Appendix B: Safety and Toxicity of Individual Antiretroviral Agents in Pregnancy

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Updated: January 31, 2024
Reviewed: January 31, 2024

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	Last Reviewed
NRTIs NRTIs interfere with HIV reverse transcriptase by competitive inhibition. Nucleoside analogue drugs require three intracellular phosphorylation steps to form the triphosphate nucleoside, which is the active drug moiety. The nucleotide analogue tenofovir contains a monophosphate component attached to the adenine base and requires only two phosphorylation steps to form the active moiety.				
Abacavir (ABC) *Ziagen* (ABC/3TC) *Epzicom* (ABC/DTG/3TC) *Triumeq* (ABC/3TC/ZDV) *Trizivir* Note: Generic products are available for some formulations.	ABC (Ziagen)[c] *Tablet* • 300 mg *Oral Solution* • 20 mg/mL ABC/3TC (Epzicom)[c] • ABC 600-mg/3TC 300-mg tablet ABC/DTG/3TC (Triumeq) • ABC 600-mg/DTG 50-mg/3TC 300-mg tablet	Pregnancy *PK in Pregnancy* • PK not significantly altered in pregnancy *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., 3TC, ZDV, DTG). Standard Adult Doses *ABC (Ziagen)* • ABC 300 mg twice daily or ABC 600 mg once daily, without regard to food *ABC/3TC (Epzicom)*	High placental transfer to fetus[b] No evidence of human teratogenicity (can rule out 1.5-fold increase in overall birth defects) HSRs occur in approximately 5% to 8% of nonpregnant individuals. A small percentage of reactions are fatal, and these fatal reactions are usually associated with re-challenge. Rate of reactions during pregnancy is unknown. Testing for HLA-B*5701 identifies patients at risk of reactions, and a patient's status should be documented as negative before initiating ABC. Patients should be educated regarding symptoms of HSR.	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
	ABC/3TC/ZDV (Trizivir)[c] • ABC 300-mg/3TC 150-mg/ZDV 300-mg tablet	• One tablet once daily without regard to food *ABC/DTG/3TC (Triumeq)* • One tablet once daily without regard to food *ABC/3TC/ZDV (Trizivir)* • One tablet twice daily without regard to food		
Emtricitabine (FTC) *Emtriva* (FTC/EFV/TDF) *Atripla* (FTC/BIC/TAF) *Biktarvy* (FTC/RPV/TDF) *Complera* (FTC/TAF) *Descovy* (FTC/EVG/c/TAF) *Genvoya* (FTC/RPV/TAF) *Odefsey* (FTC/EVG/c/TDF) *Stribild* (FTC/DRV/c/TAF) *Symtuza*	FTC (Emtriva) *Capsule*[c] • 200 mg *Oral Solution* • 10 mg/mL FTC/EFV/TDF (Atripla)[c] • FTC 200-mg/ EFV 60-mg/ TDF 300-mg tablet FTC/BIC/TAF (Biktarvy) • FTC 200-mg/ BIC 50-mg/ TAF 25-mg tablet FTC/RPV/TDF (Complera) • FTC 200-mg/ RPV 25-mg/ TDF 300-mg tablet	Pregnancy *PK in Pregnancy* • PK of FTC are not significantly altered in pregnancy. *Dosing in Pregnancy* • No change in dose indicated For guidance about the use of combination products in pregnancy, please see the specific sections on other components (i.e., TDF, TAF, EFV, RPV, DRV, EVG, BIC, COBI). Standard Adult Doses *FTC (Emtriva)* • Capsule o FTC 200 mg once daily without regard to food • Oral Solution o FTC 240 mg (24 mL) once daily without regard to food	High placental transfer to fetus[b] No evidence of human teratogenicity (can rule out 1.5-fold increase in overall birth defects) If patient has HBV/HIV coinfection, it is possible that an HBV flare may occur if the drug is stopped; see Hepatitis B Virus/HIV Coinfection.	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
(FTC/TDF) *Truvada* Note: Generic products are available for some formulations.	FTC/TAF (Descovy) • FTC 200-mg/ TAF 25-mg tablet FTC/EVG/c/TAF (Genvoya) • FTC 200-mg/ EVG 150-mg/ COBI 150-mg/ TAF 10-mg tablet FTC/RPV/TAF (Odefsey) • FTC 200-mg/ RPV 25-mg/ TAF 25-mg tablet FTC/EVG/c/TDF (Stribild) • FTC 200-mg/ EVG 150-mg/ COBI 150-mg/ TDF 300-mg tablet FTC/DRV/c/TAF (Symtuza) • FTC 200-mg/ DRV 800-mg/ COBI 150-mg/ TAF 10-mg tablet FTC/TDF (Truvada)[c] • FTC 200-mg/ TDF 300-mg tablet	*FTC/EFV/TDF (Atripla)* • One tablet once daily at or before bedtime • Take on an empty stomach to reduce or mitigate side effects. *FTC/BIC/TAF (Biktarvy)* • One tablet once daily with or without food *FTC/RPV/TDF (Complera)* • One tablet once daily with food *FTC/TAF (Descovy)* • One tablet once daily with or without food *FTC/EVG/c/TAF (Genvoya)* • One tablet once daily with food *FTC/RPV/TAF (Odefsey)* • One tablet once daily with food *FTC/EVG/c/TDF (Stribild)* • One tablet once daily with food *FTC/DRV/c/TAF (Symtuza)* • One tablet once daily with food *FTC/TDF (Truvada)* • One tablet once daily without regard to food		

