GILEAD | Medical Information

Descovy® (FTC/TAF)

Use in Pregnancy and Lactation

This document is in response to your request for information regarding Descovy® (emtricitabine/tenofovir alafenamide [FTC/TAF]) for the treatment of HIV-1 in women during pregnancy or lactation. This document includes content from, or references to, clinical practice guidelines, and inclusion should not be interpreted as a treatment recommendation or an endorsement of the guidelines by Gilead Sciences, Inc.

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The full indication, important safety information, and boxed warnings are available at: www.gilead.com/-/media/files/pdfs/medicines/hiv/descovy/descovy_pi.

Summary

Product Labeling[1]

Available data from the APR show no statistically significant difference in the overall risk of major birth defects for FTC or TAF compared with the background rate for major birth defects of 2.7% in a US reference population of the MACDP. The rate of miscarriage for individual drugs is not reported in the APR. The estimated background rate of miscarriage in the clinically recognized pregnancies in the US general population is 15% to 20%.

In animal studies, no adverse developmental effects were observed when the components of FTC/TAF were administered separately during the period of organogenesis at exposures 60 and 108 times (mice and rabbits, respectively) the FTC exposure and at exposure equal to or 53 times (rats and rabbits, respectively) the TAF exposure at the recommended daily dose of FTC/TAF.

Clinical Data on the Use of FTC/TAF During Pregnancy

The APR was established to monitor fetal outcomes of pregnant women exposed to ARV agents. No significant increases in risk of overall birth defects have been detected to date with FTC or TAF.[2]

PK Data on the Use of FTC/TAF During Pregnancy

The available PK data for FTC suggest a general decrease in AUC during pregnancy and the postpartum period. However, no dose adjustments were described or recommended in the literature.[3-6] Available TAF PK data suggest a reduction in plasma TAF exposures during pregnancy compared with postpartum period.[7,8] In boosted TAF regimens, the exposures were within the range of those typically observed in non-pregnant adult women who received TAF (either boosted with COBI or unboosted).[8]

Clinical Guidelines for the Use of FTC/TAF During Pregnancy

See below for the US DHHS guidelines for the recommendations on the use of ARVs in pregnant people.

Use of FTC/TAF During Lactation[1]

Data from the published literature report the presence of FTC, TAF, and tenofovir in human milk. Data from the published literature have not reported adverse effects of FTC or TAF on a breastfed child. There are no data on the effects of FTC or TAF on milk production.

Potential risks of breastfeeding include: 1) HIV transmission to infants without HIV-1; 2) developing viral resistance in infants with HIV-1; and 3) adverse reactions in a breastfed infant similar to those seen in adults.

Clinical Data on the Use of FTC/TAF During Pregnancy

APR[2]

Health care providers are encouraged to register patients who become pregnant to the APR by calling 1-800-258-4263.

The APR is intended to provide an early signal of teratogenicity associated with prenatal use of ARVs. The registry is ongoing; healthcare providers are strongly encouraged to report eligible patients to the registry. Further information is available at https://apregistry.com/.

FTC/TAF component data in the APR

The June 2025 interim report included prospective reports of 24,443 pregnancies with follow-up data through January 31, 2025. Birth defect prevalence by trimester of earliest exposure for all ARVs and FTC- and TAF-containing regimens is described in Error! Reference source not found.. For FTC and TAF, there are sufficient numbers of first-trimester exposures to detect at least a 1.5-fold increase in the risk of overall birth defects and a 2-fold increase in the risk of birth defects in the most common classes. No such increase has been detected to date.

The prevalence of pregnancies exposed to TAF in the first trimester was 4.06% (95% CI: 3.13–5.16%), which is significantly higher than the reports included in the CDC MACDP population-based birth defects surveillance system (2.72%; 95% CI: 2.68–2.76%) but not those included in the Texas Birth Defects Registry (4.66%; 95% CI: 4.64–4.67%). A detailed review of cases did not identify any pattern of birth defects related to TAF. The APR will continue to monitor TAF for any pattern of birth defects.

