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GILEAD | Medical Information

Vemlidy® (tenofovir alafenamide) Storage and Stability

This document is in response to your request for extended storage and stability information of Vemlidy® (tenofovir alafenamide [TAF]) 25 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. Vemlidy® (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/liver-disease/vemlidy/vemlidy_pi.

Product Labeling[1]

Each bottle contains 30 tablets, a silica gel desiccant, polyester coil, and is closed with a child-resistant closure. Store below 30°C (86°F). Keep container tightly closed. Dispense only in original container.

Alternative Storage and Stability Information[2]

The table below summarizes available data from in-house studies regarding the storage of TAF tablets in varying conditions. The “acceptable duration” refers to the stability of 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 TAF Tablets[2]

Storage Conditions	Package Type	Acceptable Duration
Open dish 25°C (77°F)/60% relative humidity[a]	Petri dish[a]	4 weeks
Open dish 30°C (86°F)/75% relative humidity[a]	Petri dish[a]	4 weeks
25°C (77°F)/60% relative humidity	Original bottle, in-use[b]	90 days
60°C (140°F)	Original bottle	7 days
50°C (122°F)	Original bottle	7 days
40°C (104°F)/75% relative humidity	Original bottle	6 months
-20°C (-4°F)	Original bottle	6 months
-80°C (-112°F)	Original bottle	7 days
-20°C (-4°F)	Original Gilead blister	4 weeks
50°C (122°F)	Original Gilead blister	6 days
25°C (77°F)/60% relative humidity	Blister, in-use[c]	120 days
30°C (86°F)/75% relative humidity	Blister, in-use[c]	120 days

[a]Tablets were stored outside of the commercial packaging configuration in an open petri dish in a stability chamber.
[b]In use=bottle opened, and 1 tablet removed every 3 days.
[c]In use=blister card pouch opened for up to 120 days.

References

1. Enclosed. Gilead Sciences Inc, VEMLIDY® (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 Vemlidy US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/liver-disease/vemlidy/vemlidy_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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