

# Truvada<sup>®</sup> (FTC/TDF) Storage and Stability

This document is in response to your request for extended storage and stability information of Truvada<sup>®</sup> (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<sup>®</sup> (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](http://www.gilead.com/-/media/files/pdfs/medicines/hiv/truvada/truvada_pi).**

## Product Labeling<sup>1</sup>

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 Information<sup>2</sup>

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 Tablets<sup>2</sup>**

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 <sup>a</sup>	Open petri dish	6 weeks
Open dish, 30°C (86°F)/75% RH <sup>a</sup>	Open petri dish	5 days

Abbreviation: RH=relative humidity.

<sup>a</sup>Tablets are stored outside of the commercial packaging configuration in an open petri dish.

## References

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

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## 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](http://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](http://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](http://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](http://www.accessdata.fda.gov/scripts/medwatch)

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