GILEAD | Medical Information

Atripla® (EFV/FTC/TDF) Storage and Stability

This document is in response to your request for extended storage and stability information of Atripla® (efavirenz/emtricitabine/tenofovir disoproxil fumarate [EFV/FTC/TDF]) 600/200/300 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. Atripla® (EFV/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/atripla/atripla_pi.

Product Labeling[1]

EFV/FTC/TDF tablets are packaged in bottles containing 30 tablets with a silica gel desiccant and is closed with a child-resistant closure. Store at 25°C (77°F); excursions permitted from 15°C to 30°C (59–86°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 EFV/FTC/TDF tablets in varying conditions. The “acceptable duration” refers to the stability of EFV/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 EFV/FTC/TDF Tablets[2]

Storage Condition	Package Type	Acceptable Duration
40°C (104°F)/75% RH	Original sealed bottle	6 months
50°C (122°F)	Original sealed bottle	1 month
25°C (77°F)/80% RH	Original sealed bottle	3 months
5°C (41°F)	Original sealed bottle	2 months
-20°C (-4°F)	Original sealed bottle	4 weeks
Open dish, 25°C (77°F)/60% RH	Open petri dish	4 weeks

Abbreviation: RH=relative humidity.

References

1. Enclosed, ATRIPLA®, Gilead Sciences Inc. ATRIPLA® (efavirenz, emtricitabine, and tenofovir disoproxil fumarate) tablets, for oral use. US 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 Atripla US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/hiv/atripla/atripla_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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