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
Lamivudine (3TC) *Epivir* (3TC/TDF) *Cimduo* (3TC/ZDV) *Combivir* (3TC/DOR/TDF) *Delstrigo* (3TC/DTG) *Dovato* (3TC/ABC) *Epzicom* (3TC/EFV/TDF) *Symfi* (3TC/EFV/TDF) *Symfi Lo* (3TC/TDF) *Temixys* (3TC/ABC/DTG) *Triumeq* (3TC/ABC/DTG) *Triumeq PD* (3TC/ABC/ZDV) *Trizivir*	3TC (Epivir)[c] *Tablets* • 150 mg • 300 mg *Oral Solution* • 10 mg/mL 3TC/TDF (Cimduo) • 3TC 300-mg/TDF 300-mg tablet 3TC/ZDV (Combivir)[c] • 3TC 150-mg/ZDV 300-mg tablet 3TC/DOR/TDF (Delstrigo) • 3TC 300-mg/DOR 100-mg/ TDF 300-mg tablet 3TC/DTG (Dovato) • 3TC 300-mg/DTG 50-mg tablet 3TC/ABC (Epzicom)[c] • 3TC 300-mg/ABC 600-mg tablet 3TC/EFV/TDF (Symfi)[c] • 3TC 300-mg/EFV 600-mg/ TDF 300-mg tablet	Pregnancy *PK in Pregnancy* • PK not significantly altered in pregnancy *Dosing in Pregnancy* • No change in dose indicated For guidance about the use of combination products in pregnancy, please see the specific sections on other components (i.e., ABC, DOR, DTG, EFV, TDF, ZDV). Standard Adult Doses *3TC (Epivir)* • 3TC 150 mg twice daily or 300 mg once daily, without regard to food *3TC/TDF (Cimduo)* • One tablet once daily without regard to food *3TC/ZDV (Combivir)* • One tablet twice daily without regard to food *3TC/DOR/TDF (Delstrigo)* • One tablet once daily without regard to food *3TC/DTG (Dovato)* • One tablet once daily without regard to food *3TC/ABC (Epzicom)* • One tablet once daily without regard to food	High placental transfer to fetus[b] No evidence of human teratogenicity (can rule out 1.5-fold increase in overall birth defects) If patient has HBV/HIV coinfection, it is possible that an HBV flare may occur if the drug is stopped; see Hepatitis B Virus/HIV Coinfection. 3TC products that were developed specifically for treatment of HBV (e.g., Epivir-HBV) contain a lower dose of 3TC that is not appropriate for treatment of HIV.	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
Note: Generic products are available for some formulations.	3TC/EFV/TDF (Symfi Lo)[c] • 3TC 300-mg/EFV 400-mg/ TDF 300-mg tablet 3TC/TDF (Temixys) • 3TC 300-mg/TDF 300-mg tablet 3TC/ABC/DTG (Triumeq) • 3TC 300-mg/ABC 600-mg/ DTG 50-mg tablet 3TC/ABC/DTG (Triumeq PD) • Pediatric dispersible tablet: 3TC 30-mg/ABC 60-mg/ DTG 5-mg 3TC/ABC/ZDV (Trizivir)[c] • 3TC 150-mg/ABC 300-mg/ ZDV 300-mg tablet	*3TC/EFV/TDF (Symfi or Symfi Lo)* • One tablet once daily on an empty stomach and preferably at bedtime *3TC/TDF (Temixys)* • One tablet once daily without regard to food *3TC/ABC/DTG (Triumeq)* • One tablet once daily without regard to food *3TC/ABC/DTG (Triumeq PD)* • Triumeq PD is a pediatric dispersible tablet not intended for use in adults; it is not recommended for use in patients weighing 25 kg or more. *3TC/ABC/ZDV (Trizivir)* • One tablet twice daily without regard to food		
Tenofovir Alafenamide (TAF) *Vemlidy* (TAF/BIC/FTC) *Biktarvy* (TAF/FTC) *Descovy* (TAF/EVG/c/FTC) *Genvoya*	TAF (Vemlidy) • 25-mg tablet TAF/BIC/FTC (Biktarvy) • TAF 25-mg/ BIC 50-mg/FTC 200-mg tablet TAF/FTC (Descovy) • TAF 25-mg/FTC 200-mg tablet	Pregnancy *PK in Pregnancy* • AUC is lower in pregnancy, depending on the dose and concomitant ARV, but overall exposures are adequate. *Dosing in Pregnancy* • No change in dose indicated.	TAF: low placental transfer to fetus[b] TFV: high placental transfer to fetus; plasma and cord blood concentrations lower than TDF[b] No evidence of human teratogenicity (can rule out twofold increase in overall birth defects) Renal function should be monitored because of the potential for renal toxicity.	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
(TAF/FTC/RPV) *Odefsey* (TAF/DRV/c/FTC) *Symtuza*	TAF/EVG/c/FTC (Genvoya) • TAF 10-mg/EVG-150-mg/ COBI 150-mg/FTC 200-mg tablet TAF/FTC/RPV (Odefsey) • TAF 25-mg/FTC 200-mg/ RPV 25-mg tablet TAF/DRV/c/FTC (Symtuza) • TAF 10-mg/DRV 800-mg/ COBI 150-mg/FTC 200-mg tablet	For guidance about the use of combination products in pregnancy, please see the specific sections on other components (i.e., BIC, COBI, DRV, EVG, FTC, RPV). Standard Adult Doses *TAF (Vemlidy)* • One tablet once daily with food *TAF/BIC/FTC (Biktarvy)* • One tablet once daily with or without food *TAF/FTC (Descovy)* • One tablet once daily with or without food • Same dose (TAF 25 mg) can be used with or without PK enhancers. *TAF/EVG/c/FTC (Genvoya)* • One tablet once daily with food *TAF/FTC/RPV (Odefsey)* • One tablet once daily with food *TAF/DRV/c/FTC (Symtuza)* • One tablet once daily with food		
