Lenacapavir (LEN)

Updated: March 31, 2026
Reviewed: March 31, 2026

Summary

- Pharmacokinetic (PK) data are insufficient to make dosing recommendations for oral or long-acting injectable lenacapavir (LEN) during pregnancy or breastfeeding.
- Clinical data are insufficient to characterize the risk for congenital anomalies associated with *in utero* exposure to LEN. No reproductive toxicity or teratogenicity concerns were identified in animal studies.
- LEN is U.S. Food and Drug Administration (FDA) approved for heavily treatment-experienced adults with multidrug-resistant HIV-1 infection whose current antiretroviral (ARV) regimen is failing due to resistance, intolerance, or safety considerations.
- LEN is FDA approved for HIV pre-exposure prophylaxis (PrEP).

Human Studies in Pregnancy

Pharmacokinetics

In the PURPOSE 1 study,[1] a Phase 3, double-blind, randomized controlled trial of adolescent girls and young women in South Africa and Uganda, participants were assigned to receive twice-yearly subcutaneous (SQ) LEN versus daily oral emtricitabine (FTC) plus tenofovir alafenamide (TAF) or daily oral FTC plus tenofovir disoproxil fumarate (TDF; active control) for HIV PrEP. A population PK analysis of the PURPOSE 1 study showed no statistically significant differences in LEN exposure with pregnancy trimester or postpartum status compared with non-pregnant and non-lactating individuals.[2]

Placental and Breast Milk Passage

No data are available regarding placental transfer of LEN. Among eight matched pairs in the PURPOSE 1 study, LEN was present in breastmilk with a median milk-to-plasma ratio of 0.63. Median infant-to-mother plasma ratio among breastfed infants was low at 0.05 in 11 dyads.[2]

Teratogenicity/Adverse Pregnancy Outcomes

The Antiretroviral Pregnancy Registry (APR) provides updated birth defect data for LEN and other ARV drugs twice a year through an interim report released in June and December. The APR has not monitored sufficient numbers of first-trimester exposures to LEN to report on the risk of overall birth defects.

In the PURPOSE 1 study,[1] a Phase 3, double-blind, randomized controlled trial of adolescent girls and young women in South Africa and Uganda, participants were assigned to receive twice-yearly SQ LEN versus daily oral FTC plus TAF or daily oral FTC plus TDF (active control) for HIV PrEP. At the time of the interim analysis, there were 510 pregnancies among 487 participants—193 in the LEN group, 219 in the FTC/TAF group, and 98 in the FTC/TDF group—with 277 delivery outcomes

and 233 ongoing pregnancies. Pregnancy outcomes were similar to those expected for the general population. No documented incident HIV was reported among participants receiving LEN (see PrEP to Prevent HIV During Periconception, Antepartum, and Postpartum Periods).

Animal Studies

Carcinogenicity

LEN was not mutagenic in a series of *in vitro* and animal *in vivo* genotoxic assays; LEN was not carcinogenic in a mouse model.[3]

Reproduction/Fertility

In rats, no effects on fertility, mating performance, or early embryonic development were observed at LEN exposures 5 times greater than the exposure in humans at recommended doses.[3]

Teratogenicity/Adverse Pregnancy Outcomes

No significant toxicological effects on embryo-fetal development in rats and rabbits or pre- and postnatal development in rats were observed at area under the curve drug exposures approximately 16 times (rats) and 39 times (rabbits) the exposure in humans at recommended doses.[3]

Placental and Breast Milk Passage

LEN was detected at low levels in the plasma of nursing rat pups.[3]

Excerpt From Table 14

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy
Lenacapavir (LEN) *Sunlenca (treatment) Yeztugo (PrEP)*	**LEN (Sunlenca and Yeztugo)** • LEN 300-mg tablets for oral administration • LEN 463.5 mg/1.5 mL for SQ injection	**Pregnancy** *PK in Pregnancy* • Insufficient data to make dosing recommendations *Dosing in Pregnancy* • Insufficient data to make dosing recommendations **Standard Adult Doses** *Initiation Option 1* • Day 1: 927 mg by SQ 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). *Initiation Option 2* • Day 1: 600 mg orally (2 x 300-mg tablets) • Day 2: 600 mg orally (2 x 300-mg tablets) • Day 8: 300 mg orally (1 x 300-mg tablet) • Day 15: 927 mg by SQ injection (2 x 1.5 mL injections) *Maintenance Dosing* • 927 mg by SQ injection (2 x 1.5 mL injections) every 26 weeks +/- 2 weeks from date of last injection	No human data are available regarding placental passage. There is passage via breastmilk. Data are insufficient to assess for teratogenicity in humans. No evidence of teratogenicity in rats or rabbits. **Note:** Please see FDA label for full list of drugs with potential interactions and drugs for which administration with LEN is contraindicated.

[a] Individual ARV drug doses may need to be adjusted in patients with renal or hepatic insufficiency (for details, see the Adult and Adolescent Antiretroviral Guidelines, Appendix B).

Key: ARV = antiretroviral; LEN = lenacapavir; PK = pharmacokinetic; SQ = subcutaneous

References

1. Bekker LG, Das M, Abdool Karim Q, et al. Twice-yearly lenacapavir or daily F/TAF for HIV prevention in cisgender women. *N Engl J Med*. 2024. Available at: https://pubmed.ncbi.nlm.nih.gov/39046157.

2. Bekker LG, Moodley D, Harkoo I, et al. Inclusion of pregnant and lactating people in the PURPOSE 1 study: efficacy, safety, and pharmacokinetics. Presented at: 13th International AIDS Society Conference on HIV Science; 2025. Kigali, Rwanda. Available at: https://onlinelibrary.wiley.com/doi/epdf/10.1002/jia2.26518.

3. Sunlenca (lenacapavir) package insert [package insert]. Food and Drug Administration. 2024. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/215973s006,215974s008lbl.pdf.