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Biktarvy® (BIC/FTC/TAF) Use in Continuous Renal Replacement Therapy

This document is in response to your request for information regarding Biktarvy® (bictegravir/emtricitabine/tenofovir alafenamide [BIC/FTC/TAF]) and its use in individuals on continuous renal replacement therapy.

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 Labeling¹

BIC/FTC/TAF is not recommended in individuals with severe renal impairment (estimated CrCl of 15 to <30 mL/min) or ESRD (estimated CrCl <15 mL/min) who are not receiving chronic HD. BIC/FTC/TAF is also not recommended in individuals with no antiretroviral treatment history and ESRD who are receiving chronic HD.

Literature Search

A literature search was conducted in Ovid MEDLINE and Embase databases for studies published between 1946 and March 26, 2025 using search terms that included Biktarvy, bictegravir, tenofovir alafenamide, emtricitabine, continuous renal replacement therapy, and other related search terms. No relevant citations were identified.

References

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

Abbreviations

BIC=bictegravir ESRD=end stage renal disease FTC=emtricitabine HD=hemodialysis

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:

21-866-MEDI-GSI (1-866-633-4474) or 1-866-MEDI-GSI (1-866-633-4474) or 1-866-MEDI-GSI

Adverse Event Reporting

Please report all adverse events to:

Gilead Global Patient Safety (22) 1-800-445-3235, option 3 or https://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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