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Yeztugo® (lenacapavir) Oral Tablet Storage and Stability

This document is in response to your request for information regarding Yeztugo® (lenacapavir [LEN]) 300 mg oral tablets and extended storage and stability information.

This document 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. LEN should be stored according to the product label.

Some data may be outside of the US FDA-approved prescribing information. In providing this data, Gilead Sciences, Inc. is not making any representation as to its clinical relevance or to the use of any Gilead product(s). For information about the approved conditions of use of any Gilead drug product, please consult the FDA-approved prescribing information.

The full indication, important safety information, and boxed warning are available at: www.gilead.com/-/media/files/pdfs/medicines/hiv/yeztugo/yeztugo_pi.

Product Labeling[1]

LEN 300 mg tablets are beige, capsule-shaped, and film-coated with “GSI” debossed on one side and “62L” on the other side.

Each LEN bottle contains 4 tablets, a silica gel desiccant, polyester coil, and is closed with a child-resistant closure. Do not remove the desiccant packet.

Keep bottle tightly closed.

Store bottle at 20°C to 25°C (68–77°F), excursions permitted to 15°C to 30°C (59–86°F). Dispense and store only in original container.

Alternative Storage and Stability Information[2]

The table below summarizes available data from in-house temperature excursion studies regarding the storage of LEN oral tablets in varying conditions.

There is no change to the product expiration date if it has been stored for less than the acceptable duration specified for each temperature in Table 1. The “acceptable duration” refers to the stability of LEN oral 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 LEN Oral Tablets[2]

Storage Condition	Package Type	Acceptable Duration
Open dish, 30°C (86°F)/75% relative humidity	Open petri dish	1 month
50°C (122°F)	Original sealed bottle[a]	2 weeks
-20°C (-4°F)	Original sealed bottle[a]	1 month

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[a] A 4-count bottle

References

1. Enclosed, Gilead Sciences Inc. YEZTUGO® (lenacapavir) tablets, for oral use. YEZTUGO® (lenacapavir) injection, for subcutaneous 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, please refer to the Yeztugo US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/hiv/yeztugo/yeztugo_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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