Elvitegravir (EVG)

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Summary

- Elvitegravir (EVG) trough concentrations (C_{trough}) are reduced during pregnancy by approximately 85% with use of EVG in fixed-dose combination (FDC) with cobicistat (EVG/c).
- EVG/c **is not recommended** for use in pregnancy; see Table 7.
- First-trimester exposure to EVG is not associated with increased risk of congenital anomalies.

Human Studies in Pregnancy

Pharmacokinetics

Pharmacokinetics (PK) and safety data from 30 pregnant U.S. women with HIV who received an FDC of EVG, cobicistat (COBI), emtricitabine, and tenofovir disoproxil fumarate demonstrate that EVG exposure (based on area under the curve [AUC]) was 24% lower during the second trimester and 44% lower during the third trimester than during the postpartum period. EVG concentration at 24 hours postdose (C_{24h}) was 81% lower during the second trimester and 89% lower during the third trimester than during the postpartum period. COBI AUC was 44% and 59% lower and C_{24h} was 60% and 76% lower during the second and third trimesters, respectively, than during the postpartum period. EVG AUC failed to reach the exposure target of 23 mcg•h/mL (the 10th percentile for nonpregnant adults) in 53% of women during the second trimester and 62% of women during the third trimester, while 28% of women failed to reach the exposure target during the postpartum period. Plasma HIV RNA at birth was <50 copies/mL in 19 of 25 women (76%) for whom data were available.[1] In a European study that evaluated the PK of EVG administered with COBI in 14 pregnant women, EVG AUC was reduced by 34%, and C_{trough} was reduced by 77% during the third trimester compared with the postpartum period. EVG C_{trough} was below the 90% effective concentration (0.13 mg/L) in 85% of women in the third trimester and in none postpartum. Two women experienced virologic failure during the third trimester and were switched to alternative regimens.[2]

Two case reports of EVG and COBI PK, safety, and efficacy in individual pregnant women found similar reductions in EVG and COBI exposure during pregnancy, although viral loads in both women remained undetectable throughout pregnancy.[3,4] One case report described unbound EVG concentrations and found that the unbound fraction was 0.3% during pregnancy and 0.5% at 6 months postpartum. Reductions in both total EVG concentration and unbound EVG concentration increase the risk of suboptimal exposure.[4]

Because studies have reported reduced EVG exposure when pregnant women receive FDC tablets that contain EVG and COBI, the prescribing information for these products has been changed to indicate that these formulations **are not recommended** for use in pregnancy and should not be initiated in pregnancy; frequent viral load monitoring or use of an alternative regimen **is recommended** if these formulations are being taken when pregnancy occurs.[5] If these formulations are used in pregnancy, to maximize absorption, they should be administered with a meal and should not be administered within 2 hours of intake of preparations containing minerals, such as iron or calcium, including prenatal vitamins.[5]

Placental and Breast Milk Passage

Placental passage of EVG has been evaluated in two studies. A U.S. study of EVG PK and safety observed that EVG crossed the placenta well, with a median cord blood–to–maternal plasma ratio of 0.91 in 15 women. The median EVG elimination half-life in neonates was 7.6 hours, similar to that in nonpregnant adults. COBI concentrations were low in cord blood and were not detected in the plasma of any neonates.[1] A European study reported similar results, with a median cord blood–to–maternal delivery plasma ratio of 0.75 in seven women.[2] No data are available on human breast milk transfer of EVG.

Teratogenicity/Adverse Pregnancy Outcomes

The Antiretroviral Pregnancy Registry (APR) provides updated birth defect data for EVG 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 EVG to allow the detection of at least a twofold increase in the risk of overall birth defects. No such increase in the risk of birth defects has been observed with EVG.[6] 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 EVG 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 prevalence 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).

In the largest prospective PK and safety study of EVG in pregnancy, which included data on 26 live-born infants, congenital anomalies were reported in two infants: one infant with amniotic band syndrome, microcephaly, and intrauterine growth restriction and one infant with ulnar postaxial polydactyly (supernumerary digit).[1] In a retrospective report of 137 infants in the United States who were born to mothers who received EVG during pregnancy, two birth defects were noted: one case of hydronephrosis and one case of encephalocele. Two cases of intrauterine fetal demise among the 134 pregnancies also were included in this report.[7]

Animal Studies

Carcinogenicity

In long-term studies of EVG, no carcinogenicity was detected at exposures that were 14-fold higher in mice and rats and 27-fold higher in rats than those achieved in humans during systemic exposure to the recommended doses.[5]

Reproduction/Fertility

EVG did not affect fertility in male and female rats at approximately 16-fold and 30-fold higher exposures than those seen in humans who received standard doses. Fertility was normal in the offspring of these rats.[5]

Teratogenicity/Adverse Pregnancy Outcomes

Studies have shown no evidence of teratogenicity and no effect on reproductive function in rats and rabbits receiving EVG.[5]

Placental and Breast Milk Passage

No data are available on the placental transfer of EVG in nonhuman primates. Studies in rats have demonstrated that EVG is secreted in breast milk.[5]

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**
Elvitegravir (EVG) **Note:** As of October 2017, the single-drug formulation of EVG (Vitekta) is no longer available. **(**EVG/c/FTC/TAF) *Genvoya* (EVG/c/FTC/TDF) *Stribild*	**EVG/c/FTC/TAF (Genvoya)** • EVG 150-mg/ COBI 150-mg/ FTC 200-mg/ TAF 10-mg tablet **EVG/c/FTC/TDF (Stribild)** • EVG 150-mg/ COBI 150-mg/ FTC 200-mg/ TDF 300-mg tablet	**Pregnancy** *PK in Pregnancy* • PK studies in women who received EVG/c demonstrated significant reduction in EVG plasma exposure during pregnancy. *Dosing in Pregnancy* • EVG plasma concentrations are reduced with use of standard adult doses during pregnancy; however, higher-than-standard doses of EVG have not been studied. Insufficient data are available to recommend a dose for use in pregnancy. For guidance about use of combination products in pregnancy, please see the specific sections on other components (i.e., COBI, FTC, TAF). **Standard Adult Doses** *Genvoya and Stribild* • One tablet once daily with food	Evidence of high placental transfer of EVG and low transfer of COBI[b] Insufficient data to assess for teratogenicity in humans. No evidence of teratogenicity in rats or rabbits. EVG/c **is not recommended** for use in pregnancy. If EVG/c is being taken when pregnancy occurs, consider frequent viral load monitoring or switching to a more effective recommended regimen. If a regimen that contains EVG/c is continued during pregnancy, doses should be administered with a meal and should not be administered within 2 hours of ingesting any preparation that contains minerals, such as iron or calcium, including prenatal vitamins. **Note:** Please see FDA label for full list of drugs with potential interactions and drugs for which administration with EVG 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, Table 12).

[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; COBI = cobicistat; EVG = elvitegravir; EVG/c = elvitegravir/cobicistat; FTC = emtricitabine; PK = pharmacokinetics; TAF = tenofovir alafenamide; TDF = tenofovir disoproxil fumarate

References

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