GILEAD | Medical Information

Yeztugo® (lenacapavir) Lipid Safety Profile

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

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 use of FTC/TAF for prevention of HIV-1 in individuals at risk of HIV-1 from receptive vaginal sex is investigational and has not been approved by any regulatory authority. The full indication, important safety information, and boxed warning(s) are available at:
www.gilead.com/-/media/files/pdfs/medicines/hiv/yeztugo/yeztugo_pi;
www.gilead.com/-/media/files/pdfs/medicines/hiv/descovy/descovy_pi;
www.gilead.com/-/media/files/pdfs/medicines/hiv/truvada/truvada_pi.

Summary

Product Labeling[1]

There is no information in the LEN product labeling about the lipid safety profile of LEN.

Clinical Data on Lipid Safety[2-5]

In PURPOSE 1 and PURPOSE 2, participants received metabolic assessments including fasting lipid panels on Day 1, Week 26, and Week 52, followed by every 26 weeks after. In PURPOSE 1, no hyperlipidemia, including Grade 3, was reported in the LEN and FTC/TDF groups, and 1 (<0.1%) was reported in the FTC/TAF group. In PUROSE 2, there was one case of Grade 3 hyperlipidemia which was reported in the LEN group (<0.1%) and none in the FTC/TDF group.

Clinical Data on Lipid Safety

PURPOSE 1 is an ongoing, phase 3, double-blind, randomized study evaluating the efficacy and safety of twice-yearly SUBQ LEN (n=2134) and once-daily oral FTC/TAF (n=2136) or FTC/TDF (active control; n=1068) for HIV-1 PrEP in 5338 cisgender women and adolescent girls (16–25 years old) across South Africa and Uganda. Among the clinical laboratory assessments conducted, participants received metabolic assessments including fasting lipid panels on Day 1, Week 26, and Week 52, followed by every 26 weeks after.[2] No hyperlipidemia, including Grade 3, was reported in the LEN and FTC/TDF groups, and 1 (<0.1%) was reported in the FTC/TAF group.[3]

PURPOSE 2 is an ongoing, phase 3, double-blind, randomized study evaluating the efficacy and safety of twice-yearly SUBQ LEN (n=2179) or once-daily oral FTC/TDF (n=1086) for HIV-1 PrEP in cisgender gay, bisexual, and other men, TGW, TGM, and GNB individuals in

Argentina, Brazil, Mexico, Peru, South Africa, Thailand, and the US who have condomless receptive anal sex with partners assigned male at birth (N=3265). Among the clinical laboratory assessments conducted, participants received metabolic assessments including fasting lipid panels on Day 1, Week 26, and Week 52, followed by every 26 weeks after.[4] One case of hyperlipidemia which was Grade 3 was reported in the LEN group (<0.1%) and none in the FTC/TDF group.[5]

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. Bekker LG, Das M, Abdool Karim Q, et al. Twice-Yearly Lenacapavir or Daily F/TAF for HIV Prevention in Cisgender Women [Supplementary Appendix]. *N Engl J Med.* 2024:1-69.
4. 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.
5. Kelley CF, Acevedo-Quinones M, Agwu AL, et al. Twice-Yearly Lenacapavir for HIV Prevention in Men and Gender-Diverse Persons [Supplementary Appendix]. *N Engl J Med.* 2024.

Abbreviations

FTC=emtricitabine
GNB=gender non-binary
LEN=lenacapavir
PrEP=pre-exposure prophylaxis
SUBQ=subcutaneous(ly)
TAF=tenofovir alafenamide
TDF=tenofovir disoproxil fumarate
TGM=transgender men
TGW=transgender women

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Yeztugo, Descovy, and Truvada US Prescribing Information available at:
www.gilead.com/-/media/files/pdfs/medicines/hiv/yeztugo/yeztugo_pi;
www.gilead.com/-/media/files/pdfs/medicines/hiv/descovy/descovy_pi;
www.gilead.com/-/media/files/pdfs/medicines/hiv/truvada/truvada_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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