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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.

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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

Available data from a randomized, controlled trial with lenacapavir use during pregnancy in individuals without HIV-1 have not identified a drug-associated risk for miscarriage, or adverse maternal or fetal outcomes when compared to an active control. The rate of major birth defects in LEN-exposed pregnancies did not exceed the background prevalence rates. The risk estimates are imprecise due to small numbers of exposed pregnancies. 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 of LEN.

The background risk of major birth defects and miscarriage for the indicated population is unknown. The background rate of major birth defects in a U.S. reference population of the Metropolitan Atlanta Congenital Defects Program (MACDP) 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 U.S. general population is 15 to 20%

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Data

Human data

In a randomized, controlled trial of individuals without HIV-1 in Uganda and South Africa, there were 208 pregnancies exposed to LEN with known outcomes and 132 deliveries (both live and non-live). In the active control arm of this trial, there were 109 pregnancies with known outcomes and 61 deliveries (both live and non-live). The adverse pregnancy outcomes of spontaneous abortion, stillbirth, preterm birth, and small for gestational age were similar across both treatment groups.

There were two major birth defects in the LEN arm. Both were ventricular septal defects. This resulted in a rate of major birth defects that fell within the background prevalence rate for major birth defects.

Concentrations of LEN during each trimester of pregnancy and postpartum were comparable to those in non-pregnant participants.

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 of LEN.

Lactation

Risk summary

LEN is present in human milk. LEN was detected at very low levels in infants who were breastfed by individuals who became pregnant while receiving LEN. No adverse effects of LEN in breastfed infants have been observed. It is not known if LEN affects milk production.

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

Human data

The median LEN concentration in human breast milk to maternal plasma ratio in participants (n=8) who received LEN was 0.63 (range: 0.29 to 1.90). The median infant-to-mother plasma ratio for LEN in infants (n=10) who were breastfed by individuals receiving LEN from 0 to less than 13 weeks after delivery was 0.06 (range: 0.01 to 0.20).

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 2026 interim report includes prospective reports of 24,898 pregnancies with follow-up data through January 31, 2026. The current APR reported 8 cases of LEN exposure during pregnancy. 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 Pregnancy

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]

Pregnancy and Breastfeeding Data 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 planned substudy evaluated endpoints including pregnancy outcomes, HIV acquisitions, AEs during pregnancy and postpartum, and observed and model-derived LEN plasma concentrations by pregnancy trimester and postpartum period.[7]

At the data cutoff, there were 509 pregnancies among 487 participants: 193 pregnancies in the LEN group, 218 in the FTC/TAF group, and 98 in the FTC/TDF group (Table 1.).[7] The study authors determined that pregnancy outcomes – including rates of spontaneous abortions, stillbirths, preterm births, and small-for-gestational-age births – were within the expected background rates reported in South Africa and Uganda.[7-9]

Overall, 10 congenital abnormalities were reported: LEN, n=6 (congenital hemangioma, umbilical hernia, left hand polydactyly, perimembranous ventricular septal defect, congenital ventricular septal defect, and congenital reducible umbilical hernia; each, n=1); FTC/TAF,

n=4 (infant bilateral hydrocele; right inguinal hernia, umbilical hernia, and neonatal jaundice; Down syndrome; and clubfoot; each, n=1).[10] All congenital anomalies were assessed by investigators as unrelated to study drug except for one ventricular septal defect in the LEN group, which was considered treatment-related.[7] The participant with an infant with polydactyly had a reported strong maternal family history of polydactyly.[11] The heterogeneous anomalies observed were considered consistent with background incidence and did not suggest a drug-related pattern.

Table 1. PURPOSE 1: Pregnancy Outcomes[7]

