

Yeztugo[®] (lenacapavir) HIV-2 Pre-Exposure Prophylaxis

This document is in response to your request for information regarding Yeztugo[®] (lenacapavir [LEN]) and its use for HIV-2 pre-exposure prophylaxis (PrEP).

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

LEN is indicated for PrEP to reduce the risk of sexually acquired HIV-1 in adults and adolescents weighing at least 35 kg who are at risk for HIV-1 acquisition. Individuals must have a negative HIV-1 test prior to initiating LEN.

Antiviral Activity in Cell Culture

LEN has antiviral activity that is specific to human immunodeficiency virus (HIV-1 and HIV-2). The antiviral activity of LEN against laboratory and clinical isolates of HIV-1 was assessed in T-lymphoblastoid cell lines, peripheral blood mononuclear cells (PBMCs), primary monocyte/macrophage cells, and CD4+ T-lymphocytes with half maximal effective concentration (EC₅₀) values ranging from 30 to 190 pM. LEN displayed antiviral activity in cell culture against all HIV-1 groups (M, N, O), including subtypes A, A1, AE, AG, B, BF, C, D, E, F, G with EC₅₀ values ranging from 20 and 160 pM. The median EC₅₀ value for subtype B isolates (n=8) was 40 pM. LEN was 15- to 25-fold less active against HIV-2 isolates relative to HIV-1.

Literature Search

A literature search was conducted in Ovid MEDLINE and Embase databases for studies published between 1946 and May 1, 2026 using search terms that included Yeztugo, lenacapavir, PrEP, HIV-2 and related search terms. No relevant citations were found.

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.

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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