GILEAD | Medical Information

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

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

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

Since BIC/FTC/TAF is indicated as a complete regimen, coadministration with other ARV medications for the treatment of HIV-1 infection is not recommended. Comprehensive information regarding potential DDI with other ARV medications is not provided in the US Prescribing Information because the safety and efficacy of concomitant HIV-1 ARV therapy is unknown.[1]

This interaction has not been studied between the single-tablet regimen BIC/FTC/TAF and fostemsavir. Based on the pharmacokinetic profile of each active ingredient within BIC/FTC/TAF and fostemsavir, a PK interaction would be predicted, however the interaction is not expected to be clinically significant.[1,2] Coadministration of the agents may result in increased concentrations of TAF due to inhibition of BCRP and OATP1B1/1B3 by fostemsavir.[2,3] While TAF is a substrate of BCRP and OAT1B1/1B3,[3] it is not considered a sensitive substrate for OATP transporters.[4] For more information about fostemsavir, please refer to its product labeling.[2]

BIC/FTC/TAF PK[1,3]

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.[1]

Relevant BIC/FTC/TAF Label Information[1]

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

Available Data

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

Additionally, a literature search was conducted in Ovid MEDLINE, BIOSIS Previews, and Embase databases for studies published between 1946 and December 23, 2024 using search terms that included Biktarvy, bictegravir, emtricitabine, tenofovir alafenamide, fostemsavir, and related search terms. No relevant citations were found.

References

1. Enclosed, Gilead Sciences Inc. BIKTARVY® (bictegravir, emtricitabine, and tenofovir alafenamide) tablets, for oral use. U.S. Prescribing Information. Foster City, CA.
2. ViiV Healthcare. RUKOBIA (fostemsavir) extended-release tablets, for oral use. U.S. Prescribing Information. Durham, NC
3. Enclosed. Gilead Sciences Inc, DESCOVY® (emtricitabine and tenofovir alafenamide) tablets, for oral use. U. S. Prescribing Information. Foster City, CA.
4. Gilead Sciences Inc. Data on File.

Abbreviations

ARV=antiretroviral
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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