Tenofovir Disoproxil Fumarate (TDF) *Viread* (TDF/EFV/FTC) *Atripla*	TDF (Viread) *Tablet*[c] • 300 mg	Pregnancy *PK in Pregnancy* • AUC is lower in third trimester than postpartum, but trough levels are adequate.	High placental transfer to fetus[b] No evidence of human teratogenicity (can rule out 1.5-fold increase in overall birth defects)	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
(TDF/3TC) *Cimduo* (TDF/FTC/RPV) *Complera* (TDF/DOR/3TC) *Delstrigo* (TDF/EVG/c/FTC) *Stribild* (TDF/EFV/3TC) *Symfi* (TDF/EFV/3TC) *Symfi Lo* (TDF/3TC) *Temixys* (TDF/FTC) *Truvada* Note: Generic products are available for some formulations.	*Powder* • 40-mg/1-g oral powder TDF/EFV/FTC (Atripla) • TDF 300-mg/EFV 600-mg/ FTC 200-mg tablet TDF/3TC (Cimduo) • TDF 300-mg/3TC 300-mg tablet TDF/FTC/RPV (Complera) • TDF 300-mg/FTC 200-mg/ RPV 25-mg tablet TDF/DOR/3TC (Delstrigo) • TDF 300-mg/DOR 100-mg/ 3TC 300-mg tablet TDF/EVG/c/FTC (Stribild) • TDF 300-mg/EVG 150-mg/ COBI 150-mg/FTC 200-mg tablet TDF/EFV/3TC (Symfi) • TDF 300-mg/EFV 600-mg/ 3TC 300-mg tablet TDF/EFV/3TC (Symfi Lo) • TDF 300-mg/EFV 400-mg/ 3TC 300-mg tablet	*Dosing in Pregnancy* • No change in dose is indicated. For guidance about the use of combination products in pregnancy, please see the specific sections on other components (i.e., 3TC, COBI, DOR, EFV, EVG, FTC, RPV). Standard Adult Doses *TDF (Viread)* • Tablet o TDF 300 mg once daily without regard to food • Powder o TDF 8 mg/kg daily (up to a maximum of TDF 300 mg). Take with food. *TDF/EFV/FTC (Atripla)* • One tablet once daily at or before bedtime. Take on an empty stomach to reduce side effects. *TDF/3TC (Cimduo)* • One tablet once daily without regard to food *TDF/FTC/RPV (Complera)* • One tablet once daily with food *TDF/DOR/3TC (Delstrigo)* • One tablet once daily without regard to food	Human studies demonstrate no consistent link to LBW, but data are conflicting about potential effects on growth outcomes later in infancy. If patient has HBV/HIV coinfection, an HBV flare may occur if TDF is stopped; see Hepatitis B Virus/HIV Coinfection. Renal function should be monitored because of potential for renal toxicity.	

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
	TDF/3TC (Temixys) • TDF 300-mg/3TC 300-mg tablet TDF/FTC (Truvada) • TDF 300-mg/FTC 200-mg tablet	*TDF/EVG/c/FTC (Stribild)* • One tablet once daily with food *TDF/EFV/3TC (Symfi or Symfi Lo)* • One tablet once daily on an empty stomach and preferably at bedtime *TDF/3TC (Temixys)* • One tablet once daily without regard to food *TDF/FTC (Truvada)* • One tablet once daily without regard to food		
Zidovudine (ZDV) *Retrovir* (ZDV/3TC) *Combivir* (ZDV/ABC/3TC) *Trizivir* Note: Generic products are available for all formulations.	ZDV (Retrovir) *Capsule* • 100 mg *Tablet* • 300 mg *Oral Solution* • 10 mg/mL *IV Solution* • 10 mg/mL ZDV/3TC (Combivir) • ZDV 300-mg/3TC 150-mg tablet	Pregnancy *PK in Pregnancy* • PK not significantly altered in pregnancy *Dosing in Pregnancy* • No change in dose indicated • Patients in active labor should receive ZDV 2 mg/kg IV as a loading dose, followed by ZDV 1 mg/kg/hour continuous infusion from beginning of active labor until delivery. For guidance about the use of combination products in pregnancy, please see the specific sections on other components (i.e., ABC, 3TC).	High placental transfer to fetus[b] No evidence of human teratogenicity (can rule out 1.5-fold increase in overall birth defects)	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
	ZDV/ABC/3TC (Trizivir) • ZDV 300-mg/ABC 300-mg/3TC 150-mg tablet	Standard Adult Doses *ZDV (Retrovir)* • ZDV 300 mg twice daily or ZDV 200 mg three times a day without regard to food *ZDV/3TC (Combivir)* • One tablet twice daily without regard to food *ZDV/ABC/3TC (Trizivir)* • One tablet twice daily without regard to food		
NNRTIs NNRTIs interfere with HIV reverse transcriptase by binding directly to the enzyme.				
