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Odefsey® (FTC/RPV/TAF) Storage and Stability

This document is in response to your request for extended storage and stability information of Odefsey® (emtricitabine/rilpivirine/tenofovir alafenamide [FTC/RPV/TAF]) 200/25/25 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. Odefsey® (FTC/RPV/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/odefsey/odefsey_pi

Product Labeling[1]

Each bottle contains 30 tablets, a silica gel desiccant, and a polyester coil, and is closed with a child-resistant closure. Store below 30°C (86°F). Keep 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 FTC/RPV/TAF tablets in varying conditions. The “acceptable duration” refers to the stability of FTC/RPV/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/RPV/TAF 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	4 days
60°C (140°F)	Original sealed bottle	4 days
-20°C (-4°F)	Original sealed bottle	14 days
25°C (77°F)/60% RH	Original bottle in-use[b] with desiccant	30 days
30°C (86°F)/75% RH	Original bottle in-use[b] with desiccant	30 days
Open dish, 25°C (77°F)/60% RH[a]	Open petri dish	4 weeks
Open dish, 30°C (86°F)/75% RH[a]	Open petri dish	1 week

RH=relative humidity.
[a]Tablets are stored outside of the commercial packaging configuration in an open petri dish.
[b]In-use=bottle opened, and one tablet removed daily.

References

1. Enclosed. Gilead Sciences Inc, ODEFSEY® (emtricitabine, rilpivirine, and tenofovir alafenamide) 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 Odefsey US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/hiv/odefsey/odefsey_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
🖱 https://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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