Lamivudine (Epivir, 3TC)

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

Summary

- No dose adjustments are required for lamivudine (3TC) during pregnancy.
- First-trimester exposure to 3TC is not associated with increased risk of congenital anomalies.
- 3TC use during pregnancy has not been associated with adverse maternal, obstetric, or infant outcomes.

Human Studies in Pregnancy

Pharmacokinetics

In an analysis of specimens obtained from 228 pregnant women in the antepartum (114), intrapartum (123), and postpartum (47) periods in which all participants received standard adult once-daily or twice-daily 3TC doses,[1] the apparent clearance rate during pregnancy was 22% higher than in the postpartum period, but the resulting lower 3TC exposure was not subtherapeutic and was relatively close to exposure reported previously for nonpregnant adults.[1] Thus, no dose adjustment is necessary for 3TC during pregnancy.

Placental and Breast Milk Passage

3TC readily crosses the placenta in humans, achieving cord blood concentrations comparable to maternal plasma concentrations.[2] In a study of 123 mother–infant pairs, the placental transfer, expressed as the fetal-to-maternal area under the curve (AUC) ratio, was 0.86. The 3TC amniotic fluid accumulation, expressed as the amniotic fluid–to–fetal AUC ratio, was 2.9. Urinary excretion of 3TC by the fetus can cause 3TC to accumulate in the amniotic fluid.[1,3]

3TC is excreted into human breast milk. In a study in Kenya of 67 nursing mothers who received a combination regimen of zidovudine, 3TC, and nevirapine, the median breast milk 3TC concentration was 1,214 ng/mL and the median ratio of 3TC concentration in breast milk to the 3TC concentration in plasma was 2.56.[4] In infants who were exposed to 3TC only via breast milk, the median plasma 3TC concentration was 23 ng/mL (inhibitory concentration 50% of 3TC against wild-type HIV = 0.6–21 ng/mL). In a separate study of breastfeeding women in Malawi who were receiving 3TC in combination with tenofovir disoproxil fumarate and efavirenz, concentrations of 3TC in breast milk were higher than those in maternal plasma at 1 month (3.29-fold higher) and 12 months (2.35fold higher) after delivery. Infant evaluations at ages 6 and 12 months, on the other hand, revealed median plasma 3TC concentrations of only 2.5 ng/mL (with an interquartile range [IQR] of 2.5–7.6) and 0 ng/mL (with an IQR of 0–2.5), respectively.[5] Lower 3TC exposure in these older infants is attributable to increased renal clearance with age.

Teratogenicity/Adverse Pregnancy Outcomes

Based on prospective reports to the Antiretroviral Pregnancy Registry (APR), the U.S. Food and Drug Administration has concluded that no difference exists between the overall risk of birth defects for 3TC and the background birth defect rate in the United States.

In a large French cohort with data collected between 1994 and 2010, first-trimester 3TC exposure was associated with an increased risk of overall birth defects (adjusted odds ratio 1.37; 95% confidence interval [CI], 1.06–1.73), but not of a defect in any specific organ system or of a specific birth defect.[6] In the United States, the APR provides updated birth defect data for 3TC and other antiretroviral (ARV) drugs twice a year through an interim report released in June and December. The APR has monitored sufficient numbers of first-trimester exposures to 3TC to detect at least a 1.5-fold increase in the risk of overall birth defects and at least a twofold increase in the risk of cardiovascular and genitourinary defects (the more common classes of birth defects in the general population). No such increase in the risk of birth defects has been observed with 3TC. Figure 1. Summary of Birth Defects Among First Trimester Exposures in the APR interim report provides a summary of the number and prevalence of birth defects per live birth among cases of first-trimester exposure to 3TC and other ARV drugs reported to the APR where there are sufficient data to determine 95% confidence intervals. The data in Figure 1 can be compared with the total prevalence of birth defects in the U.S. population (2.72 birth defects per 100 live births) based on the Centers for Disease Control and Prevention surveillance system (The Metropolitan Atlanta Congenital Defects Program [MACDP]) and with the Texas Birth Defects Registry ([TBDR] 5.07 per 100 live births).