Doravirine (DOR) *Pifeltro* (DOR/3TC/TDF) *Delstrigo*	DOR (Pifeltro) • 100-mg tablet DOR/3TC/TDF (Delstrigo) • DOR 100-mg/ 3TC 300-mg/ TDF 300-mg tablet	Pregnancy *PK in Pregnancy* • No PK studies in human pregnancy *Dosing in Pregnancy* • Insufficient data to make dosing recommendations For guidance about the use of combination ARV drug products in pregnancy, please see the specific sections on other drug components (i.e., 3TC, TDF). Standard Adult Doses *DOR (Pifeltro)* • DOR 100 mg once daily with or without food *DOR/3TC/TDF (Delstrigo)* • One tablet once daily with or without food	No human *in vivo* data are available on the placental transfer of DOR, but passage is noted in *ex vivo* models. Insufficient data are available to assess for teratogenicity in humans. No evidence exists of teratogenicity in rats or rabbits.	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
Efavirenz (EFV) *Sustiva* (EFV/FTC/TDF) *Atripla* (EFV/3TC/TDF) *Symfi* (EFV/3TC/TDF) *Symfi Lo* Note: Generic products are available for some formulations.	EFV (Sustiva)[c] *Capsules* • 50 mg • 200 mg *Tablet* • 600 mg EFV/FTC/TDF (Atripla) • EFV 600-mg/FTC 200-mg/TDF 300-mg tablet EFV/3TC/TDF (Symfi) • EFV 600-mg/3TC 300-mg/TDF 300-mg tablet EFV/3TC/TDF (Symfi Lo) • EFV 400-mg/3TC 300-mg/TDF 300-mg tablet	Pregnancy *PK in Pregnancy* • AUC is decreased during the third trimester compared with postpartum, but nearly all third-trimester participants exceeded target exposure. *Dosing in Pregnancy* • No change in dose is indicated. For guidance about the use of combination products in pregnancy, please see the specific sections on other components (i.e., 3TC, FTC, TDF). Standard Adult Doses *EFV (Sustiva)* • EFV 600 mg once daily at or before bedtime • Take on an empty stomach to reduce side effects. *EFV/FTC/TDF (Atripla)* • One tablet once daily at or before bedtime • Take on an empty stomach to reduce side effects. *EFV/3TC/TDF (Symfi or Symfi Lo)* • One tablet once daily on an empty stomach and preferably at bedtime	Moderate placental transfer to fetus[b] The FDA advises women to avoid becoming pregnant while taking EFV and advises health care providers to avoid administration during the first trimester of pregnancy because fetal harm may occur. However, the data on more than 7,900 periconception EFV exposures from Botswana rule out a threefold or greater increased risk of NTDs. As a result, the current Perinatal Guidelines do not restrict the use of EFV in pregnant women or in women who are planning to become pregnant. This is consistent with both the British HIV Association and WHO guidelines for use of ARV drugs in pregnancy. EFV should be continued in pregnant women who are on a virally suppressive, EFV-based regimen, because ARV drug changes during pregnancy may be associated with loss of viral control and an increased risk of perinatal transmission (see People with HIV Who Are Taking Antiretroviral Therapy When They Become Pregnant).	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
Etravirine (ETR) *Intelence*	Tablet • 25 mg • 100 mg • 200 mg For patients who are unable to swallow tablets whole, the tablets may be dissolved in a glass of water.	Pregnancy *PK in Pregnancy* • PK data in pregnancy suggest 1.2-fold to 1.6-fold increases in ETR exposure during pregnancy. *Dosing in Pregnancy* • No change in dose is indicated. Standard Adult Doses • 200 mg twice daily with food	Placental transfer varies; it is usually in the moderate-to-high category, ranging from 0.19 to 4.25.[b] Insufficient data to assess for teratogenicity in humans. No evidence of teratogenicity in rats or rabbits.	January 31, 2024
Nevirapine (NVP) Viramune Viramune XR Note: Generic products are available for some formulations.	NVP (Viramune) *Tablet* • 200 mg[c] *Oral Suspension* • 50 mg/5 mL[c] Viramune XR *Tablets* • 100 mg • 400 mg[c]	Pregnancy *PK in Pregnancy* • PK of immediate-release tablets not significantly altered in pregnancy • No data available on extended-release formulations in pregnancy *Dosing in Pregnancy* • No change in dose indicated Standard Adult Doses • NVP 200 mg once daily (using Viramune immediate release) for a 14-day lead-in period; thereafter, NVP 200 mg twice daily or 400 mg (using Viramune XR tablet) once daily, without regard to food • Repeat the lead-in period if therapy is discontinued for >7 days.	High placental transfer to fetus[b] No evidence of human teratogenicity (can rule out 1.5-fold increase in overall birth defects and 2-fold increase in cardiovascular and genitourinary defects) An increased risk of symptomatic liver toxicity exists when first initiating therapy in women with CD4 counts ≥250/mm^3. Liver toxicity is often associated with a rash and can be fatal. Pregnancy does not appear to increase this risk. NVP should be initiated in pregnant people with CD4 counts ≥250 cells/mm^3 only if benefit clearly outweighs risk. A potential increased risk of life-threatening hepatotoxicity exists in pregnant people with high CD4 counts. Elevated transaminase levels at baseline may increase the risk of NVP toxicity.	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
		• In patients who develop mild-to-moderate rash without constitutional symptoms during the lead-in period, continue lead-in dosing until rash resolves, but administer for ≤28 days total.	Patients who become pregnant while taking NVP-containing regimens and who are tolerating their regimens well can continue taking those regimens, regardless of their CD4 counts.	
Rilpivirine (RPV) *Edurant* (RPV/FTC/TDF) *Complera* (RPV/DTG) *Juluca* (RPV/FTC/TAF) *Odefsey* (CAB and RPV) *Cabenuva* CAB and RPV is a two-drug co-packaged product for IM injection.	RPV (Edurant) *Tablets* • 25 mg RPV/FTC/TDF (Complera) • RPV 25-mg/ FTC 200-mg/ TDF 300-mg tablet RPV/DTG (Juluca) • RPV 25-mg/DTG 50-mg tablet RPV/FTC/TAF (Odefsey) • RPV 25-mg/FTC 200-mg/ TAF 25-mg tablet CAB and RPV (Cabenuva) • CAB 200-mg/mL suspension for IM injection • RPV 300-mg/mL suspension for IM injection	Pregnancy *PK in Pregnancy* • RPV PK are highly variable during pregnancy. RPV AUC and trough concentrations are 20% to 50% lower in pregnancy than postpartum. Although most pregnant women exceeded target exposure, those with detectable viral loads had lower RPV troughs. *Dosing in Pregnancy* • Although RPV plasma concentration is reduced during pregnancy, higher-than-standard doses have not been studied, and not enough data are available to recommend a dosing change during pregnancy. Pregnant people receiving standard dosing should have their viral loads monitored more frequently than people who are not receiving RPV. For guidance about the use of combination products in pregnancy, please see the specific sections on other components (i.e., CAB, DT G, FTC, TAF, TDF). Standard Adult Doses *RPV (Edurant)* • RPV 25 mg once daily with food	Moderate-to-high placental transfer to fetus[b] No evidence of human teratogenicity (can rule out twofold increase in overall birth defects) Two-drug regimens (e.g., the RPV/DTG FDC) are not recommended for use in pregnancy.	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
		RPV/FTC/TDF (Complera) • One tablet once daily with food *RPV/DTG (Juluca)* • One tablet once daily with food *RPV/FTC/TAF (Odefsey)* • One tablet once daily with food *CAB and RPV (Cabenuva)* • Refer to Cabotegravir for dosing and instructions.		
PIs PIs block the activity of the protease enzyme, which is required to assemble new HIV viral particles that are capable of infecting new cells.				
