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Biktarvy® (BIC/FTC/TAF) Coadministration with Enzalutamide

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

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

This interaction has not been studied between the single-tablet regimen BIC/FTC/TAF and enzalutamide. Based on the PK profile of each active ingredient within BIC/FTC/TAF and enzalutamide, a PK interaction would be predicted.[1,2] Enzalutamide is a strong CYP3A inducer: coadministration with enzalutamide decreases the concentrations of certain CYP3A substrates which may reduce the efficacy of these substrates. Avoid the coadministration of enzalutamide with certain CYP3A substrates for which a minimal decrease in concentration may lead to therapeutic failure of the substrate.[1] BIC is a substrate of CYP3A and UGT1A1. A drug that is a strong inducer of CYP3A and also an inducer of UGT1A1 can substantially decrease the plasma concentrations of BIC which may lead to loss of therapeutic effect of BIC/FTF/TAF and development of resistance.[2] For more information about enzalutamide, 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

[a]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.[2]

Relevant BIC/FTC/TAF Label Information[2]

There is no information in the BIC/FTC/TAF product labeling about the coadministration of BIC/FTC/TAF and enzalutamide.

Available Data

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

Additionally, a literature search was conducted in Ovid MEDLINE and Embase databases for studies published between 1946 and February 18, 2025 using search terms that included Biktarvy, bictegravir, emtricitabine, tenofovir alafenamide, enzalutamide, and related search terms. No relevant citations were found.

References

1. Astellas Pharma US, Inc, XTANDI® (enzalutamide) capsules, for oral use, XTANDI® (enzalutamide) tablets, for oral use. U.S. Prescribing Information. Northbrook, IL.
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.

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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