GILEAD | Medical Information

Yeztugo® (lenacapavir) Bone Safety Profile

This document is in response to your request for information regarding Yeztugo® (lenacapavir [LEN]) and bone safety data. Currently, there are no data to address this inquiry.

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]

There is no information in the LEN product labeling about bone safety related to LEN.

Clinical Data on Bone Safety

In the PURPOSE 1 and PURPOSE 2 studies, no bone safety data was collected per protocol and therefore the effect of LEN for HIV-1 pre-exposure prophylaxis (PrEP) on bone safety in HIV-negative individuals was not reported.[2,3]

Literature Search

A literature search was conducted in Ovid MEDLINE and Embase databases for studies published between 1946 and June 18, 2025 using search terms that included Yeztugo, lenacapavir, PrEP, bone, bone mineral density, DXA, osteoporosis, osteopenia, Vitamin D, calcium, 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.
2. Bekker LG, Das M, Abdool Karim Q, et al. Twice-Yearly Lenacapavir or Daily F/TAF for HIV Prevention in Cisgender Women [Protocol]. *N Engl J Med.* 2024:1-672.
3. Kelley CF, Acevedo-Quinones M, Agwu AL, et al. Twice-Yearly Lenacapavir for HIV Prevention in Men and Gender-Diverse Persons [Protocol]. *N Engl J Med.* 2024.

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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