Atazanavir (ATV) *Reyataz* Note: Generic products are available for some formulations. Note: ATV must be combined with low-dose RTV boosting in pregnancy. (ATV/c) *Evotaz*	ATV (Reyataz) *Capsules* • 100 mg (generic product only) • 150 mg[c] (generic product only) • 200 mg[c] • 300 mg[c] *Oral Powder* • 50-mg packet ATV/c (Evotaz) • ATV 300-mg/COBI 150-mg tablet	Pregnancy *PK in Pregnancy* • ATV (Reyataz) o ATV concentrations are reduced during pregnancy, and they are further reduced when ATV is given concomitantly with TDF or an H2-receptor antagonist. o Intracellular ATV levels in women taking the standard dose (ATV/r 300 mg/100 mg) without concomitant TDF appear reassuringly stable throughout pregnancy. • ATV/c (Evotaz) o Use of ATV/c is not recommended during pregnancy because ATV trough concentrations are 80% to 85% lower than the ATV concentrations seen in nonpregnant adults.	Low placental transfer to fetus[b] No evidence of human teratogenicity (can rule out 1.5-fold increase in overall birth defects) Must be given with RTV boosting in pregnancy Effect of *in utero* ATV exposure on infant indirect bilirubin levels is unclear. Nonpathologic elevations of neonatal bilirubin have been observed in some, but not all, clinical trials to date. Oral powder (but not capsules) contains phenylalanine, which can be harmful to patients with phenylketonuria.	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
		Dosing in Pregnancy • ATV (Reyataz) o Use of unboosted ATV **is not recommended** during pregnancy. o Use of unboosted ATV **is not recommended** during pregnancy for ARV-experienced patients who are taking TDF and an H2-receptor antagonist. o Use of an increased dose (ATV/r 400 mg/ 100 mg once daily with food) during the second and third trimesters results in plasma ATV concentrations equivalent to those seen in nonpregnant adults receiving standard dosing. Increased ATV dosing is recommended for pregnant people in the second and third trimesters who are also receiving either TDF or an H2-receptor antagonist. • ATV/c (Evotaz) o ATV/c should not be used in pregnancy because atazanavir C_{min} is substantially reduced (see COBI). For guidance about the use of combination products in pregnancy, see the specific sections on other components (i.e., COBI). Standard Adult Doses *In ARV-Naive Patients without RTV Boosting* • ATV 400 mg once daily with food; ATV without RTV boosting **is not recommended** when used with TDF, H2-receptor antagonists, PPIs, or during pregnancy.	Use of ATV/c **is not recommended** during pregnancy. See Recommendations for Use of Antiretroviral Drugs During Pregnancy, Table 6, and Table 7 for discussions about avoiding the use of ATV/c during pregnancy.	

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
		In ARV-Naive Patients with RTV Boosting • ATV/r 300 mg/100 mg once daily with food • When combined with EFV in ARV-naive patients: ATV/r 400 mg/100 mg once daily with food *In ARV-Experienced Patients* • ATV 300 mg plus RTV 100 mg once daily with food • Do not use with PPIs or EFV. *In ARV-Experienced Patients Who Are Receiving an H2-Receptor Antagonist* • ATV/r 300/100 mg once daily with food *In ARV-Experienced Patients Who Are Receiving an H2-Receptor Antagonist and TDF* • ATV/r 400 mg/100 mg once daily with food *Powder Formulation* • Oral powder is taken with RTV once daily with food at the same recommended adult dose as the capsules. *ATV/c (Evotaz)* • One tablet once daily with food		
Darunavir (DRV) *Prezista*	DRV (Prezista) *Tablet* • 75 mg • 150 mg	Pregnancy *PK in Pregnancy* • Decreased exposure in pregnancy with use of DRV/r	Low placental transfer to fetus[b] No evidence of teratogenicity in mice, rats, or rabbits. No evidence of human teratogenicity.	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
Note: Must be combined with low-dose RTV or COBI boosting. (DRV/c) *Prezcobix* (DRV/c/FTC/TAF) *Symtuza*	• 600 mg • 800 mg *Oral Suspension* • 100 mg/mL DRV/c (Prezcobix) • DRV/c 800-mg/ 150-mg tablet DRV/c/FTC/TAF (Symtuza) • DRV 800-mg/ COBI 150-mg/ FTC 200-mg/ TAF 10-mg tablet	*Dosing in Pregnancy* • The Panel **does not recommend** once-daily dosing with DRV/r during pregnancy or the use of DRV/c during pregnancy. • Twice-daily DRV/r dosing (DRV/r 600 mg/100 mg with food) is recommended for all pregnant people. • Increased twice-daily DRV dose (DRV/r 800 mg/ 100 mg with food) during pregnancy does not result in an increase in DRV exposure and **is not recommended**. 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 *ARV-Naive Patients* • DRV/r 800 mg/100 mg once daily with food • DRV/c 800 mg/150 mg once daily with food *ARV-Experienced Patients If Patient Has No DRV Resistance Mutations* • DRV/r 800 mg/100 mg once daily with food • DRV/c 800 mg/150 mg once daily with food *ARV-Experienced Patients If Any DRV Resistance Mutations Are Present* • DRV/r 600 mg/100 mg twice daily with food	Must be boosted with low-dose RTV The Panel **does not recommend** once-daily dosing with DRV/r during pregnancy or the use of DRV/c during pregnancy. If a DRV/c regimen is continued during pregnancy, viral load should be monitored frequently.	

