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

Table 10. Antiretroviral Drug Use in Pregnant Women with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 1 of 21)

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	Last Reviewed
NRTIs NRTIs are recommended for use as part of combination regimens, usually including 2 NRTIs with either an NNRTI or 1 or more PIs. Use of single or dual NRTIs alone is not recommended for treatment of HIV infection. See text for discussion of potential maternal and infant mitochondrial toxicity.				
Abacavir (ABC) *Ziagen* (ABC/3TC) *Epzicom* (ABC/DTG/3TC) *Triumeq* (ABC/3TC/ZDV) *Trizivir* **Note:** Generic available for some formulations.	ABC (Ziagen)[d] *Tablet:* • 300 mg *Solution:* • 20 mg/mL ABC/3TC (Epzicom):[d] • ABC 600 mg plus 3TC 300 mg tablet ABC/DTG/3TC (Triumeq): • ABC 600 mg plus 3TC 300 mg plus DTG 50 mg tablet ABC/3TC/ZDV (Trizivir):[d] • ABC 300 mg plus 3TC 150 mg plus ZDV 300 mg tablet	Standard Adult Doses *ABC (Ziagen):* • ABC 300 mg twice daily or ABC 600 mg once daily, without regard to food *ABC/3TC (Epzicom):* • 1 tablet once daily without regard to food *ABC/DTG/3TC (Triumeq):* • 1 tablet daily without regard to food *ABC/3TC/ZDV (Trizivir):* • 1 tablet twice daily without regard to food Dosing in Pregnancy: • No change in dose indicated. PK in Pregnancy: • PK not significantly altered in pregnancy. • For guidance about use of combination products in pregnancy, please see the specific sections on other components (i.e., 3TC, ZDV, DTG).	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 should be done and documented as negative before starting ABC. Patients should be educated regarding symptoms of HSR.	December 7, 2018
Didanosine (ddI) *Videx* *Videx EC* **Note:** Generic available for some formulations	ddI (Videx) *Buffered Tablets (Non-EC):* • No longer available *Solution:* • 10 mg/mL oral solution Videx EC (EC Beadlets) Capsules: • 125 mg • 200 mg • 250 mg • 400 mg Delayed-Release Capsules:[d] • 200 mg • 250 mg • 400 mg	Standard Adult Doses *Body Weight ≥60 kg:* • ddI 400 mg once daily *With TDF:* • ddI 250 mg once daily; take 1/2 hour before or 2 hours after a meal. *Body Weight <60 kg:* • ddI 250 mg once daily *With TDF:* • ddI 200 mg once daily; take 1/2 hour before or 2 hours after a meal. **Note:** Preferred dosing with oral solution is twice daily (total daily dose divided into 2 doses). Take 1/2 hour before or 2 hours after a meal. Dosing in Pregnancy: • No change in dose indicated.	ddI **is not recommended** for pregnant women. Low-moderate placental transfer to fetus.[b] ddI **should not be used** with d4T. Lactic acidosis, sometimes fatal, has been reported in pregnant women receiving ddI and d4T together.	December 7, 2018

