



Descovy[®] (FTC/TAF) Storage and Stability

This document is in response to your request for extended storage and stability information of Descovy[®] (emtricitabine/tenofovir alafenamide [FTC/TAF]) 200 mg/25 mg and 120 mg/15 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. Descovy[®] (FTC/TAF) 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/descovy/descovy_pi.

Product Labeling¹

FTC/TAF tablets are available in bottles and blister packs containing 30 tablets:

- Bottles contain a silica gel desiccant, polyester coil, and child-resistant closure. Keep bottle tightly closed.
- Blister packs are sealed with a child-resistant laminated foil lidding material (peel-push) and each blister cavity contains a die-cut desiccant film which is heat staked to the foil lidding material.

Store at 25°C (77°F); excursions permitted to 15°C to 30°C (59°F–86°F). Dispensed only in the original container.

Alternative Storage and Stability Information²

The tables below summarize available data from in-house studies regarding the storage of FTC/TAF tablets in varying conditions. The “acceptable duration” refers to the stability of FTC/TAF 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/TAF 200 mg/25 mg Tablets²

Storage Condition	Package Type	Acceptable Duration
40°C (104°F)/75% RH	Original sealed bottle	6 months
60°C (140°F)	Original sealed bottle	7 days
-20°C (-4°F)	Original sealed bottle	4 days
40°C (104°F)/75% RH	Original Gilead blister packaging ^a	6 months
60°C (140°F)	Original Gilead blister packaging ^a	14 days
-20°C (-4°F)	Original Gilead blister packaging ^a	28 days
Open dish, 25°C (77°F)/60% RH	Open petri dish ^b	4 weeks
Open dish, 30°C (86°F)/75% RH	Open petri dish ^b	4 weeks
25°C (77°F)/60% RH	Original bottle without induction seal ^c	30 days
30°C (86°F)/75% RH	Original bottle without induction seal ^c	30 days

Abbreviation: RH=relative humidity.

^aThis data is specific to the original Gilead Descovy blister packaging which is custom made for Descovy and cannot be extrapolated to other blister packages. The stability of an individual blister or strip is the same as the stability of the unseparated Gilead blister packaging, as long as any of the cavities have not been punctured.

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

^cWith and without desiccant.

Table 2. Summary of Extended Stability Data for FTC/TAF 120 mg/15 mg Tablets²

Storage Condition	Package Type	Acceptable Duration
40°C (104°F)/75% RH	Original sealed bottle	6 months
60°C (140°F)	Original sealed bottle	7 days
-20°C (-4°F)	Original sealed bottle	4 days

References

1. Enclosed. Gilead Sciences Inc, DESCOVY® (emtricitabine and tenofovir alafenamide) 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 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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