarvy_pi,
www.gilead.com/-/media/files/pdfs/medicines/hiv/descovy/descovy_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 Global Patient Safety ☎ 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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