Pregnancy Outcomes, n or n/N (%)	LEN (n=184)	FTC/TAF (n=208)	FTC/TDF (n=95)	Total (n=487)
Participants with confirmed pregnancies	184	208	95	487
Confirmed pregnancies	193	218	98	509
Pregnancy incidence rate per 100 person-years[a]	10.0	11.2	10.2	10.5
Total pregnancy outcomes[b]	195	219	98	512
Live births	128/195 (66)	119/219 (54)	56/98 (57)	303/512 (59)
At term (≥37 to ≤42 weeks' gestation)	105/128 (82)	93/119 (78)	40/56 (71)	238/303 (79)
Preterm (<37 weeks' gestation)	14/128 (11)	19/119 (16)	11/56 (20)	44/303 (15)
Post-term (>42 weeks' gestation)	9/128 (7)	7/119 (6)	5/56 (9)	21/303 (7)
Congenital abnormality[c]	6/127 (5)	4/117 (3)	0	10/300 (3)
Small for gestational age[d]	11/128 (9)	12/119 (10)	9/56 (16)	32/303 (11)
Pregnancy losses	60/195 (31)	89/219 (41)	41/98 (42)	190/512 (37)
Stillbirth[e]	5/195 (3)	6/219 (3)	3/98 (3)	14/512 (3)
Induced or elective abortions	35/195 (18)	50/219 (23)	23/98 (23)	108/512 (21)
Spontaneous abortions[f]	20/195 (10)	33/219 (15)	15/98 (15)	68/512 (13)
Pregnancies with unknown outcomes[g]	7/195 (4)	11/219 (5)	1/98 (1)	19/512 (4)

[a]Pregnancy incidence rate is the number of confirmed pregnancies divided by person-years of follow-up; person-years of follow-up are the sum of all participants' total number of years (365.25 days) in the randomised, masked phase for the primary analysis (LEN 1934.1 years, FTC/TAF 1943.5 years, FTC/TDF 956.7, and total 4834.4).

[b]Total pregnancy outcomes includes the number of live births, pregnancy losses, and pregnancies with unknown outcome; one pregnancy can include multiple outcomes or births (three sets of twins: two sets in participants randomly allocated to LEN [one set of stillborn twins and one set of liveborn healthy twins] and one set in participants randomly allocated to FTC/TAF [liveborn and premature]); birth outcomes are reported for each individual infant.

[c]Includes one infant reported to have had a healthy outcome at birth whose congenital abnormality of umbilical hernia was first detected at approximately 4 months of age.

[d]Small for gestational age was defined as a weight under the 10th percentile by sex and gestational age.

[e]Stillbirth or intrauterine fetal demise defined as occurring at 20 weeks' gestation or longer. There was one set of stillbirth twins in the LEN group.

[f]Spontaneous abortion defined as occurring at less than 20 weeks' gestation; estimated gestational age data are missing for one infant in the FTC/TAF group.

[g]Unknown due to participant discontinuation for the following reasons: pregnancy (LEN [two]; FTC/TAF [two]); investigator's discretion (FTC/TAF [one]); withdrawal of consent (LEN [five] and FTC/TAF [four]); and loss to follow-up (FTC/TAF [four]; FTC/TDF [one]).

Additional safety outcomes during pregnancy and postpartum are presented in Table 2.[7]

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Table 2. PURPOSE 1: Safety Outcomes During Pregnancy and Postpartum[7]

AEs During Pregnancy and Postpartum,[a] n (%)		LEN (n=184)	FTC/TAF (n=208)	FTC/TDF (n=95)
Any AEs[b]		135 (73)	142 (68)	68 (72)
Grade ≥2		112 (61)	112 (54)	55 (58)
Grade ≥3		36 (20)	39 (19)	22 (23)
SAEs[b]		41 (22)	50 (24)	22 (23)
AEs leading to discontinuation of study drug[b]		1 (1)[c]	0	0
AEs occurring in ≥5% of participants in any randomized group[d]	Urinary tract infection	39 (21)	34 (16)	27 (28)
	Upper respiratory tract infection	20 (11)	16 (8)	6 (6)
	Vulvovaginal candidiasis	17 (9)	22 (11)	8 (8)
	Genitourinary chlamydia infection	16 (9)	10 (5)	8 (8)
	Vaginal discharge	13 (7)	6 (3)	6 (6)
	Vomiting	10 (5)	16 (8)	9 (9)
	Headache	10 (5)	15 (7)	4 (4)
	Malaria	10 (5)	6 (3)	4 (4)
	Nausea	7 (4)	10 (5)	8 (8)
	Morning sickness	3 (2)	5 (2)	6 (6)
	Death	0	0	0

[a]Adverse events and laboratory abnormalities that are reported here were those that occurred in participants who had received at least one dose of a study drug or placebo. Adverse events were coded according to the Medical Dictionary for Regulatory Activities (version 27.1) and graded according to the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events version 2.1. The pregnancy and postpartum period were defined as the time from the last menstrual period through to 6 weeks after the pregnancy outcome.
[b]Injection site reactions to non-study medications are included, but injection site reactions to the study SUBQ injection are excluded.
[c]Spontaneous abortion (investigator assessed as unrelated to study drug).
[d]Injection site reactions and spontaneous abortions have been excluded.

