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Sunlenca® (lenacapavir) Injection Solution Storage and Stability

This document is in response to your request for extended storage and stability information of Sunlenca® (lenacapavir [LEN]) 463.5 mg/1.5 mL (309 mg/mL) injection 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. Sunlenca® (LEN) 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/sunlenca/sunlenca_pi.

Product Labeling[1]

Store at 20°C to 25°C (68°F–77°F), excursions permitted to 15°C to 30°C (59°F–86°F).

Keep the vials in the original carton until just prior to preparation of the injections in order to protect from light.

Once the solution has been drawn into the syringes, the injections should be administered as soon as possible.

Discard any unused portion of the solution.

Formulation Description

LEN injection is packaged in one of two different injection kits containing the following:

- Vial access device injection kit:
  - Two single-dose clear glass vials, each containing sufficient volume to allow withdrawal of 463.5 mg/1.5 mL (309 mg/mL) of LEN. The injection solution is sterile, preservative-free, clear, and yellow with no visible particles. Vials are sealed with a stopper and aluminium overseal with flip-off cap.
  - Two vial access devices, 2 disposable syringes, and 2 injection safety needles for subcutaneous injection (22-gauge, ½ inch).
- Withdrawal needle injection kit:
  - Two single-dose clear glass vials, each containing sufficient volume to allow withdrawal of 463.5 mg/1.5 mL (309 mg/mL) of LEN. The injection solution is sterile, preservative-free, clear, and yellow with no visible particles. Vials are sealed with a stopper and aluminium overseal with flip-off cap.
  - Two disposable syringes, 2 withdrawal needles (18-gauge, 1.5 inch), and 2 injection safety needles for subcutaneous injection (22-gauge, ½ inch).

The vial stoppers are not made with natural rubber latex.

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Additional Storage and Handling Recommendations[2]

Storage and Handling

Refer to Product Labeling section for storage and handling. Do not use vials beyond expiration date.

In-Use

After the vial is removed from the original carton, the solution should be administrated as soon as possible. If the solution is not used within 4 hours, discard the solution.

Photosensitivity

LEN injection, 309 mg/mL, is photosensitive. Minimize exposure to light before and after preparation for use.

Alternative Storage and Stability Information[2]

The table below summarizes available data from in-house studies regarding the storage of LEN injection solution in varying conditions. The "acceptable duration" refers to the stability of LEN injection 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 LEN injection Solution[2]

Storage Condition	Package Type	Acceptable Duration
-20°C (-4°F)[a]	Original vial[b]	1 month
50°C (122°F)[a]	Original vial[b]	2 weeks
5°C (41°F)[a]	Original vial[b]	12 months
In-use photostability (exposure to ultraviolet/visible light)	In original vial or in syringe	4 hours total

[a]No exposure to light.
[b]Original vial removed from dosing kit.

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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