A full review of the available data evaluating TAF safety in pregnancy, including the APR, cases from Gilead's global safety database, published literature, and preclinical data, was conducted in January 2020; no association between TAF exposure and birth defects was found.[9]

Table 1. Number of Birth Defects by Trimester of Earliest Exposure[2]

Drug Regimen	Pregnancies Enrolled, n	First Trimester		Second/Third Trimester	
		Defects per Live Births[a]	Prevalence % (95% CI)[b]	Defects per Live Births[a]	Prevalence % (95% CI)[b]
Any ARV-containing	24,443	382/12,853	3 (2.7, 3.3)	292/10,273	2.8 (2.5, 3.2)
FTC-containing	7939	165/5430	3 (2.6, 3.5)	56/2037	2.7 (2.1, 3.6)
TAF-containing	2044	63/1552	4.1 (3.1, 5.2)	16/394	4.1 (2.3, 6.5)

[a]Proportion of defects was calculated by dividing the number of defects that met the CDC criteria by the number of live births reported.
[b]Prevalence and 95% CIs were reported for drugs associated with ≥200 defect -positive live births, where the earliest exposure to drug was the first trimester.

Data From Clinical Trials, Cohorts, and Case Reports

FTC/TAF

Study GS-US-236-0128 (WAVES), a phase 3, randomized, double-blind, active-controlled study, compared the safety and efficacy of EVG/COBI/FTC/TDF with those of boosted

ATV + FTC/TDF in ARV-naïve adult women. In this study, women who became pregnant were allowed to remain in the study if they re-consented following the confirmation of pregnancy. The double-blinded treatment phase concluded after 48 weeks and was followed by an OLE phase (WAVES OLE), where 212 women were re-randomized in a ratio of 3:1 to switch to E/C/F/TAF or continue to receive boosted ATV + FTC/TDF. In the E/C/F/TAF arm (n=159), there were 14 pregnancies with the following outcomes: 4 uncomplicated term deliveries with no reported congenital malformations, 4 elective abortions, 5 spontaneous abortions (4 occurred before Week 10 of pregnancy and 1 occurred during Week 15 of pregnancy), and 1 outcome was unknown.[9,10]

IMPAACT 2010, a phase 3, randomized, open-label trial, compared the safety and efficacy of DTG + FTC/TAF, DTG + FTC/TDF, or EFV/FTC/TDF in pregnant women with HIV-1 (N=634). Maternal follow up was conducted at gestation Weeks 12 to 26 prior to delivery and maternal and infant follow-up was conducted through postpartum Week 50. DTG + FTC/TAF was associated with significantly fewer overall adverse pregnancy outcomes compared with DTG + FTC/TDF (*P*=0.043) and compared with EFV/FTC/TDF (*P*=0.047). Adverse pregnancy outcomes included preterm delivery, small for gestational age, and stillbirth.[11] Through postpartum Week 50 there were no statistically significant differences between the three study arms in maternal and infant Grade ≥3 adverse events. There were no statistically significant differences in infant death rates between the DTG arms; however, infant death rates were significantly lower in both DTG-containing arms compared with the EFV/FTC/TDF arm. Congenital anomalies occurred in a total of 4 infants: 2 were in in the DTG + FTC/TAF arm (atrial septal defect and talipes equinovarus) and 2 in the EFV/FTC/TDF arm. There were similar, low rates of HIV infection in infants across study arms, and all occurred in breastfed infants.[12]

PK Data on the Use of FTC/TAF During Pregnancy

FTC

An analysis of four studies that evaluated the PK of FTC along with other ARVs in HIV-1–infected pregnant women concluded that adequate drug plasma exposure was achieved, and no dose modification of FTC was needed.[3-6] From the PANNA study, Colbers et al noted a 25% lower AUC for FTC during pregnancy than the postpartum period. However, this decreased exposure was not associated with virological failure and did not result in mother-to-child transmission.[4] Valade et al reported that FTC AUC (regardless of trimester) and concentrations 24 hours post-administration (in the third trimester) were lower in pregnant than in non-pregnant participants. However, no dosing adjustments were required, as FTC concentrations were still above the inhibitory concentration 50%.[6] FTC crosses the placenta. The reported ratios of FTC cord blood to maternal plasma concentrations during the third trimester of pregnancy in HIV-1–infected women were a median of 1.03 (n=9), a mean of 1.2 (n=11), and a median of 1.63 (n=10).[3-5]

TAF[8]

IMPAACT P1026s was an open-label, multicenter, phase 4, prospective study of ARV PK and safety in pregnant women infected with HIV. Pregnant women were eligible to enroll in the study TAF arms if they were receiving either TAF 10 mg as part of a COBI-boosted regimen or TAF 25 mg as part of an un-boosted standard of care regimen. In the TAF 10 mg arm with COBI, all participants received E/C/F/TAF (n=31). In the TAF 25 mg arm, all

participants received FTC in combination with rilpivirine (n=20), DTG (n=5), zidovudine (n=2), raltegravir (n=1), and/or nevirapine (n=1). Intensive steady-state PK profiles (pre-dose and 1, 2, 4, 6, 8, 12, and 24 hours post-dose sampling) were obtained at steady state during the second trimester, third trimester, and 6 to 12 weeks postpartum. Additional samples were collected from maternal plasma and cord blood, which were collected at delivery, and infant washout samples were collected from infants after birth (range: 2 hours to 9 days).

