Cobicistat (Tybost, COBI)

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Summary

- Cobicistat (COBI) concentrations are decreased substantially—by approximately 45% to 85%—during pregnancy. The pharmaco-enhancing effects of COBI for atazanavir (ATV), darunavir (DRV), and elvitegravir (EVG) concentrations are similarly decreased.
- Although COBI exposure is reduced markedly during pregnancy, higher-than-standard doses have not been studied. The Panel on Treatment of HIV During Pregnancy and Interventions to Reduce Perinatal HIV Transmission does not recommend COBI for use with protease inhibitors and integrase strand transfer inhibitors during pregnancy; see Table 7.
- First-trimester exposure to COBI is not associated with increased risk of congenital anomalies.

Human Studies in Pregnancy

Pharmacokinetics

COBI pharmacokinetics (PK) have been described in pregnant and postpartum women who were taking concomitant EVG, ATV, and DRV. In a study of 30 pregnant women who were receiving elvitegravir/cobicistat (EVG/c), the area under the curve (AUC) for COBI was 44% lower in the second trimester and 59% lower in the third trimester than during the postpartum period. COBI trough concentrations (C_{trough}) (24 hours postdose) were 60% lower in the second trimester and 76% lower in the third trimester than during the postpartum period. COBI C_{trough} were below the assay quantitation limit (<10 ng/mL) in 65% of women during the second trimester, 73% of women during the third trimester, and 24% of postpartum women.[1] Another study of 14 women taking EVG/c reported COBI AUC reduced by 49% during pregnancy.[2] Studies have also described decreases of similar magnitudes in COBI exposures when COBI is coadministered with DRV[3,4] or ATV[1] in pregnant women. In one of these studies, COBI AUC was decreased by 63% in the second trimester and 49% in the third trimester compared to the AUC postpartum. COBI C_{trough} decreased by 83% in both the second and third trimesters.

The pharmaco-enhancing effect of COBI on EVG was impacted during pregnancy; EVG AUC was reduced by 44% and C_{trough} were reduced by 89% in the third trimester when compared to postpartum AUC and C_{trough}. EVG apparent oral clearance during pregnancy and postpartum was associated negatively with COBI AUC.[5] Similarly, another study reported that EVG C_{trough} were reduced by 77% in the third trimester, with 85% of women having EVG C_{trough} below the 90% maximal effective concentration.[2]

The pharmaco-enhancing effect of COBI on DRV and ATV also was reduced during pregnancy. Two studies have described DRV exposures with COBI boosting in pregnancy. In a study of 29 pregnant women, the AUC of DRV was reduced by 53% in the second trimester and 56% in the third trimester compared to postpartum.[4] In a smaller study of seven pregnant women, DRV AUC was reduced by 56% in the second trimester and 50% in the third trimester compared to postpartum. This study also reported unbound DRV concentrations, and unbound DRV AUC was 45% and 40% lower during the second and third trimesters, respectively. The effect on DRV C_{trough} was more pronounced, with both total and unbound concentrations showing essentially identical decreases of 92% (in the second trimester) and 88% to 89% (in the third trimester) when compared to postpartum C_{trough}. One of six women in this study experienced virologic failure during the third trimester, and virologic failure

continued through the postpartum period.[3] ATV C_{trough} were 80% and 85% lower in the second and third trimesters, respectively, compared to historical ATV C_{trough} in nonpregnant adults with HIV.[1] Because of these substantial reductions in drug exposures during pregnancy, use of COBI-boosted EVG, DRV, or ATV **is not recommended** when starting or changing regimens during pregnancy.[6-8]

One study evaluated tenofovir alafenamide (TAF) exposure in pregnant women when TAF was administered as a daily 10-mg dose with COBI 150 mg. No differences were seen between TAF exposure during pregnancy and TAF exposure postpartum in the same women. The authors concluded that no dose adjustment is needed during pregnancy for TAF when it is coadministered with COBI.[9] However, TAF 10 mg with COBI is available only in fixed-dose combination products that also include either DRV or EVG, which are not recommended for use during pregnancy. Another study described TAF exposure in pregnant women when administered as a 25-mg dose with a pharmaco-enhancer (either ritonavir 100 mg or COBI 150 mg). TAF exposures during pregnancy and postpartum did not differ.[10]

Placental and Breast Milk Passage

A study in 10 pregnant women who received EVG/c found a median ratio of cord blood–to–maternal plasma COBI concentrations of 0.09. This study also found measurable concentrations of COBI in placental tissue and cord blood peripheral blood mononuclear cells (PBMC), with a cord blood–to–maternal PBMC ratio of 0.49.[11] In another study, median maternal plasma COBI concentration at delivery in 15 pregnant women was 172 ng/mL, and COBI was quantifiable in cord blood from seven of their births with a median cord blood–to–maternal plasma ratio of 0.09.[5] In 27 neonates born to mothers who were receiving EVG/c, COBI was below the assay quantitation limit of 10 ng/mL in all washout PK samples taken between 2 hours and 9 days post birth.[5] No data are available on breast milk passage of COBI in humans.

