GILEAD | Medical Information

Yeztugo® (lenacapavir) Administration Outside the Dosing Window

This document is in response to your request for information regarding Yeztugo® (lenacapavir [LEN]) and its administration outside the dosing window.

Gilead Sciences is unable to provide treatment recommendations. We recommend that you use your best clinical judgment in guiding therapy based on the individual's therapeutic goals.

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]

Dosing Schedule

The efficacy of LEN has only been established with the following initiation and every 6-month continuation injection dosing schedule as shown below in Table 1. There is a ±2 week range (4-week injection window) to the continuation injection given every 26 weeks from the date of last injection.

Table 1. Dosing Schedule for LEN Initiation and Continuation in Adults and Adolescents Weighing ≥35 kg

Time	Dosage
Dosage of LEN: Initiation[a]	
Day 1	927 mg by SUBQ injection (2 x 1.5 mL injections) and 600 mg orally (2 x 300 mg tablets)
Day 2	600 mg orally (2 x 300 mg tablets)
Dosage of LEN: Continuation	
Every 6-months (26 weeks)[b] +/- 2 weeks	927 mg SUBQ injection (2 x 1.5 mL injections)

Abbreviations: SUBQ=subcutaneous

[a] The complete initiation dosing schedule, consisting of SUBQ injections and oral tablets, is required; the efficacy of LEN has only been established with this dosing schedule.

[b] From the date of the last injection.

Adherence

Prior to starting LEN, healthcare providers should select individuals who agree to the required testing and every 6-month injection dosing schedule, and counsel individuals about the importance of adherence to scheduled LEN dosing visits to help reduce the chance of acquiring HIV-1 and development of resistance.

It is important to select individuals who agree to the required injection dosing schedule because non-adherence to every-6-month injections or missed doses could lead to HIV-1 acquisition and development of resistance. In the event of a missed injection, please refer to Section 2.4 of the Prescribing Information for the appropriate dosing schedule.

Available Data

A literature search was conducted in Ovid MEDLINE and Embase databases for studies published between 1946 and June 18, 2025 using the search terms Yeztugo, lenacapavir, pre-exposure prophylaxis, PrEP, early dosing, late dosing, and other related search terms. No relevant citations were identified.

Reference

1. Enclosed, Gilead Sciences Inc. YEZTUGO® (lenacapavir) tablets, for oral use. YEZTUGO® (lenacapavir) injection, for subcutaneous use. U.S. Prescribing Information. Foster City, CA.

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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