GILEAD | Medical Information

Biktarvy® (BIC/FTC/TAF) Therapeutic Drug Monitoring

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

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: https://www.gilead.com/-/media/files/pdfs/medicines/hiv/biktarvy/biktarvy_pi.

Product Labeling

The BIC/FTC/TAF US Prescribing Information does not provide guidance for therapeutic drug monitoring for HIV-1 positive individuals.[1]

Available Data

Based on analyses of exposure quartiles from two Phase 3 registrational clinical trials, BIC and TAF did not demonstrate an exposure-safety or exposure-efficacy relationship. IQ ranges of 4.7—12.2 were observed in the lowest exposure quartile range for BIC C_{Tau} with a 99.3% virologic response rate. IQ is defined as the ratio of C_{Tau} to protein-adjusted IC_{95} for wild type HIV-1, which measures minimum in vivo exposure relative to in vitro potency.[2] Although BIC/FTC/TAF therapeutic drug monitoring is not required during HIV-1 treatment, drug level testing may be available through select commercial laboratories; please check with the individual laboratories for additional information.

References

1. Enclosed, Gilead Sciences Inc. BIKTARVY® (bictegravir, emtricitabine, and tenofovir alafenamide) tablets, for oral use. US Prescribing Information. Foster City, CA.
2. Lutz J, Shao Y, Ling J, et al. Bictegravir/Emtricitabine/Tenofovir Alafenamide Phase 3 Exposure-Response Analysis of Safety and Efficacy in the Treatment of HIV Infection [Poster 6]. Paper presented at: 19th International Workshop on Clinical Pharmacology of Antiviral Therapy, May 22–24; May 22–24, 2018; Baltimore, Maryland.

Abbreviations

C_{Tau}=drug concentration at trough 20-24 hours post-dose
FTC=emtricitabine
IC_{95}=95% inhibitory quotient
IQ=inhibitory quotient
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:
https://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

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