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
		DRV/c (Prezcobix) • One tablet once daily with food *DRV/c/FTC/TAF (Symtuza)* • One tablet once daily with food		
Lopinavir/Ritonavir (LPV/r) *Kaletra* Note: Generic products are available for all formulations.	LPV/r (Kaletra)[c] *Tablets* • LPV/r 200 mg/50 mg • LPV/r 100 mg/25 mg *Oral Solution* • Each 5 mL contains LPV/r 400 mg/100 mg.	Pregnancy *PK in Pregnancy* • With twice-daily dosing, LPV exposure is reduced in pregnant women who receive standard adult doses, increasing the dose by 50% results in exposure equivalent to that seen in nonpregnant adults receiving standard doses. • No PK data are available for once-daily dosing in pregnancy. *Dosing in Pregnancy* • Once-daily dosing **is not recommended** during pregnancy. • Some experts recommend that an increased dose (i.e., LPV/r 600 mg/150 mg twice daily without regard to meals or LPV/r 500 mg/125 mg twice daily without regard to meals) should be used in the second and third trimesters, especially in PI-experienced pregnant women and women who start treatment during pregnancy with a baseline viral load >50 copies/mL. • When standard dosing is used, monitor virologic response and, if possible, LPV drug levels.	Low placental transfer to fetus[b] No evidence of human teratogenicity (can rule out 1.5-fold increase in overall birth defects) Oral solution contains 42% alcohol and 15% propylene glycol and **is not recommended** for use in pregnancy. Once-daily LPV/r dosing **is not recommended** during pregnancy.	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
		Standard Adult Doses • LPV/r 400 mg/100 mg twice daily, *or* • LPV/r 800 mg/20 mg once daily *Tablets* • Take without regard to food. *Oral Solution* • Take with a meal. *With EFV or NVP in PI-Naive or PI-Experienced Patients* • LPV/r 500-mg/125-mg tablets twice daily without regard to meals (use a combination of two LPV/r 200-mg/50-mg tablets and one LPV/r 100-mg/25-mg tablet), *or* • LPV/r 520-mg/130-mg oral solution (6.5 mL) twice daily with food		
Entry Inhibitors Entry and attachment inhibitors block viral binding or fusion of HIV to host cells.				
Fostemsavir (FTR) *Rukobia*	• Extended-release tablet: 600 mg	Pregnancy *PK in Pregnancy* • No PK studies in human pregnancy *Dosing in Pregnancy* • Insufficient data to make dosing recommendation	No human data are available regarding placental passage. A study in rats demonstrates placental passage of temsavir or other metabolites. Insufficient data to assess for teratogenicity in humans. No evidence of teratogenicity in rats or rabbits.	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
		Standard Adult Doses *(FTR) Rukobia* • FTR 600 mg twice daily with or without food		
Ibalizumab-uiyk (IBA) *Trogarzo*	IV Solution • 150 mg/mL	Pregnancy *PK in Pregnancy* • No PK studies in human pregnancy *Dosing in Pregnancy* • Insufficient data to make dosing recommendations Standard Adult Doses • IBA 2,000-mg loading dose, followed by IBA 800-mg maintenance doses administered every 2 weeks	No human data are available, but placental transfer of IBA, a monoclonal antibody, is possible and documented in monkeys. Based on data in cynomolgus monkeys with *in utero* exposure, the potential exists for reversible immunosuppression (CD4 T cell and B cell lymphocytopenia) in infants born to mothers exposed to IBA during pregnancy. The FDA requires collection of prospective data in individuals exposed to IBA during pregnancy to monitor maternal and pregnancy outcomes, including adverse effects on the developing fetus, neonate, and infant. Insufficient data to assess for teratogenicity in humans	January 31, 2024
Maraviroc (MVC) *Selzentry*	Tablets • 150 mg • 300 mg	Pregnancy *PK in Pregnancy* • A PK study in human pregnancy demonstrated a 20% to 30% overall decrease in MVC AUC, but C_{trough} exceeded the recommended minimum concentration of 50 ng/mL.	Moderate placental transfer to fetus[b] No evidence of teratogenicity in rats or rabbits; insufficient data to assess teratogenicity in humans	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
		Dosing in Pregnancy • Adjusting the standard adult MVC dose for concomitant use with ARV drugs seems appropriate. Standard Adult Doses • MVC 300 mg twice daily with or without food • MVC should be used only for patients with CCR5-tropic virus (and no X4-tropic virus). *Dose Adjustments* • Increase to MVC 600 mg twice daily when used with the potent CYP3A inducers EFV, ETR, and rifampin • Decrease to MVC 150 mg twice daily when used with CYP3A inhibitors, which include all PIs except TPV/r and itraconazole		
Capsid Inhibitor Capsid inhibitors are a class of drugs that interfere with HIV capsid, a protein shell that protects HIV's genetic material and enzymes needed for replication. Capsid inhibitors can disrupt HIV capsid during multiple stages of the viral life cycle.				
Lenacapavir (LEN) *Sunlenca*	LEN (Sunlenca) • LEN 300-mg tablets for oral administration • LEN 463.5 mg/1.5 ml for SQ injection	Pregnancy *PK in Pregnancy* • No PK studies in human pregnancy *Dosing in Pregnancy* • Insufficient data to make dosing recommendations	No human data are available regarding placental passage or through breast milk. Data are insufficient to assess for teratogenicity in humans. No evidence of teratogenicity in rats or rabbits.	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
		Standard Adult Doses *Initiation Option 1* • Day 1: 927 mg by SQ injection (2 x 1.5 mL injections) and 600 mg orally (2 x 300-mg tablets) • Day 2: 600 mg orally (2 x 300-mg tablets). *Initiation Option 2* • Day 1: 600 mg orally (2 x 300-mg tablets) • Day 2: 600 mg orally (2 x 300-mg tablets) • Day 8: 300 mg orally (1 x 300-mg tablet) • Day 15: 927 mg by SQ injection (2 x 1.5 mL injections) *Maintenance Dosing* • 927 mg by SQ injection (2 x 1.5 mL injections) every 26 weeks +/- 2 weeks from date of last injection		
INSTIs INSTIs are the viral enzyme that catalyzes the two-step process that inserts HIV DNA into the genome of the host cell.				
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	High placental transfer to fetus[b] No evidence of human teratogenicity (can rule out twofold increase in overall birth defects)	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
		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	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.	
