GILEAD | Medical Information

Descovy for PrEP® (FTC/TAF) Use in HBV Monoinfection

This document is in response to your request for information regarding the use of Descovy for PrEP® (emtricitabine/tenofovir alafenamide [FTC/TAF] for HIV-1 pre-exposure prophylaxis [PrEP]) in HIV-1 negative individuals with HBV monoinfection.

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/descovy/descovy_pi; www.gilead.com/-/media/files/pdfs/medicines/hiv/sunlenca/sunlenca_pi.

Product Labeling[1]

Indications and Usage

HIV-1 PrEP

FTC/TAF is indicated in at-risk adults and adolescents weighing ≥35 kg for PrEP to reduce the risk of HIV-1 infection from sexual acquisition, excluding individuals at risk from receptive vaginal sex. Individuals must have a negative HIV-1 test immediately prior to initiating FTC/TAF for HIV-1 PrEP.

Limitations of use:

The indication does not include the use of FTC/TAF in individuals at risk of HIV-1 from receptive vaginal sex because effectiveness in this population has not been evaluated.

Warnings and Precautions

Severe acute exacerbation of hepatitis B in individuals with HBV infection

All individuals should be tested for the presence of HBV before or when initiating FTC/TAF.

Severe acute exacerbations of hepatitis B (eg, liver decompensation and liver failure) have been reported in HBV-infected individuals who have discontinued products containing FTC and/or TDF and may occur with discontinuation of FTC/TAF. Individuals infected with HBV who discontinue FTC/TAF should be closely monitored with both clinical and laboratory follow-up for at least several months after stopping treatment. If appropriate, anti-hepatitis B therapy may be warranted, especially in individuals with advanced liver disease or cirrhosis, since post-treatment exacerbation of hepatitis may lead to hepatic decompensation and liver failure. HBV-uninfected individuals should be offered vaccination.

Please refer to the Descovy US Prescribing Information for complete product information.

Clinical Data on FTC/TAF Use in HBV Monoinfection

DISCOVER: FTC/TAF vs FTC/TDF for HIV-1 PrEP in MSM and TGW[2]

DISCOVER (NCT02842086) is an ongoing phase 3, randomized, double-blind, active-controlled, multinational study in HIV-negative adult MSM and TGW that is evaluating the safety and efficacy of FTC/TAF (n=2694) vs FTC/TDF (n=2693), both of which are fixed-dose combination products administered once daily for HIV-1 PrEP. Participants with HBV are excluded from the study.

PURPOSE 1: SUBQ LEN vs FTC/TAF for HIV-1 PrEP in AGYW

PURPOSE 1 (NCT04994509) is an ongoing phase 3, double-blind, randomized study evaluating the efficacy and safety of twice-yearly, SUBQ LEN (n=2138) vs once-daily oral FTC/TAF (n=2137) for HIV-1 PrEP in cisgender AGYW across South Africa and Uganda. Additionally, a third group was assigned once-daily FTC/TDF (n=1070), which served as the active control.[3] Participants with HBV are excluded from the study.[4]

Literature Search

A literature search was conducted in Ovid MEDLINE and Embase databases for studies published up to May 12, 2025, using the search terms Descovy, emtricitabine, tenofovir alafenamide, PrEP, hepatitis B, HBV, and related search terms. No relevant citations on the use of FTC/TAF in HIV-1 negative individuals with HBV monoinfection were identified.

References

1. Enclosed. Gilead Sciences Inc, DESCOVY® (emtricitabine and tenofovir alafenamide) tablets, for oral use. U. S. Prescribing Information. Foster City, CA.
2. Mayer KH, Molina JM, Thompson MA, et al. Emtricitabine and tenofovir alafenamide vs emtricitabine and tenofovir disoproxil fumarate for HIV pre-exposure prophylaxis (DISCOVER): primary results from a randomised, double-blind, multicentre, active-controlled, phase 3, non-inferiority trial. *Lancet.* 2020;396(10246):239-254.
3. Bekker LG, Das M, Abdool Karim Q, et al. Twice-Yearly Lenacapavir or Daily F/TAF for HIV Prevention in Cisgender Women. *N Engl J Med.* 2024;391(13):1179-1192.
4. Bekker LG, Das M, Abdool Karim Q, et al. Twice-Yearly Lenacapavir or Daily F/TAF for HIV Prevention in Cisgender Women [Protocol]. *N Engl J Med.* 2024:1-672.

Abbreviations

AGYW=adolescent girls and young women
FTC=emtricitabine
LEN=lenacapavir
MSM=men who have sex with men
PrEP=pre-exposure prophylaxis
SUBQ=subcutaneous
TAF=tenofovir alafenamide
TDF=tenofovir disoproxil fumarate
TGW=transgender women

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Descovy and Sunlenca US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/hiv/descovy/descovy_pi; www.gilead.com/-/media/files/pdfs/medicines/hiv/sunlenca/sunlenca_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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