GILEAD | Medical Information

Sunlenca® (lenacapavir) Use in Pregnancy or Breastfeeding

This document is in response to your request for information regarding the use of Sunlenca® (lenacapavir [LEN]) for the treatment of HIV-1 in women who are pregnant or breastfeeding.

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 warnings are available at: www.gilead.com/-/media/files/pdfs/medicines/hiv/sunlenca/sunlenca_pi.

Product Labeling[1]

Pregnancy

Pregnancy exposure registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in individuals exposed to LEN during pregnancy. Healthcare providers are encouraged to register patients by calling the Antiretroviral Pregnancy Registry (APR) at 1-800-258-4263.

Risk summary

There are insufficient human data on the use of LEN during pregnancy to inform a drug-associated risk of birth defects and miscarriage. In animal reproduction studies, no adverse developmental effects were observed when LEN was administered to rats and rabbits at exposures (AUC) ≥16 times the exposure in humans at the recommended human dose (RHD) of LEN (see Data).

The background risk of major birth defects and miscarriage for the indicated population is unknown. The background rate of major birth defects in a US reference population of the Metropolitan Atlanta Congenital Defects Program is 2.7%. The rate of miscarriage is not reported in the APR. The estimated background rate of miscarriage in clinically recognized pregnancies in the US general population is 15% to 20%.

Data

Animal data

LEN was administered intravenously to pregnant rabbits (up to 20 mg/kg/day on gestation days (GD) 7 to 19), orally to rats (up to 300 mg/kg/day on GD 6 to 17), and subcutaneously to rats (up to 300 mg/kg on GD 6). No significant toxicological effects on embryo-fetal (rats and rabbits) or pre/postnatal (rats) development were observed at exposures (AUC) approximately 16 times (rats) and 39 times (rabbits) the exposure in humans at the recommended human dose (RHD) of LEN.

Lactation

Risk summary

It is not known whether LEN is present in human breast milk, affects human milk production, or has effects on the breastfed infant. After administration to pregnant rats, LEN was detected in the plasma of nursing rat pups, without effects on these nursing pups (see Data).

Potential risks of breastfeeding include: (1) HIV-1 transmission (in infants without HIV-1), (2) developing viral resistance (in infants with HIV-1), and (3) adverse reactions in a breastfed infant similar to those seen in adults.

Data

LEN was detected at low levels in the plasma of nursing rat pups in the pre/postnatal development study (post-natal day 10).

APR Data on LEN Use in Pregnancy

Healthcare providers are encouraged to register patients who become pregnant to the APR by calling 1-800-258-4263.

The APR is intended to provide an early signal of teratogenicity associated with prenatal use of ARVs. The registry is ongoing; healthcare providers are strongly encouraged to report eligible patients to the registry. Further information is available at https://apregistry.com/.[2]

LEN Data in the APR[2]

The June 2025 interim report includes prospective reports of 24,443 pregnancies with follow-up data through January 31, 2025. The current APR reported 2 cases of LEN exposure during the first trimester. Currently, there are insufficient exposure data on LEN to detect a pattern of increase in risk of birth defects.

Clinical Data on LEN Use During Lactation

Pregnancy and Breastfeeding Data from Clinical Studies in PWH

CAPELLA (GS-US-200-4625) is an ongoing, phase 2/3, double-blinded, placebo-controlled clinical study designed to evaluate LEN as an add-on therapy to a failing regimen in heavily treatment-experienced PWH with multidrug resistance.[3]

CALIBRATE (GS-US-200-4334) was a phase 2, randomized, open-label, active-controlled clinical study that evaluated LEN in treatment-naïve PWH.[4]

In both studies, a negative serum pregnancy test was required for all women at screening and lactating women must agree to discontinue nursing before the study drug(s) is administered.[5]