Cabotegravir (CAB) *Vocabria (oral)* *Apretude (injection for HIV pre-exposure prophylaxis)* (CAB) *Cabenuva* Note: CAB and RPV is a two-drug co-packaged product for IM injection.	CAB • CAB 30-mg tablets for oral administration • CAB 200-mg/mL suspension for IM injection CAB and RPV • CAB 200-mg/mL suspension for IM injection • RPV 300-mg/mL suspension for IM injection	Pregnancy *PK in Pregnancy* • No PK studies in human pregnancy *Dosing in Pregnancy* • Insufficient data to make dosing recommendations For guidance about the use of combination products in pregnancy, please see the specific sections on other components (i.e., RPV). Standard Adult Doses *Oral Lead-In Therapy (Optional)* • CAB (Vocabria) o One 30-mg tablet once daily in combination with RPV (Edurant) 25-mg once daily taken with a meal for 4 weeks • CAB (Apretude) o Initiation	No human data are available regarding placental passage. Insufficient data to assess for teratogenicity in humans. No evidence of teratogenicity in rats or rabbits.	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
		▪ CAB 600-mg (3 mL) injections given 1 month apart for 2 consecutive months (on the last day of an oral lead-in, if used, or within 3 days) o Continuation Therapy ▪ CAB 600-mg (3 mL) injections every 2 months thereafter • CAB and RPV (Cabenuva) o Initiation ▪ CAB 600-mg (3 mL) and RPV 900-mg (3 mL), given as two separate injections in separate ventrogluteal sites for 2 consecutive months (on the last day of an oral lead-in if used) o Continuation Therapy ▪ *Monthly:* CAB 400-mg (2 mL) and RPV 600-mg (2 mL), given as two separate injections in separate ventrogluteal sites once a month with allowance for a +/- 7-day administration window ▪ *Every 2 months:* Starting in month 4, CAB 600-mg (2 mL) and RPV 900-mg (2 mL), given as two separate injections in separate ventrogluteal sites once a month with allowance for a +/- 7-day administration window		

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
		▪ Patients should be monitored for approximately 10 minutes for post-injection reactions. A 23-gauge, 1.5-inch IM needle is recommended for the injection and is provided in the packaging. Longer, 2-inch needles should be used in patients with BMIs >30 kg/m^2. *Changing Dosing Frequency and Managing Missed Doses* • Refer to the package insert for instructions about changing the frequency of continuation doses and managing missed doses (see Apretude and Cabenuva).		
Dolutegravir (DTG) *Tivicay* *Tivicay PD* (DTG/3TC) *Dovato* (DTG/RPV) *Juluca* (DTG/ABC/3TC) *Triumeq*	DTG (Tivicay) • DTG 10-mg, 25-mg, and 50-mg film-coated tablets DTG (Tivicay PD) • DTG 5-mg dispersible tablet for oral suspension DTG film-coated tablets and DTG dispersible tablets are not bioequivalent and are not interchangeable. DTG/3TC (Dovato) • DTG 50-mg/3TC 300-mg tablet	Pregnancy *PK in Pregnancy* • AUC may be 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 the use of combination products in pregnancy, please see the specific sections on other components (i.e., ABC, 3TC, RPV). Standard Adult Doses *In ARV-Naive or ARV-Experienced (but INSTI-Naive) Patients* • DTG (Tivicay)	High placental transfer to fetus[b] No evidence of teratogenicity in rats or rabbits. The most recent data from Botswana indicate the prevalence of NTDs in infants born to pregnant women with HIV receiving DTG at conception is no longer statistically different than in those receiving other antiretrovirals. DTG is a *Preferred* antiretroviral drug for use during pregnancy, irrespective of trimester, and for people who are trying to conceive (see Recommendations for Use of Antiretroviral Drugs During Pregnancy and Table 7).	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
	DTG/RPV (Juluca) • DTG 50-mg/RPV 25-mg tablet DTG/ABC/3TC (Triumeq) • DTG 50-mg/ABC 600-mg/ 3TC 300-mg tablet	o One 50-mg tablet once daily, without regard to food • DTG (Tivicay PD) o Six 5-mg tablets (30 mg) dissolved in water once daily, without regard to food • DTG/3TC (Dovato) o One tablet once daily, without regard to food • DTG/RPV (Juluca) o One tablet once daily, with food • DTG/ABC/3TC (Triumeq) o One tablet once daily, without regard to food *In ARV-Naive or ARV-Experienced (but INSTI-Naive) Patients Who Are Also Receiving EFV, FPV/r, TPV/r, or Rifampin* • DTG (Tivicay) o One 50-mg tablet twice daily, without regard to food • DTG (Tivicay PD) o Six 5-mg tablets (30 mg) dissolved in water twice daily, without regard to food *In INSTI-Experienced Patients* • DTG (Tivicay) o One tablet twice daily, without regard to food	To maximize DTG absorption, doses should not be administered within 2 hours of ingesting any preparation that contains such minerals as iron or calcium, including prenatal vitamins.	

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
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. For persons who become pregnant while taking EVG/c, consider frequent viral load monitoring or switching to a more effective, recommended regimen. If a pregnant person continues taking a regimen that contains EVG/c, 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.	January 31, 2024
Raltegravir (RAL) *Isentress* *Isentress HD*	RAL (Isentress) *Film-Coated Tablets* • 400 mg *Chewable Tablets* • 25 mg • 100 mg	Pregnancy *PK in Pregnancy* • Decreased drug concentrations in the third trimester are not of sufficient magnitude to warrant a change in dosing. *Dosing in Pregnancy* • No change in dose is indicated.	High placental transfer to fetus[b] No evidence of human teratogenicity (can rule out a 1.5-fold increase in overall birth defects) There is a case report of markedly elevated liver transaminases with RAL use in late pregnancy. Severe, potentially life-threatening, and fatal skin reactions and HSRs have been reported in nonpregnant adults.	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
	RAL (Isentress HD) *Film-Coated Tablets* • 600 mg	• Once-daily dosing (i.e., two RAL 600-mg film-coated tablets) **should not be used** in pregnant individuals until more information is available. Standard Adult Doses *In Patients Who Are Not Receiving Rifampin* • RAL 400-mg film-coated tablets twice daily without regard to food • Two RAL 600-mg film-coated tablets (1,200 mg) once daily without regard to food for ARV-naive patients or patients who are already virologically suppressed on an initial regimen of RAL 400 mg twice daily • Chewable tablets and oral suspension doses **are not interchangeable** with either film-coated tablets or each other. *In Patients Who Are Receiving Rifampin* • Two RAL 400-mg film-coated tablets (800 mg) twice daily without regard to food	RAL chewable tablets contain phenylalanine. To maximize RAL absorption, doses should not be administered within 2 hours of ingestion of any preparation containing minerals—such as iron or calcium—including prenatal vitamins.	
