

# Biktarvy® (BIC/FTC/TAF)

## Coadministration with Carbamazepine

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

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](http://www.gilead.com/-/media/files/pdfs/medicines/hiv/biktarvy/biktarvy_pi)  
[www.gilead.com/-/media/files/pdfs/medicines/hiv/descovy/descovy\\_pi](http://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 carbamazepine, a PK interaction would be predicted. Coadministration of carbamazepine, an inducer of CYP3A and other enzymes, is expected to decrease the concentrations of both BIC and TAF, which may lead to loss of therapeutic effect and development of resistance. Consider administration of an alternative anticonvulsant.<sup>1,2</sup> For more information about carbamazepine, please refer to its product labeling.<sup>1</sup>

## BIC/FTC/TAF PK<sup>2,3</sup>

Table 1. BIC/FTC/TAF PK

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 <sup>a</sup>	N/A	Minor Substrate
	UGT1A1	Substrate <sup>a</sup>	N/A	N/A

<sup>a</sup>A 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.<sup>2</sup>

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

Per the BIC/FTC/TAF US Prescribing Information, carbamazepine and BIC/FTC/TAF coadministration can lead to decreases in the concentrations of both BIC and TAF.

Coadministration with alternative anticonvulsants should be considered. Available PK data regarding the effect of carbamazepine on TAF are presented in the table below.

**Table 2. Effect of Carbamazepine on TAF<sup>a2</sup>**

Coadministered Drug	Dose of Coadministered Drug	TAF	Mean Ratio of TAF PK Parameters (90% CI); No effect = 1.00		
			C <sub>max</sub>	AUC	C <sub>min</sub>
Carbamazepine	300 mg twice daily	25 mg single dose <sup>b</sup>	0.43 (0.36, 0.51)	0.46 (0.40, 0.54)	N/A

<sup>a</sup> All interaction studies conducted in healthy volunteers.

<sup>b</sup> Study conducted with FTC/TAF.

## Available Data

There are no Gilead studies evaluating coadministration of BIC/FTC/TAF with carbamazepine.

A literature search was conducted in Ovid MEDLINE and Embase databases for studies published between 1946 and January 23, 2025 using search terms that included Biktarvy, bictegravir, emtricitabine, tenofovir alafenamide, carbamazepine, and related search terms. No relevant citations were found.

## References

1. Novartis Pharmaceuticals Corporation. Tegretol® (carbamazepine USP) Chewable Tablets of 100 mg - red-speckled, pink; Tablets of 200 mg - pink; Suspension of 100 mg/5 mL. Tegretol®-XR (carbamazepine extended-release tablets) 100 mg, 200 mg, 400 mg. U.S. Prescribing Information. East Hanover, New Jersey.
2. Enclosed, Gilead Sciences Inc. BIKTARVY® (bictegravir, emtricitabine, and tenofovir alafenamide) tablets, for oral use. US 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.

## Abbreviations

AUC=area under the curve  
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'-diphosphoglucourosyltransferase

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## 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](http://www.gilead.com/-/media/files/pdfs/medicines/hiv/biktarvy/biktarvy_pi),  
[www.gilead.com/-/media/files/pdfs/medicines/hiv/descovy/descovy\\_pi](http://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](http://www.askgileadmedical.com)

## Adverse Event Reporting

Please report all adverse events to:

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🌐 [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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