

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

This document is in response to your request for extended storage and stability information of Complera<sup>®</sup> (emtricitabine/rilpivirine/tenofovir disoproxil fumarate [FTC/RPV/TDF]) 25/200/300 mg oral 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. Complera<sup>®</sup> (FTC/RPV/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/complera/complera\\_pi](http://www.gilead.com/-/media/files/pdfs/medicines/hiv/complera/complera_pi).**

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

FTC/RPV/TDF tablets are packaged in child-resistant bottles containing 30 tablets, a silica gel desiccant, and a polyester fiber coil. 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.

## Alternative Storage and Stability Information<sup>2</sup>

The table below summarizes available data from in-house studies regarding the storage of FTC/RPV/TDF tablets in varying conditions. The “acceptable duration” refers to the stability of FTC/RPV/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/RPV/TDF Tablets<sup>2</sup>**

Storage Condition	Package Type	Acceptable Duration
40°C (104°F)/75% RH	Original sealed bottle	6 months
25°C (77°F)/80% RH	Original sealed bottle	6 weeks
50°C (122°F)	Original sealed bottle	6 weeks
-20°C (-4°F)	Original sealed bottle	4 weeks
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	N/A <sup>b</sup>
Open dish, 30°C (86°F)/75% RH <sup>a</sup>	Open petri dish	N/A <sup>b</sup>

Abbreviation: RH=relative humidity.

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

<sup>b</sup>Tablets did not meet required specifications at the first studied timepoint of 2 weeks when removed from the original container and placed in an open petri dish.

## References

1. Enclosed. Gilead Sciences Inc, COMPLERA® (emtricitabine, rilpivirine, 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 Complera US Prescribing Information available at:

[www.gilead.com/-/media/files/pdfs/medicines/hiv/complera/complera\\_pi](http://www.gilead.com/-/media/files/pdfs/medicines/hiv/complera/complera_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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