Pharmacoenhancers Pharmacoenhancers reduce the metabolism of antiretroviral drugs and prolong their presence in plasma, allowing for more convenient dosing regimens.				
Cobicistat (COBI) *Tybost* (ATV/c) *Evotaz* (EVG/c/FTC/TAF) *Genvoya*	COBI (Tybost) *Tablet* • COBI 150 mg ATV/c (Evotaz) • ATV 300-mg/ COBI 50-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.	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.	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
(DRV/c) *Prezcobix* (EVG/c/FTC/TDF) *Stribild* (DRV/c/FTC/TAF) Symtuza	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	*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 *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		

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
		DRV/c/FTC/TAF (Symtuza) • One tablet once daily with food		
Ritonavir (RTV) *Norvir* (LPV/r) *Kaletra*	RTV (Norvir) *Capsule* • RTV 100 mg *Tablet* • RTV 100 mg *Oral Solution* • RTV 80 mg/mL *Powder* • RTV 100 mg/sachet LPV/r (Kaletra) *Tablets* • LPV/r 200 mg/50 mg • LPV/r 100 mg/25 mg *Oral Solution* • Each 5 mL contains LPV/r 400 mg/100 mg.	Pregnancy *PK in Pregnancy* • Lower RTV levels are seen during pregnancy than during postpartum, which may reduce the pharmaco-enhancing effect of RTV in pregnancy. *RTV Dosing in Pregnancy* • No dose adjustment is necessary when RTV is used as booster. *LPV/r Dosing in Pregnancy* • Once-daily dosing is not recommended during pregnancy. • Some experts recommend that an increased dose (i.e., LPV/r 600 mg/ 150 mg twice daily without regard to meals or LPV/r 500 mg/125 mg twice daily without regard to meals) should be used in the second and third trimesters of pregnancy, especially in patients who are PI-experienced and in those who start treatment during pregnancy with a baseline viral load >50 copies/mL. • When standard dosing is used, monitor virologic response and, if possible, LPV drug levels. For guidance about use of combination products in pregnancy, please see the specific sections on other components (i.e., LPV/r).	Low placental transfer to fetus[b] No evidence of increased risk of human teratogenicity (can rule out 1.5-fold increase in overall birth defects) RTV should only be used as a low-dose booster for other PIs. RTV oral solution contains 43% alcohol and, therefore, is not recommended for use during pregnancy because no safe level of alcohol exposure during pregnancy is known. LPV/r oral solution contains 42% alcohol and 15% propylene glycol and is not recommended for use in pregnancy. Once-daily LPV/r dosing is not recommended during pregnancy.	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
		Standard Adult Dose of RTV (Norvir) When Used as a PK Booster for Other PIs • RTV 100–400 mg per day in one or two divided doses (refer to other PI sections for specific dosing recommendations). *Tablet* • Take with food. *Capsule or Oral Solution* • To improve tolerability, take with food, if possible. Standard Adult Doses of LPV/r (Kaletra) • LPV/r 400 mg/100 mg twice daily, *or* • LPV/r 800 mg/200 mg once daily *Tablet* • Take without regard to food. *Oral Solution* • Take with food. With EFV or NVP in PI-Naive or PI-Experienced Patients • LPV/r 500-mg/125-mg tablets twice daily without regard to meals (use a combination of two LPV/r 200-mg/50-mg tablets and one LPV/r 100-mg/25-mg tablet), *or* • LPV/r 520-mg/130-mg oral solution (6.5 mL) twice daily with food		

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

[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

[c] Generic product available

Key: 3TC = lamivudine; ABC = abacavir; ART = antiretroviral therapy; ARV = antiretroviral; ATV = atazanavir; ATV/c = atazanavir/cobicistat; ATV/r = atazanavir/ritonavir; AUC = area under the curve; BIC = bictegravir; BMI = body mass index; C_{24h} = concentrations at 24 hours postdose; CAB = cabotegravir; CD4 = CD4 T lymphocyte; COBI = cobicistat; CYP = cytochrome P; DOR = doravirine; DRV = darunavir; DRV/c = darunavir/cobicistat; DRV/r = darunavir/ritonavir; DTG = dolutegravir; EFV = efavirenz; ETR = etravirine; EVG = elvitegravir; EVG/c = elvitegravir/cobicistat; FDA = U.S. Food and Drug Administration; FDC = fixed-dose combination; FPV/r = fosamprenavir/ritonavir; FTC = emtricitabine; FTR = fostemsavir; HBV = hepatitis b virus; HSR = hypersensitivity reaction; IBA = ibalizumab; IM = intramuscular; INSTI = integrase strand transfer inhibitor; IV = intravenous; LEN = lenacapavir; LPV = lopinavir; LPV/r = lopinavir/ritonavir; MVC = maraviroc; NNRTI = non-nucleoside reverse transcriptase inhibitor; NRTI = nucleoside reverse transcriptase inhibitor; NTD = neural tube defect; NVP = nevirapine; PI = protease inhibitor; PK = pharmacokinetic; PPI = proton pump inhibitor; RAL = raltegravir; RPV = rilpivirine; RTV = ritonavir; SQ = subcutaneous; TAF = tenofovir alafenamide; TDF = tenofovir disoproxil fumarate; TPV = tipranavir; TPV/r = tipranavir/ritonavir; WHO = World Health Organization; ZDV = zidovudine