

Truvada[®] (FTC/TDF) Storage and Stability

This document is in response to your request for extended storage and stability information of Truvada[®] (emtricitabine/tenofovir disoproxil fumarate [FTC/TDF]) 200/300 mg, 167/250 mg, 133/200 mg, and 100/150 mg tablets and does not intend to offer an opinion regarding the clinical relevance of these data or the advisability of storing or administering any drug in a manner inconsistent with its approved labeling. Truvada[®] (FTC/TDF) should be stored according to the product label.

The full indication, important safety information, and boxed warnings are available at: www.gilead.com/-/media/files/pdfs/medicines/hiv/truvada/truvada_pi.

Product Labeling¹

FTC/TDF tablets are packaged in bottles containing 30 tablets with child-resistant closure. Store at 25°C (77°F), excursions permitted to 15°C to 30°C (59–86°F). Keep container tightly closed. Dispense only in original container. Tablets should be used within 6 weeks after first opening the bottle.

Alternative Storage and Stability Information²

The table below summarizes available data from in-house studies regarding the storage of FTC/TDF tablets in varying conditions. The “acceptable duration” refers to the stability of FTC/TDF tablets in the specified packaging and storage condition, but it does not endorse alternative packaging or use beyond the expiration date stated on the original packaging.

Table 1. Summary of Extended Stability Data for FTC/TDF Tablets²

Storage Condition	Package Type	Acceptable Duration
40°C (104°F)/75% RH	Original sealed bottle	6 months
50°C (122°F)	Original sealed bottle	3 days
5°C (41°F)	Original sealed bottle	2 months
-20°C (-4°F)	Original sealed bottle	14 days
25°C (77°F)/60% RH	Original bottle without induction seal	6 weeks
30°C (86°F)/75% RH	Original bottle without induction seal	6 weeks
Open dish, 25°C (77°F)/60% RH ^a	Open petri dish	6 weeks
Open dish, 30°C (86°F)/75% RH ^a	Open petri dish	5 days

Abbreviation: RH=relative humidity.

^aTablets are stored outside of the commercial packaging configuration in an open petri dish.

References

1. Enclosed. Gilead Sciences Inc, TRUVADA[®] (emtricitabine/tenofovir disoproxil fumarate) tablets, for oral use. U.S. Prescribing Information. Foster City, CA.
2. Gilead Sciences Inc. Data on File.

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Truvada US Prescribing Information available at:

www.gilead.com/-/media/files/pdfs/medicines/hiv/truvada/truvada_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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