Among women who received TAF 10 mg + COBI, TAF exposure was not significantly different between pregnancy (second or third trimester) and postpartum assessments. Lower TAF exposures were observed in the TAF 25 mg arm during the second and third trimesters compared to postpartum (43% lower, *P*=0.091; 33% lower, *P*=0.0035, respectively). TAF exposure levels during pregnancy were consistent with historical data in non-pregnant adults[8].

A total of 44 cord blood samples were collected across both arms and TAF concentrations were below the lower limit of quantification (3.9 ng/mL) in all but one of the samples. TAF was below the lower limit of quantification in all infant washout samples collected.

Safety results were based on both TAF arms (TAF as part of either boosted or un-boosted regimens). One Grade 1 maternal adverse event (hepatic steatosis) was considered possibly related to study drug by the investigator and 2 preterm deliveries were deemed probably not related (Grade 1, at 35 weeks) and possibly related (Grade 3, at 27 weeks). Regardless of attribution, infant birth abnormalities were observed in 5 infants in the TAF 10 mg + COBI arm and in 3 infants in the TAF 25 mg arm.

HIV-1 RNA <50 c/mL was observed in 86.7% of participants in the TAF 10 mg + COBI arm and in 88.9% of participants in the TAF 25 mg arm. Of the 57 infants with HIV infection status, 56 were uninfected and 1 infant did not have HIV test results available.

Additional data from the PANNA network investigated the plasma PK parameters of TAF in pregnant women. PK sampling was performed during the third trimester and postpartum in 20 pregnant women living with HIV-1. The study participants were all taking FTC/TAF-containing regimens. A 46% decrease in TAF AUC_{last} and 33% decrease in TFV AUC_{last} were reported in the third trimester compared with postpartum. Only 1 participant had a viral load >50 c/mL at third trimester visit; however, all participants were suppressed with a viral load <50 c/mL at the postpartum visit. No mother-to-child transmission occurred.[7]

Clinical Guidelines

Please see the US DHHS guidelines for recommendations on the use of ARVs in pregnant people: https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/perinatal-hiv/guidelines-perinatal.pdf.

Use of FTC/TAF During Lactation[1]

Risk Summary

Data from the published literature report the presence of FTC, TAF, and tenofovir in human milk. Data from the published literature have not reported adverse effects of FTC or TAF on a breastfed child. There are no data on the effects of FTC or TAF on milk production.

Potential risks of breastfeeding include: 1) HIV transmission to infants without HIV-1; 2) developing viral resistance in infants with HIV-1; and 3) adverse reactions in a breastfed infant similar to those seen in adults.

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Abbreviations

APR=Antiretroviral Pregnancy Registry
ARV=antiretroviral
ART=antiretroviral therapy
ATV=atazanavir
AUC=area under the curve
AUC_{last}=area under the curve from the time of dosing to the last measurable concentration
c/mL=copies/mL
CDC=Centers for Disease Control and Prevention
COBI=cobicistat
DHHS=Department of Health and Human Services
DTG=dolutegravir
E/C/F/TAF=EVG/COBI/FTC/TAF
EFV=efavirenz
EVG=elvitegravir
FTC=emtricitabine
MACDP=Metropolitan Atlanta Congenital Defects Program
OLE=open-label extension
PANNA=Pharmacokinetics of ANtiretroviral agents in HIV-infected pregNAnt women
PK=pharmacokinetic
TAF=tenofovir alafenamide
TBDR=Texas Birth Defects Registry
TDF=tenofovir disoproxil fumarate

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Descovy US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/hiv/descovy/descovy_pi.

Follow-Up

For any additional questions, please contact Gilead Medical Information at:

☎1-866-MEDI-GSI (1-866-633-4474) or 🖱 www.askgileadmedical.com

Adverse Event Reporting

Please report all adverse events to:

Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or
🖱 www.gilead.com/utility/contact/report-an-adverse-event

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or 🖱 www.accessdata.fda.gov/scripts/medwatch

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