Teratogenicity/Adverse Pregnancy Outcomes

The Antiretroviral Pregnancy Registry (APR) provides updated birth defect data for COBI 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 COBI to detect at least a twofold increase in the risk of overall birth defects in the general population. However, no such increase in the risk of birth defects has been observed with COBI. 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 COBI 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 of birth defects in the U.S. population (2.72 birth defects per 100 live births) according to 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).

Animal Studies

Carcinogenicity

No increases in tumor incidence relevant to humans were seen in rodent studies.[12]

Reproduction/Fertility

COBI did not affect fertility in male or female rats.[6]

Teratogenicity/Adverse Pregnancy Outcomes

Studies in pregnant rats and rabbits have shown no evidence of teratogenicity, even with rat COBI exposures that were 1.4 times higher than the recommended human exposure and rabbit COBI exposures that were 3.3 times higher than the recommended human exposure.[12]

Placental and Breast Milk Passage

No information is available on placental passage of COBI. Studies in rats have shown that COBI is secreted in breast milk.[12]

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**
Cobicistat (COBI) *Tybost* (ATV/c) *Evotaz* (EVG/c/FTC/TAF) *Genvoya* (DRV/c) *Prezcobix* (EVG/c/FTC/TDF) *Stribild* (DRV/c/FTC/TAF) *Symtuza*	**COBI (Tybost)** *Tablet* • COBI 150 mg **ATV/c (Evotaz)** • ATV 300-mg/ COBI 50-mg tablet **EVG/c/FTC/TAF (Genvoya)** • EVG 150-mg/ COBI 150-mg/ FTC 200-mg/ TAF 10-mg tablet **DRV/c (Prezcobix)** • DRV 800-mg/ COBI 150-mg tablet **EVG/c/FTC/TDF (Stribild)** • EVG 150-mg/ COBI 150-mg/ FTC 200-mg/ TDF 300-mg tablet **DRV/c/FTC/TAF (Symtuza)** • DRV 800-mg/ COBI 150-mg/ FTC 200-mg/ TAF 10-mg tablet	**Pregnancy** *PK in Pregnancy* • Based on limited data, COBI exposure and its pharmaco-enhancing effect on ATV, DRV, and EVG are reduced markedly in pregnancy. • When coadministered with COBI, TAF exposure is not significantly different between pregnancy and the postpartum period. *Dosing in Pregnancy* • Although COBI exposure is reduced markedly during pregnancy, higher-than-standard doses have not been studied. The Panel recommends RTV as the preferred pharmaco-enhancer for PIs and INSTIs during pregnancy until more data are available on COBI activity during pregnancy. For guidance about the use of combination products in pregnancy, please see the specific sections on other components (i.e., FTC, TAF, TDF, ATV, DRV, EVG). **Standard Adult Doses** *COBI (Tybost)* • When used as an alternative PK booster with ATV or DRV, the dose is one tablet once daily with food. *ATV/c (Evotaz)* • One tablet once daily with food	Low placental transfer to fetus[b] No evidence of human teratogenicity (can rule out twofold increase in overall birth defects) Use of COBI-boosted ATV, DRV, or EVG **is not recommended** in pregnancy. **Note:** Please see FDA label for full list of drugs with potential interactions and drugs for which administration with COBI is contraindicated.

Excerpt From Table 14

Generic Name (Abbreviation) *Trade Name*	**Formulation**	**Dosing Recommendations**[a]	**Use in Pregnancy**
		EVG/c/FTC/TAF (Genvoya) • One tablet once daily with food *DRV/c (Prezcobix)* • One tablet once daily with food *EVG/c/FTC/TDF (Stribild)* • One tablet once daily with food *DRV/c/FTC/TAF (Symtuza)* • One tablet once daily with food	

[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; ATV = atazanavir; ATV/c = atazanavir/cobicistat; COBI = cobicistat; DRV = darunavir; DRV/c = darunavir/cobicistat; EVG = elvitegravir; EVG/c = elvitegravir/cobicistat; FTC = emtricitabine; INSTI = integrase strand transfer inhibitor; the Panel = Panel on Treatment of HIV During Pregnancy and Interventions to Reduce Perinatal HIV Transmission; PI = protease inhibitor; PK = pharmacokinetics; RTV = ritonavir; TAF = tenofovir alafenamide; TDF = tenofovir disoproxil fumarate

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