Bictegravir (BIC)

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Summary

- No dose adjustment for bictegravir (BIC) is recommended in pregnancy.
- First-trimester exposure to BIC has not been associated with an increased risk of congenital anomalies.

Human Studies in Pregnancy

Pharmacokinetics

BIC pharmacokinetics (PK) during pregnancy have been reported in two clinical studies,[1,2] a case series,[3,4] and one case report.[5]

IMPAACT 2026[6] evaluated the PK of BIC among 27 pregnant women, which showed that total BIC area under the curve (AUC) was decreased by 46% to 52%; the concentrations at 24 hours postdose (C_{24h}) were 62% to 68% lower during pregnancy compared to postpartum.[1] Seven of 12 (58%) participants during the second trimester and 13 of 21 (62%) during the third trimester fell below the 10th percentile AUC for nonpregnant adults, but none of these women had a detectable viral load. All C_{24h} values across the second and third trimesters were above the BIC protein-adjusted 95% maximal effective concentration (EC_{95}) of 0.162 ug/mL, with median values approximately 7-fold and 5.9-fold above the EC_{95}, respectively.[1] Because BIC is highly protein bound and pregnancy can be associated with decreased plasma protein binding, unbound drug concentrations were also assessed. Compared with postpartum, the BIC percent unbound was 45% and 42% higher in the second and third trimesters, respectively. However, median unbound BIC concentrations remained lower during pregnancy (3.83 ng/mL and 3.01 ng/mL for the second and third trimesters, respectively, compared to 5.83 ng/mL during postpartum). Viral suppression (defined as <40 copies/mL) was maintained in 88% to 92% of participants across pregnancy, birth, and postpartum, and no confirmed infant HIV infections occurred among the 26 for whom data are available.

A separate study[2] in 33 pregnant women showed that total BIC AUC was approximately 56% to 59% lower, and BIC trough concentrations (C_{trough}) were approximately 70% to 74% lower during the second or third trimester compared to 6 weeks or 12 weeks postpartum. Total BIC AUC in the pregnant women was 41% lower during the third trimester compared with historical data in nonpregnant adults with HIV. The AUC for unbound BIC was approximately 38% to 41% lower during pregnancy than postpartum. The mean unbound fractions were higher during pregnancy than postpartum (0.351% and 0.365% during the second and third trimester, respectively, compared with 0.261% and 0.252% at 6 weeks and 12 weeks postpartum, respectively). Mean C_{trough} values during the second and third trimesters were about 6.5-fold above the BIC protein-adjusted EC_{95}, and all but one individual C_{trough} value was above this threshold. All women maintained viral suppression (defined as <50 copies/mL) through Week 18 postpartum, including at birth, and no perinatal HIV infections occurred.

Collectively, these findings demonstrate that despite lower AUC and C_{24h} or C_{trough} values during pregnancy, drug exposures were still above those needed to maintain viral suppression when using standard BIC doses, and thus no dose adjustment is recommended. Separate larger cohort studies

have also demonstrated rates of viral suppression (<50 copies/mL) of approximately 82% to 91% through birth with BIC/tenofovir alafenamide/emtricitabine.[7,8]

Placental and Breast Milk Passage

Placental transfer of BIC is high, with a mean/median umbilical cord blood–to–maternal plasma ratio of approximately 1.4 at birth.[1,2] The estimated median half-life in neonates based on washout data is prolonged in comparison to adults, with one study estimating 43 hours (interquartile range 38–58; n = 10)[2] and another estimating 33 hours (interquartile range 26–46; n = 25).[1] These umbilical cord blood–to–maternal plasma ratios are comparable to a previous case series in which ratios of 1.49 were measured in one patient 20 hours after BIC dosing and 1.42 in another patient 7 hours after BIC dosing.[3] A separate case report conveyed an umbilical cord blood–to–maternal plasma ratio of 0.68 approximately 16 hours after BIC dosing.[4] The concentration of BIC was 2,826 ng/mL in cord blood at birth, 2,097 ng/mL in the infant on Day 3 after birth, and undetectable (<5 ng/mL) in the infant by Day 22.

Data on the passage of BIC in human breast milk are very limited. BIC milk-to-plasma ratios have only been reported in one woman, which revealed a ratio of 0.01 and subsequent estimated infant daily dose of 0.01 mg/kg.[9] Additional data are needed to refine our understanding of the breast milk passage of BIC.

