GILEAD | Medical Information

Biktarvy® (BIC/FTC/TAF) Use in Peritoneal Dialysis

This document is in response to your request for information regarding the use of Biktarvy® (bictegravir/emtricitabine/tenofovir alafenamide [BIC/FTC/TAF]) in individuals on peritoneal dialysis.

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]

Currently, there are no data or dosing recommendations in the Biktarvy US Prescribing Information for individuals on peritoneal dialysis.

Dosage and Administration

Not recommended in patients with severe renal impairment

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

Overdosage

It is not known whether FTC can be removed by peritoneal dialysis.

Clinical Data on BIC/FTC/TAF Use in Peritoneal Dialysis

Case Report

There are limitations in the interpretation of case reports. Case reports cannot be generalized. Unlike controlled clinical trials, causality cannot be inferred based on uncontrolled observational data. In addition, incidence or prevalence cannot be estimated due to the lack of a representative population sample. Other limitations of case reports include the retrospective design and publication bias.[2]

BIC/FTC/TAF use in CAPD[3]

A 75-year-old Black cisgender woman presented with a past medical history of anemia, cognitive impairment, ESRD on CAPD, type 2 diabetes mellitus, HIV, hyperlipidemia, and hypertension. The patient had been diagnosed with HIV in 2011, and she was virologically suppressed (VL <40 c/mL) on a multi-tablet regimen of dolutegravir + abacavir + lamivudine when she initiated CAPD in September 2020. The patient's concomitant medications included aspirin, atorvastatin, allopurinol, cyanocobalamin, epoetin alfa, insulin aspart, insulin degludec, lisinopril, metolazone, and nifedipine. In June 2021, she was switched to BIC/FTC/TAF to reduce the pill burden. She remained virologically suppressed (VL <40 c/mL) 11 months after switching to BIC/FTC/TAF, with a stable CD4 cell percentage (32%) and no reports of adverse drug reactions or relevant changes in laboratory parameters.

References

1. Enclosed, Gilead Sciences Inc. BIKTARVY® (bictegravir, emtricitabine, and tenofovir alafenamide) tablets, for oral use. US Prescribing Information. Foster City, CA.
2. Nissen T, Wynn R. The Clinical Case Report: A Review of Its Merits and Limitations. *BMC research notes.* 2014;7:264. https://www.ncbi.nlm.nih.gov/pubmed/24758689
3. Partosh D, Sherman EM, Eckardt PA, Unger N, Montalvo S. Bictegravir/emtricitabine/tenofovir alafenamide in a virologically suppressed adult with HIV and end-stage renal disease on chronic peritoneal dialysis: A case report. *Int J STD AIDS.* 2023;34(2):139-141.

Abbreviations

BIC=bictegravir
c/mL=copies per mL
CAPD=chronic ambulatory peritoneal dialysis
CD4=cluster of differentiation 4
ESRD=end-stage renal disease
FTC=emtricitabine
TAF=tenofovir alafenamide
VL=viral load

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
🖱 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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