



**Recommendations for the Use of Antiretroviral Drugs in  
Pregnant Women with HIV Infection and Interventions to Reduce  
Perinatal HIV Transmission in the United States**

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## **Tenofovir Alafenamide (Vemlidy, TAF)**

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Tenofovir alafenamide (TAF) is an orally bioavailable form of tenofovir. Data on its use in human pregnancy is insufficient to inform a drug-associated risk determination for birth defects or miscarriage.

### **Animal Studies**

#### *Carcinogenicity*

Because TAF is rapidly converted to tenofovir, and tenofovir exposure in rats and mice is lower after TAF administration than after tenofovir disoproxil fumarate (TDF) administration, carcinogenicity studies were performed with TDF. Long-term oral carcinogenicity studies of tenofovir in mice and rats were carried out at 167 times (mice) and 55 times (rats) tenofovir exposure than that seen after TAF administration at recommended doses in humans. In female mice, liver adenomas were increased. In rats, no carcinogenic findings were observed.<sup>1,2</sup>

#### *Reproduction/Fertility*

Reproduction studies have been performed in rats and rabbits at TAF exposures similar to and 53 times higher than human exposure, respectively, and revealed no evidence of impaired fertility or mating performance associated with TAF administration.<sup>1-3</sup>

#### *Teratogenicity/Adverse Pregnancy Outcomes*

No effects on early embryonic development were seen when TAF was administered to male or female rats at 62 times the human therapeutic exposure.<sup>1-3</sup>

#### *Placental and Breast Milk Passage*

Rat studies demonstrated secretion of tenofovir in breast milk after administration of TDF; whether TAF is present in animal milk is unknown.<sup>1,3</sup>

### **Human Studies in Pregnancy**

#### *Pharmacokinetics*

Pharmacokinetics (PKs) of TAF have been reported in 31 women taking TAF 25 mg without any pharmacoenhancer, and in 27 women taking TAF 10 mg boosted with cobicistat 150 mg.<sup>4</sup> This study evaluated plasma TAF exposures with and without boosting in pregnant and postpartum women relative to those in non-pregnant adults. No significant differences in PKs were seen between pregnant and postpartum women taking boosted TAF. Among women taking unboosted TAF, the significantly different plasma exposures during pregnancy and postpartum were driven by higher exposures postpartum.

#### *Placental and Breast Milk Passage*

TAF was below the assay limit of quantification (<3.9 ng/mL) in 15 of 15 cord blood samples tested.<sup>4</sup> Maternal plasma TAF at delivery was measurable in 2 of the 15 paired samples.

#### *Teratogenicity/Adverse Pregnancy Outcomes*

In the Antiretroviral Pregnancy Registry, the number of reported cases of TAF exposures is **insufficient** to draw any conclusions about risk of birth defects.<sup>5</sup>

**Excerpt from Table 10<sup>a</sup>**

**Note:** When using FDCs, refer to other sections in Appendix B and Table 10 for information about the dosing and safety of individual drug components of the FDC during pregnancy.

Generic Name (Abbreviation) Trade Name	Formulation	Dosing Recommendations	Use in Pregnancy
<b>Tenofovir Alafenamide</b> (TAF) <i>Vemlidy</i>	TAF ( <i>Vemlidy</i> ) <sup>d</sup> Tablet: • 25 mg	<u>Standard Adult Dose</u> <i>TAF (Vemlidy)</i> : • 1 tablet once daily with food	<b>Low placental transfer to fetus.<sup>b</sup></b>  Insufficient data to assess for teratogenicity in humans. No evidence of teratogenicity in rats.
<b>(TAF/BIC/FTC)</b> <i>Biktarvy</i>	<b>TAF/BIC/FTC (<i>Biktarvy</i>):</b> • TAF 25 mg plus BIC 50 mg plus FTC 200 mg tablet	<b>TAF/BIC/FTC (<i>Biktarvy</i>):</b> • 1 tablet once daily with or without food	
(TAF/FTC) <i>Descovy</i>	<u>TAF/FTC (<i>Descovy</i>):</u> • TAF 25 mg plus FTC 200 mg tablet	<i>TAF/FTC (Descovy)</i> : • 1 tablet once daily with or without food	
(TAF/EVG/COBI/FTC) <i>Genvoya</i>	TAF/EVG/COBI/FTC ( <i>Genvoya</i> ): • TAF 10 mg plus EVG 150 mg plus COBI 150 mg plus FTC 200 mg tablet	<i>TAF/EVG/COBI/FTC (Genvoya)</i> : • 1 tablet once daily with food	Renal function should be monitored because of potential for renal toxicity.
(TAF/FTC/RPV) <i>Odefsey</i>	<u>TAF/FTC/RPV (<i>Odefsey</i>):</u> • TAF 25 mg plus FTC 200 mg plus RPV 25 mg tablet	<i>TAF/FTC/RPV (Odefsey)</i> : • 1 tablet once daily with food	
<b>(TAF/DRV/COBI/FTC)</b> <i>Symtuza</i>	<b>TAF/DRV/COBI/FTC (<i>Symtuza</i>):</b> • TAF 10 mg plus DRV 800 mg plus COBI 150 mg plus FTC 200 mg tablet	<b>TAF/DRV/COBI/FTC (<i>Symtuza</i>):</b> • 1 tablet once daily with food	
<b>Note:</b> Generic available for some formulations.		<u>PK in Pregnancy:</u> • Plasma PK not significantly altered in pregnancy.  <u>Dosing in Pregnancy:</u> • No change in dose indicated.  • For guidance about use of combination products in pregnancy, please see the specific sections on other components (i.e., BIC, COBI, DRV, EVG, FTC, RPV).	

<sup>a</sup> Individual ARV drug dosages may need to be adjusted in patients with renal or hepatic insufficiency (for details, see the [Adult and Adolescent Guidelines, Appendix B, Table 8](#)).

<sup>b</sup> Placental transfer categories are determined by mean or median cord blood/maternal delivery plasma drug ratio:

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

<sup>d</sup> Generic formulation available

**Key to Acronyms:** COBI = cobicistat; BIC = bicitgravir; DRV = darunavir; EVG = elvitegravir; FDC = fixed-dose combination; FTC = emtricitabine; PK = pharmacokinetic; RPV = rilpivirine; TAF = tenofovir alafenamide

**References**

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