Breastfeeding Data from a PK Substudy in Participants without HIV-1

PURPOSE 1 (NCT04994509) is an ongoing, phase 3, double-blind, randomized, active-controlled study evaluating the efficacy and safety of twice-yearly SUBQ LEN and once-daily oral FTC/TAF for HIV-1 PrEP in cisgender women and adolescent girls across South Africa and Uganda. Additionally, a third group was assigned once-daily oral FTC/TDF, which served as the active control. Participants who discontinued blinded study drug were given the option to take open-label FTC/TDF. Randomized participants had body weight ≥35 kg and eGFR ≥60 mL/min.[6]

A nested PK substudy of participants who were randomly assigned to the LEN group and became pregnant during the study was conducted to assess systemic LEN concentrations during pregnancy and postpartum and to assess LEN concentrations in breast milk and infants. Pregnant participants received LEN SUBQ injections in the thigh and/or abdomen. Maternal plasma PK samples were taken at regular intervals in the first through third trimesters, and maternal plasma, infant plasma, and breast milk samples were assessed at approximately 3 and 6 months postpartum.[7]

At Weeks 26, 52, and 78, C_{trough} data were available from 107 first-trimester, 99 second-trimester, 59 third-trimester, and 65 postpartum visits. LEN exposures were similar in pregnant and non-pregnant participants. Furthermore, LEN PK were similar when LEN was injected in the thigh and the abdomen.[7]

LEN was found in breast milk, but LEN concentrations were very low in breastfed infants. In 102 matched pairs, the median (IQR) breastmilk-to-maternal plasma ratio was 0.52 (0.38–0.77). In 98 matched pairs, the median (IQR) breastfed-infant-to-maternal plasma ratio was 0.02 (0.01–0.05).[7]

Literature Search for the Use of LEN During Pregnancy or Breastfeeding in PWH

A literature search was conducted in Ovid MEDLINE and Embase databases for studies published between 1946 and September 16, 2025, using the search terms of Sunlenca, lenacapavir, pregnancy, lactation, and other related search terms. No relevant citations were identified.

References

1. Enclosed, Gilead Sciences Inc. SUNLENCA® (lenacapavir) tablets, for oral use. SUNLENCA® (lenacapavir) injection, for subcutaneous use. U.S. Prescribing Information. Foster City, CA.
2. Antiretroviral Pregnancy Registry Steering Committee. *The Antiretroviral Pregnancy Registry Interim Report: 01 January 1989 Through 31 January 2025. Morrisville, NC.* June 2025.
3. Molina JM, Segal-Maurer S, Stellbrink HJ, et al. Efficacy and Safety of Long-Acting Subcutaneous Lenacapavir in Phase 2/3 in Heavily Treatment- Experienced People with HIV: Week 26 results (CAPELLA study) [Presentation]. Paper presented at: 11th International Aids Society (IAS) Conference on HIV Science Virtual; 18-21 July, 2021.
4. Gupta SK, Berhe M, Crofoot G, et al. Long-acting Subcutaneous Lenacapavir Dosed Every 6 Months as part of a Combination Regimen in Treatment-Naïve People with HIV: Interim 16-week Results of a Randomized, Open-label, Phase 2 Induction-Maintenance Study (CALIBRATE)

[Presentation]. Paper presented at: 11th International Aids Society (IAS) Conference on HIV Science Virtual; 18-21 July, 2021.
5. Gilead Sciences Inc. Data on File.
6. 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;391(13):1179-1192.
7. Bekker L-G, Moodley D, Harkoo I, et al. Inclusion of Pregnant and Lactating People in the PURPOSE 1 Study: Efficacy, Safety, and Pharmacokinetics. [Presentation]. Paper presented at: 13th International AIDS Society (IAS) Conference on HIV Science; July 13–17, 2025; Kigali, Rwanda.

Abbreviations

APR=Antiretroviral Pregnancy Registry
AUC=area under the curve
C_{trough}=trough concentration
FTC=emtricitabine
GD=gestation day
LEN=lenacapavir
PK=pharmacokinetic(s)
PrEP=pre-exposure Prophylaxis
PWH=people with HIV
RHD=recommended human dose
SUBQ=subcutaneous
TAF=tenofovir alafenamide
TDF=tenofovir disoproxil fumarate

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Sunlenca US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/hiv/sunlenca/sunlenca_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.