GILEAD | Medical Information

Descovy for PrEP® (FTC/TAF) Use in HCV-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 HCV 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

Indication[1]

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

Pharmacokinetics[1]

The pharmacokinetics of FTC and TAF have not been fully evaluated in participants with HBV and/or HCV.

Drug Interactions

Based on drug interaction studies conducted with the components of FTC/TAF, no clinically significant drug interactions have been either observed or are expected when FTC/TAF is combined with ledipasvir and sofosbuvir.[1]

Based on drug interaction studies conducted with TAF, no clinically significant drug interactions have been observed with sofosbuvir/velpatasvir, and sofosbuvir/velpatasvir/voxilaprevir.[2]

Clinical Data

DISCOVER Study

DISCOVER (NCT02842086) is a phase 3, randomized, double-blind, active-controlled multinational study in 5387 HIV-negative adult MSM and TGW that is evaluating the safety and efficacy of FTC/TAF (n=2694) vs FTC/TDF (n=2693) for HIV-1 PrEP. Individuals with acute HCV were excluded from enrollment in DISCOVER. However, individuals who had previously completed treatment for HCV and achieved a sustained virologic response were not excluded.[3] No analysis of study participants by HCV status prior to enrollment is available at this time.

Literature Search

A literature search was conducted in Ovid MEDLINE and Embase databases for studies published between 1946 and June 30, 2025 using search terms that included Descovy, emtricitabine, tenofovir alafenamide, PrEP, hepatitis C and related search terms. No relevant citations were found.

References

1. Enclosed. Gilead Sciences Inc, DESCOVY® (emtricitabine and tenofovir alafenamide) tablets, for oral use. U.S. Prescribing Information. Foster City, CA.
2. Enclosed. Gilead Sciences Inc, VEMLIDY® (tenofovir alafenamide) tablets, for oral use. U.S. Prescribing Information. Foster City, CA.
3. 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. Last Updated: 22 October 2024*.

Abbreviations

FTC=emtricitabine
HBV=hepatitis B virus
HCV=hepatitis C virus
MSM=men who have sex with men
PrEP=pre-exposure prophylaxis
TAF=tenofovir alafenamide fumarate
TGW=transgender women

Product Label

For the full indication, important safety information, and boxed warning, 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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