In addition, supplemental pregnancy and birth outcome data for all pregnancies diagnosed through the end of the RBP were reported. A total of 712 pregnancies were identified among 665 participants, including 269 pregnancies in the LEN group, 302 in the FTC/TAF group, and 141 in the FTC/TDF group (Table 3).[7,11] Pregnancy and birth outcomes in this expanded follow-up period were generally consistent with those observed in the primary analysis.[7]

Table 3. PURPOSE 1: Supplemental Pregnancy Outcomes Through the End of the RBP[11]

Pregnancy Outcomes, n or n (%)	LEN (n=253)	FTC/TAF (n=280)	FTC/TDF (n=132)	Total (n=665)
Participants with confirmed pregnancies	253	280	132	665
Confirmed pregnancies	269	302	141	712
Total Pregnancy Outcomes[a]	272	304	141	717
Live births	172 (63)	167 (55)	84 (60)	423 (59)
At term (≥37 to ≤42 weeks' gestation)	139 (81)	127 (76)	61 (73)	327 (77)
Preterm (<37 weeks' gestation)	22 (13)	28 (17)	18 (21)	68 (16)
Post-term (>42 weeks' gestation)	11 (6)	12 (7)	5 (6)	28 (7)
Congenital abnormality	6 (3)	7 (4)	1 (1)	14 (3)

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Pregnancy Outcomes, n or n (%)	LEN (n=253)	FTC/TAF (n=280)	FTC/TDF (n=132)	Total (n=665)
Small for gestational age[b]	22 (13)	15 (9)	10 (12)	47 (11)
Pregnancy losses	91 (33)	123 (40)	53 (38)	267 (37)
Stillbirth[c]	9 (3)	8 (3)	4 (3)	21 (3)
Induced or elective abortions	49 (18)	71 (23)	28 (20)	148 (21)
Spontaneous abortions[d]	33 (12)	44 (14)	21 (15)	98 (14)
Pregnancies with Unknown Outcomes[e]	9 (3)	14 (5)	4 (3)	27 (4)

[a]A single pregnancy may include multiple outcomes/births (five sets of twins: three sets in participants randomized to LEN and two sets in participants randomized to FTC/TAF). Birth outcomes were reported for each individual infant.
[b]Small for gestational age was defined as weight <10th percentile by sex/gestational age.
[c]Stillbirth/intrauterine fetal demise defined as occurring ≥20 weeks' gestation. There was one set of stillbirth twins in the LEN group.
[d]Spontaneous abortion defined as occurring at <20 weeks' gestation.
[e]Unknown due to participant discontinuation for the following reasons: pregnancy (LEN, n=3; FTC/TAF, n=4; FTC/TDF, n=1); investigator's discretion (FTC/TAF, n=2); withdrew consent (LEN, n=5; FTC/TAF, n=5); lost to follow-up (FTC/TAF, n=2; FTC/TDF, n=1); completed study (LEN, n=1; FTC/TAF, n=1; FTC/TDF, n=1); ongoing pregnancy (FTC/TDF, n=1).

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, as well as LEN concentrations in breast milk and infants. Maternal plasma PK samples were collected in regular intervals throughout the first, second, and third trimesters, and maternal plasma, infant plasma, and breast milk samples were obtained at approximately 3 and 6 months postpartum.[7]

Overall, 601 participants were included in the population PK analysis, including 296 participants who became pregnant while receiving LEN and had at least one quantifiable PK sample collected during pregnancy. Pregnant participants received SUBQ LEN injections in the thigh or abdomen.[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.[10]

No observable trimester-related trends in LEN were identified across pregnancy trimesters or during the postpartum period.[7] Model-derived LEN C_{max} and C_{trough} concentrations were comparable across participants between pregnancy trimesters, postpartum, and non-pregnant individuals.[10] Population PK analyses further demonstrated that gestational age, pregnancy trimester, and postpartum status were not statistically significant covariates of LEN exposure. LEN PK were also similar when LEN was injected in the thigh or 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). No adverse effects were identified among breastfed infants exposed to LEN.[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 2nd, 2026, using the search terms of Sunlenca,

lenacapavir, pregnancy, lactation, and other related search terms. No relevant citations were identified.

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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

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