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GILEAD | Medical Information

Descovy for PrEP® (FTC/TAF) Missed Doses and Effect on Efficacy

This document is in response to your request for information regarding the effect of missed doses of Descovy for PrEP® (emtricitabine/tenofovir alafenamide [FTC/TAF] for HIV-1 pre-exposure prophylaxis [PrEP]) on efficacy. This response focuses on populations for which Descovy for PrEP has demonstrated efficacy and is approved for use.

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]

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.

Dosage and Administration

Recommended dosage for HIV-1 PrEP in adults and adolescents weighing ≥35 kg

The dosage of FTC/TAF for HIV-1 PrEP is one tablet (containing 200 mg of FTC and 25 mg of TAF) once daily taken orally with or without food in adults and adolescents without HIV-1 weighing ≥35 kg and with a CrCl ≥30 mL/min; or adults without HIV-1 and with CrCl <15 mL/min who are receiving chronic hemodialysis. On days of hemodialysis, administer the daily dose of FTC/TAF after completion of hemodialysis treatment.

Clinical Studies

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Clinical trial results for HIV-1 PrEP

The registrational study, DISCOVER, evaluated the efficacy and safety of FTC/TAF for HIV-1 PrEP vs FTC/TDF. In a case-control substudy of intracellular drug levels and estimated number of daily doses as measured by dried blood spot testing, median intracellular TFV-DP concentrations were substantially lower in participants infected with HIV-1 at the time of diagnosis compared with uninfected matched control participants. For both FTC/TAF and FTC/TDF, efficacy was therefore strongly correlated to adherence to daily dosing.

Patient Counseling Information

Advise individuals without HIV-1 about the importance of taking FTC/TAF on a regular dosing schedule and strict adherence to the recommended dosing schedule to reduce the risk of acquiring HIV-1. Individuals without HIV-1 who miss doses are at greater risk of acquiring HIV-1 than those who do not miss doses.

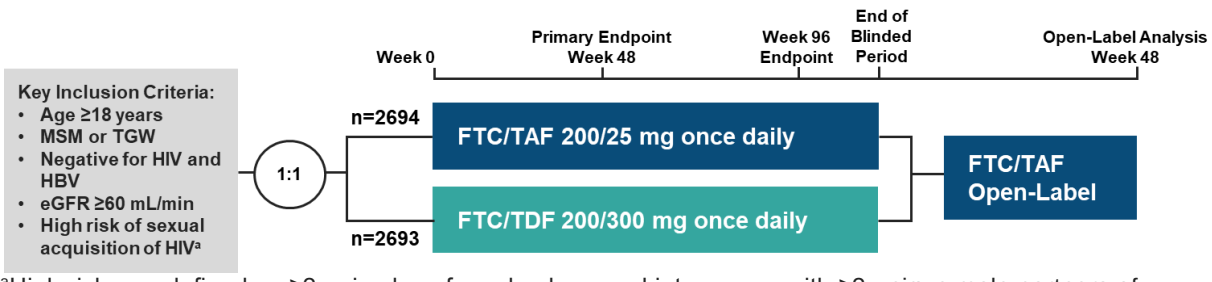
Clinical Data on Missed FTC/TAF Doses and Effect on Efficacy

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

Study design

DISCOVER was a phase 3, double-blind, active controlled, multinational study that included 5387 HIV-negative, adult MSM and TGW and evaluated the safety and efficacy of FTC/TAF vs FTC/TDF for HIV-1 PrEP (Figure 1). Prior use of FTC/TDF for HIV-1 PrEP was allowed. The primary outcome was the incidence of HIV acquisition.[2]

Figure 1. DISCOVER: Study Design[2,3]



[a]High risk was defined as ≥2 episodes of condomless anal intercourse with ≥2 unique male partners of HIV-positive or unknown HIV status within the previous 12 weeks, or a documented history of syphilis, rectal gonorrhea, or rectal chlamydia in the previous 24 weeks.

PK results

An analysis of PK data was conducted. TFV-DP concentrations in PBMCs were compared with PK data from historical phase 1 studies to estimate the onset and duration of HIV protection between the two arms. Based on a simulation at steady state with daily dosing, study investigators expect median PBMC TFV-DP levels to remain above EC_{90} longer with FTC/TAF (16 days) than FTC/TDF (10 days) after the last dose.[4] However, the impact of

these data have not been established in any clinical study. EC_{90} has not been shown to correlate with efficacy. The clinical relevance of these PK data and the correlate of HIV protection is unknown.

References

1. Enclosed. Gilead Sciences Inc, DESCOVY® (emtricitabine and tenofovir alafenamide) tablets, for oral use. U. S. Prescribing Information. Foster City, CA.
2. Wohl DA, Spinner CD, Flamm J, et al. HIV-1 infection kinetics, drug resistance, and long-term safety of pre-exposure prophylaxis with emtricitabine plus tenofovir alafenamide (DISCOVER): week 144 open-label extension of a randomised, controlled, phase 3 trial. *Lancet HIV.* 2024;11(8):508-521.
3. Wohl DA, Spinner CD, Flamm J, et al. HIV-1 infection kinetics, drug resistance, and long-term safety of pre-exposure prophylaxis with emtricitabine plus tenofovir alafenamide (DISCOVER): week 144 open-label extension of a randomised, controlled, phase 3 trial [Supplementary Appendix]. *Lancet HIV.* 2024;11(8):508-521.
4. Spinner CD, Brunetta J, Shalit P, et al. DISCOVER STUDY for HIV Pre-Exposure Prophylaxis: F/TAF has a more Rapid Onset and Longer Sustained Duration of HIV Protection Compared with F/TDF [Presentation]. Paper presented at: IAS 2019; 21-24 July, 2019; Mexico City, Mexico.

Abbreviations

EC_{90}=intracellular drug level associated with 90% HIV risk reduction
FTC=emtricitabine
MSM=men who have sex with men
PBMC=peripheral mononuclear blood cells
PK=pharmacokinetic(s)
PrEP=pre-exposure prophylaxis
TAF=tenofovir alafenamide
TDF=tenofovir disoproxil fumarate
TFV-DP=tenofovir diphosphate
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

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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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