

Yeztugo[®] (lenacapavir)

Packaging (How Supplied)

This document is in response to your request for information regarding Yeztugo[®] (lenacapavir [LEN]) and its packaging.

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 Labeling¹

How Supplied

Oral Tablets Packaged in a Bottle

- 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 (NDC 61958-3401-1), a silica gel desiccant, polyester coil, and is closed with a child-resistant closure. Do not remove the desiccant packet. Keep bottle tightly closed. Dispense and store only in the original container.

Injections Packaged in a Dosing Kit

LEN injection is packaged in a dosing kit (NDC 61958-3402-1) containing:

- 2 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 aluminum overseal with flip-off cap.
- 2 disposable syringes, 2 withdrawal needles (18-gauge, 1½ inch), and 2 injection safety needles for subcutaneous injection (22-gauge, ½ inch).

Available Data¹

The initiation of LEN requires both the oral tablets and SUBQ injections. LEN bottles and the injection dosing kit contain different NDC numbers. They are packaged separately but will be shipped together. For continuation dosing, only the SUBQ injections of LEN are required. Please see below for product packaging images, NDC numbers, and contents (note: images are not to actual size).

Figure 1. LEN Bottle and Injection Dosing Kit Packaging Contents¹

Only use the needles provided in the injection kit. All components are for single use only.

LEN Bottle (NDC 61958-3401-1) (Each tablet contains 300 mg of lenacapavir)	LEN Injection Dosing Kit (NDC 61958-3402-1) (Each single-dose vial contains 463.5 mg/1.5 mL of lenacapavir)
 <p>Each bottle contains 4 tablets:</p> <ul style="list-style-type: none">• Beige-colored• Capsule-shaped• Film-coated• Debossed with 'GSI' on one side and '62L' on the other side	 <p>Each injection dosing kit contains all the necessary components for injecting one complete dose (two 1.5 mL injections) of YEZTUGO:</p> <ul style="list-style-type: none">• 2 single-dose clear glass vials containing:<ul style="list-style-type: none">• Clear, yellow solution with no visible particles• Sterile• Preservative-free• 2 disposable syringes• 2 withdrawal needles (18-gauge, 1.5-inch)• 2 injection safety needles for subcutaneous injection (22-gauge, 0.5-inch)

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.

Abbreviations

LEN=lenacapavir

NDC=National Drug Code

SUBQ=subcutaneous(ly)

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

Data Privacy

The Medical Information service at Gilead Sciences may collect, store and use your personal information to provide a response to your medical request. We may share your information with other Gilead Sciences colleagues to ensure that your request is addressed appropriately. If you report an adverse event or concern about the quality of a Gilead or Kite product, we will need to use the information you have given us in order to meet our regulatory requirements in relation to the safety of our medicines.

It may be necessary for us to share your information with Gilead's affiliates, business partners, service providers and regulatory authorities located in countries besides your own. Gilead Sciences has implemented measures to protect the personal information you provide. Please see the Gilead Privacy Statement (www.gilead.com/privacy-statements) for more information about how Gilead handles your personal information and your rights. If you have any further questions about the use of your personal information, please contact privacy@gilead.com.

YEZTUGO, GILEAD, and the GILEAD logo are registered trademarks of Gilead Sciences, Inc., or its related companies.

© 2025 Gilead Sciences, Inc.