GILEAD | Medical Information

Descovy for PrEP® (FTC/TAF) Use in HAV-Monoinfected Individuals

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) in HIV-negative individuals with hepatitis A virus (HAV) 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.

Product Labeling[1]

Indication

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.

Clinical Data

DISCOVER: Once Daily FTC/TAF vs FTC/TDF for HIV-1 PrEP in MSM and TGW

DISCOVER is a phase 3, randomized, double-blind, active-controlled, multinational study in 5387 HIV-negative adult men and transgender women who have sex with men that evaluated the safety and efficacy of once-daily FTC/TAF (n=2694) vs FTC/TDF (n=2693); both fixed-dose combination products were administered for HIV-1 PrEP. Individuals with acute HAV were excluded from enrollment in the study.[2]

PURPOSE 1: Study of LEN and FTC/TAF for HIV-1 PrEP in AGYW

PURPOSE 1 is an ongoing, phase 3, double-blind, randomized, active-controlled study evaluating the efficacy and safety of twice-yearly, SUBQ LEN and once-daily oral FTC/TAF for HIV-1 PrEP in cisgender women and adolescent girls across South Africa and Uganda.

Additionally, a third group was assigned once-daily oral FTC/TDF, which served as the active control.[3] Individuals with acute HAV were excluded from randomization in the study.[4]

Literature Search

A literature search was conducted in Ovid MEDLINE and Embase databases for studies published between 1946 and March 24, 2025 using the search terms of Descovy, emtricitabine, tenofovir alafenamide, PrEP, hepatitis A, and related search terms. No relevant citations relevant to your inquiry 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. ClinicalTrials.gov. *Safety and Efficacy of Emtricitabine and Tenofovir Alafenamide (F/TAF) Fixed-Dose Combination Once Daily for Pre-Exposure Prophylaxis in Men and Transgender Women Who Have Sex With Men and Are At Risk of HIV-1 Infection (DISCOVER). ClinicalTrials.gov Identifier: NCT02842086. Accessed: 24 March 2025 Last Updated: 22 October 2024*.
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
HAV=hepatitis A virus
LEN=lenacapavir
MSM=men who have sex with men
PrEP=pre-exposure prophylaxis
SUBQ=subcutaneous
TAF=tenofovir alafenamide fumarate
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 US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/hiv/descovy/descovy_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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