Teratogenicity/Adverse Pregnancy Outcomes

The Antiretroviral Pregnancy Registry (APR) provides updated birth defect data for BIC 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 BIC to detect at least a twofold increase in the risk of overall birth defects. 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 births among cases of first-trimester exposure to BIC and other ARV drugs reported to the APR where there are sufficient data to determine 95% confidence intervals (CIs). The data in Figure 1 can be compared with the 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] 4.17 per 100 live births). Based on the data reported by the APR through July 31, 2025, the prevalence of birth defects is 4.43% (95% CI, 3.15% to 6.03%). This is statistically significantly elevated compared with MACDP data (2.72%; 95% CI, 2.68% to 2.76%) but is not significantly different from TBDR data (5.07%; 95% CI, 5.06% to 5.09%). A detailed review of cases did not identify a pattern of birth defects for BIC. The prevalence and CIs will be refined with continued accrual.

Separately, four retrospective studies that included smaller numbers of pregnancies with BIC exposures (approximately 50 to 170) have not identified higher rates of congenital anomalies with exposure occurring during the first trimester[7,10] or at any time during pregnancy.[8,11] In these studies, preterm birth rates among pregnancies with any BIC exposure were between 13% to 18%, which are comparable to those reported in pregnant women with HIV on other ARV regimens.[12] Larger prospective, controlled studies are needed to inform direct comparisons of pregnancy outcomes between BIC and other ARV medication options.

Animal Studies

Carcinogenicity

BIC has not been shown to be genotoxic or mutagenic *in vitro*.[13]

Reproduction/Fertility

BIC did not affect fertility, reproductive performance, or embryonic viability in male or female rats at exposures (based on AUC) that were 29 times higher than those observed in humans who received the recommended dose.[13]

Teratogenicity/Adverse Pregnancy Outcomes

No adverse embryo-fetal effects were observed in rats and rabbits at BIC exposures (based on AUC) of up to about 36 times (in rats) and 0.6 times (in rabbits) the exposures observed in humans who received the recommended dose. Spontaneous abortion, increased clinical signs (e.g., fecal changes, thin body, cold to touch), and decreased body weight were observed in rabbits at a maternally toxic dose (i.e., 1,000 mg/kg per day, which produced an exposure approximately 1.4 times higher than the exposure observed in humans who received the recommended dose).[13]

Placental and Breast Milk Passage

No data are available on placental passage of BIC in animals. In a prenatal and postnatal development study conducted in rats, BIC was detected in the plasma of nursing rat pups on postnatal Day 10, likely due to the presence of BIC in milk.[13]

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**
Bictegravir/ Emtricitabine/ Tenofovir Alafenamide (BIC/FTC/TAF) *Biktarvy* **Note:** BIC is available only as part of an FDC tablet.	**BIC/FTC/TAF (Biktarvy)** • BIC 50-mg/ FTC 200-mg/ TAF 25-mg tablet • BIC 30-mg/ FTC 120-mg/ TAF 15-mg tablet	**Pregnancy** *PK in Pregnancy* • AUC and C_{24h}/C_{trough} are decreased during the third trimester compared with postpartum, but exposures during pregnancy are well above those needed to inhibit viral replication. *Dosing in Pregnancy* • No change in dose indicated For guidance about use of combination products in pregnancy, please see the specific sections on other components (i.e., FTC, TAF). **Standard Adult Doses** • One tablet of BIC 50 mg/FTC 200 mg/TAF 25 mg once daily with or without food	High placental transfer to fetus[b] No evidence of human teratogenicity (can rule out twofold increase in overall birth defects) BIC can be taken with food at the same time as any preparation containing iron or calcium—including prenatal vitamins—but should not be administered within 2 hours of these preparations when taken on an empty stomach. BIC can be taken at least 2 hours before or 6 hours after antacids containing aluminum or magnesium. **Note:** Please see FDA label for full list of drugs with potential interactions and drugs for which administration with BIC 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).

[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

Key: ARV = antiretroviral; AUC = area under the curve; BIC = bictegravir; C_{24h} = concentration at 24 hours postdose; C_{trough} = trough concentration; FDA = U.S. Food and Drug Administration; FDC = fixed-dose combination; FTC = emtricitabine; PK = pharmacokinetics; TAF = tenofovir alafenamide

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