GILEAD | Medical Information

Biktarvy® (BIC/FTC/TAF) Use in Hepatic Impairment

This document is in response to your request for information regarding the use of Biktarvy® (bictegravir/emtricitabine/tenofovir alafenamide [BIC/FTC/TAF]) in patients with hepatic impairment.

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.

Product Labeling[1]

Use in Specific Populations

Hepatic impairment

No dosage adjustment of BIC/FTC/TAF is recommended in patients with mild (Child-Pugh Class A) or moderate (Child-Pugh Class B) hepatic impairment. BIC/FTC/TAF has not been studied in patients with severe hepatic impairment (Child-Pugh Class C). Therefore, BIC/FTC/TAF is not recommended for use in patients with severe hepatic impairment.

Clinical Pharmacology

PK

Patients with hepatic impairment

Clinically relevant changes in the PK of BIC were not observed in subjects with moderate (Child-Pugh Class B) hepatic impairment.

The PK of FTC has not been studied in subjects with hepatic impairment; however, FTC is not significantly metabolized by liver enzymes, so the impact of hepatic impairment should be limited.

Clinically relevant changes in the PK of TAF or its metabolite tenofovir were not observed in subjects with mild or moderate (Child-Pugh Class A and B) hepatic impairment.

Available Data on BIC/FTC/TAF Use in Hepatic Impairment

A literature search was conducted in Ovid MEDLINE and Embase databases for studies published between 1946 and January 20, 2025, using search terms that included bictegravir, tenofovir alafenamide, emtricitabine, hepatic impairment and other related search terms. No relevant citations were found.

Reference

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

Abbreviations

BIC=bictegravir
FTC=emtricitabine
PK=pharmacokinetic(s)
TAF=tenofovir alafenamide

Product Label

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

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

Data Privacy

The Medical Information service at Gilead Sciences may collect, store, and use your personal information to provide a response to your medical request. We may share your information with other Gilead Sciences colleagues to ensure that your request is addressed appropriately. If you report an adverse event or concern about the quality of a Gilead or Kite product, we will need to use the information you have given us in order to meet our regulatory requirements in relation to the safety of our medicines.

It may be necessary for us to share your information with Gilead's affiliates, business partners, service providers, and regulatory authorities located in countries besides your own. Gilead Sciences has implemented measures to protect the personal information you provide. Please see the Gilead Privacy Statement (www.gilead.com/privacy-statements) for more information about how Gilead handles your personal information and your rights. If you have any further questions about the use of your personal information, please contact privacy@gilead.com.