Table 10. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 2 of 21)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
Didanosine, continued		PK in Pregnancy: • PK is not significantly altered in pregnancy.		
Emtricitabine (FTC) *Emtriva* (FTC/EFV/TDF) *Atripla* (FTC/BIC/TAF) *Biktarvy* (FTC/RPV/TDF) *Complera* (FTC/TAF) *Descovy* (FTC/EVG/COBI/TAF) *Genvoya* (FTC/RPV/TAF) *Odefsey* (FTC/EVG/COBI/TDF) *Stribild* (FTC/DRV/COBI/TAF) *Symtuza* (FTC/TDF) *Truvada*	FTC (Emtriva) *Capsule:* • 200 mg *Oral Solution:* • 10 mg/mL FTC/EFV/TDF (Atripla): • FTC 200 mg plus EFV 600 mg plus TDF 300 mg tablet FTC/BIC/TAF (Biktarvy): • FTC 200 mg plus BIC 50 mg plus TAF 25 mg tablet FTC/RPV/TDF (Complera): • FTC 200 mg plus RPV 25 mg plus TDF 300 mg tablet FTC/TAF (Descovy): • FTC 200 mg plus TAF 25 mg tablet FTC/EVG/COBI/TAF (Genvoya): • FTC 200 mg plus EVG 150 mg plus COBI 150 mg plus TAF 10 mg tablet FTC/RPV/TAF (Odefsey): • FTC 200 mg plus RPV 25 mg plus TAF 25 mg tablet FTC/EVG/COBI/TDF (Stribild): • FTC 200 mg plus EVG 150 mg plus COBI 150 mg plus TDF 300 mg tablet FTC/DRV/COBI/TAF (Symtuza): • FTC 200 mg plus DRV 800 mg plus COBI 150 mg plus TAF 10 mg tablet FTC/TDF (Truvada): • FTC 200 mg plus TDF 300 mg tablet	Standard Adult Doses *FTC (Emtriva)* *Capsule:* • EVG 200 mg once daily without regard to food *Oral Solution:* • EVG 240 mg (24 mL) once daily without regard to food *FTC/EFV/TDF (Atripla):* • 1 tablet once daily at or before bedtime • Take on an empty stomach to reduce side effects. *FFTC/BIC/TAF (Biktarvy):* • 1 tablet once daily with or without food *FTC/RPV/TDF (Complera):* • 1 tablet once daily with food *FTC/TAF (Descovy):* • 1 tablet once daily with or without food *FTC/EVG/COBI/TAF (Genvoya):* • 1 tablet once daily with food *FTC/RPV/TAF (Odefsey):* • 1 tablet once daily with food *FTC/EVG/COBI/TDF (Stribild):* • 1 tablet once daily with food *FTC/DRV/COBI/TAF (Symtuza):* • 1 tablet once daily with food *FTC/TDF (Truvada):* • 1 tablet once daily without regard to food Dosing in Pregnancy: • No change in FTC dose indicated. PK in Pregnancy: • PK of FTC is not significantly altered in pregnancy. • For guidance about use of combination products in pregnancy, please see the specific sections on other components (i.e., TDF, TAF, EFV, RPV, DRV, EVG, BIC, COBI)	High placental transfer to fetus.[b] No evidence of human teratogenicity (can rule out 1.5-fold increase in overall birth defects). If patient is HBV-coinfected, it is possible that a HBV flare may occur if the drug is stopped; see HIV/Hepatitis B Virus Coinfection.	December 7, 2018

Table 10. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 3 of 21)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
Lamivudine (3TC) *Epivir* (3TC/TDF) *Cimduo* (3TC/ZDV) *Combivir* (3TC/DOR/TDF) *Delstrigo* (3TC/ABC) *Epzicom* (3TC/EFV/TDF) *Symfi* (3TC/EFV/TDF) *Symfi Lo* (3TC/TDF) *Temixys* (3TC/ABC/DTG) *Triumeq* (3TC/ABC/ZDV) *Trizivir* **Note:** Generic available for some formulations	3TC (Epivir)[d] *Tablets:* • 150 mg • 300 mg *Oral Solution:* • 10 mg/mL 3TC/TDF (Cimduo): • 3TC 300 mg plus TDF 300 mg tablet 3TC/ZDV (Combivir):[d] • 3TC 150 mg plus ZDV 300 mg tablet 3TC/DOR/TDF (Delstrigo): • 3TC 300 mg plus DOR 100 mg plus TDF 300 mg tablet 3TC/ABC (Epzicom):[d] • 3TC 300 mg plus ABC 600 mg tablet 3TC/EFV/TDF (Symfi): • 3TC 300 mg plus EFV 600 mg plus TDF 300 mg tablet 3TC/EFV/TDF (Symfi Lo): • 3TC 300 mg plus EFV 400 mg plus TDF 300 mg tablet 3TC/TDF (Temixys): • 3TC 300 mg plus TDF 300 mg tablet 3TC/ABC/DTG (Triumeq): • 3TC 300 mg plus ABC 600 mg plus DTG 50 mg tablet 3TC/ABC/ZDV (Trizivir):[d] • 3TC 150 mg plus ABC 300 mg plus ZDV 300 mg tablet	Standard Adult Doses *3TC (Epivir):* • 3TC 150 mg twice daily or 300 mg once daily, without regard to food *3TC/TDF (Cimduo):* • 1 tablet once daily without regard to food *3TC/ZDV (Combivir):* • 1 tablet twice daily without regard to food *3TC/DOR/TDF (Delstrigo):* • 1 tablet once daily without regard to food *3TC/ABC (Epzicom):* • 1 tablet once daily without regard to food *3TC/EFV/TDF (Symfi or Symfi Lo):* • 1 tablet once daily on an empty stomach and preferably at bedtime *3TC/ABC/DTG (Triumeq):* • 1 tablet once daily without regard to food *3TC/TDF (Temixys):* • 1 tablet once daily without regard to food *3TC/ABC/ZDV (Trizivir):* • 1 tablet twice daily without regard to food 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., ABC, DOR, DTG, EFV, TDF, ZDV).	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 HIV/HBV coinfection, it is possible that an HBV flare may occur if the drug is stopped; see HIV/Hepatitis B Virus Coinfection. **Note:** 3TC products developed specifically for treatment of HBV (e.g., Epivir-HBV) contain a lower dose of 3TC that **is not appropriate** for treatment of HIV.	December 7, 2018

