GILEAD | Medical Information

Sunlenca® (lenacapavir) Oral Tablet Storage and Stability

This document is in response to your request for extended storage and stability information of Sunlenca® (lenacapavir [LEN]) 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. Sunlenca® (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 warnings are available at: http://www.gilead.com/-/media/files/pdfs/medicines/hiv/sunlenca/sunlenca_pi.

Product Labeling[1]

LEN tablets are available in a bottle or blister packs, packaged as follows:

Bottle

The bottle also contains a silica gel desiccant and polyester coil, and is closed with a child-resistant closure. Do not remove the desiccant packet. Keep bottle tightly closed.

Blister Packs

Within the blister packs, tablets are packaged in a clear blister film sealed to a foil lidding material. The blister card is fitted between two paperboard cards, and packaged with silica gel desiccant in a sealed child-resistant flexible laminated pouch.

Store bottle and blister packs 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 bottle or blister pack.

Alternative Storage and Stability Information[2]

The table below summarizes available data from in-house studies regarding the storage of LEN oral tablets in varying conditions. 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
50°C (122°F)	Original Gilead blister with pouch, desiccant, and paperboard	2 weeks
-20°C (-4°F)	Original Gilead blister with pouch, desiccant, and paperboard	1 month
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

[a]A 4-count bottle

References

1. Enclosed, Gilead Sciences Inc. SUNLENCA® (lenacapavir) tablets, for oral use. SUNLENCA® (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(s), please refer to the Sunlenca US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/hiv/sunlenca/sunlenca_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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