An analysis of APR data demonstrated a lower risk of spontaneous abortions, induced abortions, and preterm births with use of 3TC-containing regimens than with use of ARV regimens that do not include 3TC.[7]

Other Safety Information

In a large U.S. cohort study of infants without HIV born to women with HIV, 3TC exposure during pregnancy was not associated with increased risk of adverse infant outcomes in any of the growth, hearing, language, neurology, neurodevelopment, metabolic, hematologic/clinical chemistry, and blood lactate domains assessed.[8]

Animal Studies

Carcinogenicity

3TC was found to have weak mutagenic activity in one *in vitro* assay, but no evidence of *in vivo* genotoxicity was found in rats at 35 to 45 times the exposure observed in humans who received the standard dose. Long-term animal studies have shown no evidence of carcinogenicity at exposures that were 10 times (in mice) and 58 times (in rats) the exposure in humans who received the standard dose.[9]

Reproduction/Fertility

In rats that received 3TC in doses up to 4,000 mg/kg per day, which produced plasma levels 47 to 70 times those in humans who received the standard dose, no evidence was found of impaired fertility or of effects on the offspring's survival, growth, or development up to the time of weaning.[9]

Teratogenicity/Adverse Pregnancy Outcomes

No evidence exists of 3TC-induced teratogenicity in rats and rabbits at plasma concentrations of 3TC that are 35 times those in human plasma. Early embryo lethality was seen in rabbits at exposures that were similar to human therapeutic exposure, but no early embryo lethality was seen in rats with 3TC exposures that were 35 times the exposure in humans who received the standard dose.[9]

Placental and Breast Milk Passage

In studies of pregnant rats, 3TC was transferred to the fetus through the placenta.[9]

Excerpt From Table 14

Note: When using fixed-dose combination (FDC) tablets, refer to other sections in Appendix B and Table 14 in the Perinatal Guidelines for information about the dosing and safety of individual drug components of the FDC tablet during pregnancy.

Generic Name (Abbreviation) *Trade Name*	**Formulation**	**Dosing Recommendations**[a]	**Use in Pregnancy**
Lamivudine (3TC) *Epivir* (3TC/TDF) *Cimduo* (3TC/ZDV) (3TC/DOR/TDF) *Delstrigo* (3TC/DTG) *Dovato* (3TC/ABC) (3TC/EFV/TDF) *Symfi* (3TC/EFV/TDF) (3TC/ABC/DTG) *Triumeq* (3TC/ABC/DTG) *Triumeq PD* (3TC/ABC/ZDV) **Note:** Generic products are available for some formulations[c].	**3TC (Epivir)**[c] *Tablets* • 150 mg • 300 mg *Oral Solution* • 10 mg/mL **3TC/TDF (Cimduo)** • 3TC 300-mg/TDF 300-mg tablet **3TC/ZDV**[c] • 3TC 150-mg/ZDV 300-mg tablet **3TC/DOR/TDF (Delstrigo)** • 3TC 300-mg/DOR 100-mg/TDF 300-mg tablet **3TC/DTG (Dovato)** • 3TC 300-mg/DTG 50-mg tablet **3TC/ABC**[c] • 3TC 300-mg/ABC 600-mg tablet **3TC/EFV/TDF (Symfi)**[c] • 3TC 300-mg/EFV 600-mg/TDF 300-mg tablet **3TC/EFV/TDF**[c] • 3TC 300-mg/EFV 400-mg/TDF 300-mg tablet **3TC/ABC/DTG (Triumeq)** • 3TC 300-mg/ABC 600-mg/DTG 50-mg tablet	**Pregnancy** *PK in Pregnancy* • PK not significantly altered in pregnancy *Dosing in Pregnancy* • No change in dose indicated For guidance about the use of combination products in pregnancy, please see the specific sections on other components (ABC, DOR, DTG, EFV, TDF, ZDV). **Standard Adult Doses** *3TC (Epivir)* • 3TC 150 mg twice daily or 300 mg once daily, without regard to food *3TC/TDF (Cimduo)* • One tablet once daily without regard to food *3TC/ZDV* • One tablet twice daily without regard to food *3TC/DOR/TDF (Delstrigo)* • One tablet once daily without regard to food *3TC/DTG (Dovato)* • One tablet once daily without regard to food *3TC/ABC* • One tablet once daily without regard to food	High placental transfer to fetus[b] No evidence of human teratogenicity (can rule out 1.5-fold increase in overall birth defects) If patient has HBV/HIV coinfection, it is possible that an HBV flare may occur if the drug is stopped; see Hepatitis B Virus/HIV Coinfection. 3TC products that were developed specifically for treatment of HBV (e.g., Epivir-HBV) contain a lower dose of 3TC that **is not appropriate** for treatment of HIV. **Note:** Please see FDA label for full list of drugs with potential interactions and drugs for which administration with 3TC is contraindicated.

