



# Emtriva<sup>®</sup> (emtricitabine) Oral Capsules and Oral Solution Storage and Stability

This document is in response to your request for extended storage and stability information of Emtriva<sup>®</sup> (emtricitabine [FTC]) 200 mg oral capsules and 10 mg/mL oral solution 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. Emtriva<sup>®</sup> (FTC) 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/emtriva/emtriva\\_pi](http://www.gilead.com/-/media/files/pdfs/medicines/hiv/emtriva/emtriva_pi).**

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

FTC capsules are packaged in bottles containing 30 capsules with child-resistant closure. Store FTC capsules at 25°C (77°F); excursions permitted to 15°C to 30°C (59–86°F). Dispense only in original container. Keep container tightly closed.

FTC oral solution is available in unit of use plastic, amber bottles containing 170 mL of oral solution closed with a child-resistant closure and packaged with a marked dosing cup. Store FTC oral solution refrigerated at 2°C to 8°C (36–46°F). FTC oral solution should be used within 3 months if stored by the patient at 25°C (77°F); excursions permitted to 15°C to 30°C (59–86°F). Keep container tightly closed.

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

The tables below summarize available data from in-house studies regarding the storage of FTC oral capsules and oral solution in varying conditions. The “acceptable duration” refers to the stability of FTC oral capsules and oral solution 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 Oral Capsules<sup>2</sup>**

Storage Condition	Package Type	Acceptable Duration
40°C (104°F)/75% RH	Original sealed bottle	6 months
-20°C (-4°F)	Original sealed bottle	4 days
50°C (122°F)	Original sealed bottle	4 days

Abbreviation: RH=relative humidity.

**Table 2. Summary of Extended Stability Data for FTC Oral Solution<sup>2</sup>**

Storage Condition	Package Type	Acceptable Duration
25°C (77°F)/40% RH	Original sealed bottle	6 months
-20°C (-4°F)	Original sealed bottle	4 days
50°C (122°F)	Original sealed bottle	4 days

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## References

1. Enclosed. Gilead Sciences Inc, EMTRIVA (emtricitabine) capsule for oral use. EMTRIVA (emtricitabine) solution for oral use. US 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 Emtriva US Prescribing Information available at:

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