Excerpt From Table 14

Generic Name (Abbreviation) *Trade Name*	**Formulation**	**Dosing Recommendations**[a]	**Use in Pregnancy**
	3TC/ABC/DTG (Triumeq PD) • Pediatric dispersible tablet: 3TC 30-mg/ABC 60-mg/ DTG 5-mg **3TC/ABC/ZDV**[c] • 3TC 150-mg/ABC 300-mg/ ZDV 300-mg tablet	*3TC/EFV/TDF (Symfi or formulation with EFV 400mg)* • One tablet once daily on an empty stomach and preferably at bedtime *3TC/ABC/DTG (Triumeq)* • One tablet once daily without regard to food *3TC/ABC/DTG (Triumeq PD)* • Triumeq PD is a pediatric dispersible tablet not intended for use in adults; it is not recommended for use in patients weighing 25 kg or more. *3TC/ABC/ZDV* • One tablet twice daily without regard to food	

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

[b] Placental transfer categories are determined by mean or median cord blood–to–maternal delivery plasma drug ratio:

High: >0.6
Moderate: 0.3–0.6
Low: <0.3

[c] Generic formulation available

Key: 3TC = lamivudine; ABC = abacavir; ARV = antiretroviral; DOR = doravirine; DTG = dolutegravir; EFV = efavirenz; HBV = hepatitis B virus; PK = pharmacokinetic; TDF = tenofovir disoproxil fumarate; ZDV = zidovudine

References

1. Benaboud S, Tréluyer JM, Urien S, et al. Pregnancy-related effects on lamivudine pharmacokinetics in a population study with 228 women. *Antimicrob Agents Chemother*. 2012;56(2):776-782. Available at: https://pubmed.ncbi.nlm.nih.gov/22106227.

2. Moodley J, Moodley D, Pillay K, et al. Pharmacokinetics and antiretroviral activity of lamivudine alone or when coadministered with zidovudine in human immunodeficiency virus type 1-infected pregnant women and their offspring. *J Infect Dis*. 1998;178(5):1327-1333. Available at: https://pubmed.ncbi.nlm.nih.gov/9780252.

3. Mandelbrot L, Peytavin G, Firtion G, Farinotti R. Maternal-fetal transfer and amniotic fluid accumulation of lamivudine in human immunodeficiency virus-infected pregnant women. *Am J Obstet Gynecol*. 2001;184(2):153-158. Available at: https://pubmed.ncbi.nlm.nih.gov/11174495.

4. Mirochnick M, Thomas T, Capparelli E, et al. Antiretroviral concentrations in breast-feeding infants of mothers receiving highly active antiretroviral therapy. *Antimicrob Agents Chemother*. 2009;53(3):1170-1176. Available at: https://pubmed.ncbi.nlm.nih.gov/19114673.

5. Palombi L, Pirillo MF, Marchei E, et al. Concentrations of tenofovir, lamivudine and efavirenz in mothers and children enrolled under the Option B-Plus approach in Malawi. *J Antimicrob Chemother*. 2016;71(4):1027-1030. Available at: https://pubmed.ncbi.nlm.nih.gov/26679247.

6. Sibiude J, Mandelbrot L, Blanche S, et al. Association between prenatal exposure to antiretroviral therapy and birth defects: an analysis of the French Perinatal Cohort Study (ANRS CO1/CO11). *PLoS Med*. 2014;11(4):e1001635. Available at: https://pubmed.ncbi.nlm.nih.gov/24781315.

7. Vannappagari V, Koram N, Albano J, et al. Abacavir and lamivudine exposures during pregnancy and non-defect adverse pregnancy outcomes: data from the Antiretroviral Pregnancy Registry. *J Acquir Immune Defic Syndr*. 2015;68(3):359-364. Available at: https://pubmed.ncbi.nlm.nih.gov/25469525.

8. Williams PL, Hazra R, Van Dyke RB, et al. Antiretroviral exposure during pregnancy and adverse outcomes in HIV-exposed uninfected infants and children using a trigger-based design. *AIDS*. 2016;30(1):133-144. Available at: https://pubmed.ncbi.nlm.nih.gov/26731758.

9. Lamivudine (Epivir) [package insert]. Food and Drug Administration. 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/020564s039,020596s038lbl.pdf.