Table 10. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 4 of 21)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
Stavudine (d4T) *Zerit* **Note:** Generic products are available for all formulations.	d4T (Zerit) *Capsules:* • 15 mg • 20 mg • 30 mg • 40 mg *Oral Solution:* • 1 mg/mL following reconstitution **Note:** Extended-release capsule formulation (Zerit XR) has been discontinued by the manufacturer.	Standard Adult Doses[e] *Body Weight ≥60 kg:* • 40 mg twice daily without regard to meals *Body Weight <60 kg:* • 30 mg twice daily without regard to meals Dosing in Pregnancy: • No change in dose indicated. PK in Pregnancy: • PK not significantly altered in pregnancy.	d4T **is not recommended** for pregnant women. High placental transfer.[b] No evidence of human teratogenicity (can rule out 2-fold increase in overall birth defects). Lactic acidosis, sometimes fatal, has been reported in pregn aant women receiving ddI and d4T together.	December 7, 2018
Tenofovir Alafenamide (TAF) *Vemlidy* (TAF/BIC/FTC) *Biktarvy* (TAF/FTC) *Descovy* (TAF/EVG/COBI/FTC) *Genvoya* (TAF/FTC/RPV) *Odefsey* (TAF/DRV/COBI/FTC) *Symtuza* **Note:** Generic available for some formulations.	TAF (Vemlidy)[d] *Tablet:* • 25 mg TAF/BIC/FTC (Biktarvy): • TAF 25 mg plus BIC 50 mg plus FTC 200 mg tablet TAF/FTC (Descovy): • TAF 25 mg plus FTC 200 mg tablet TAF/EVG/COBI/FTC (Genvoya): • TAF 10 mg plus EVG 150 mg plus COBI 150 mg plus FTC 200 mg tablet TAF/FTC/RPV (Odefsey): • TAF 25 mg plus FTC 200 mg plus RPV 25 mg tablet TAF/DRV/COBI/FTC (Symtuza): • TAF 10 mg plus DRV 800 mg plus COBI 150 mg plus FTC 200 mg tablet	Standard Adult Dose *TAF (Vemlidy):* • 1 tablet once daily with food *TAF/BIC/FTC (Biktarvy):* • 1 tablet once daily with or without food *TAF/FTC (Descovy):* • 1 tablet once daily with or without food • Same dose (TAF 25 mg) can be used with or without pharmaco-enhancers. *TAF/EVG/COBI/FTC (Genvoya):* • 1 tablet once daily with food *TAF/FTC/RPV (Odefsey):* • 1 tablet once daily with food *TAF/DRV/COBI/FTC (Symtuza):* • 1 tablet once daily with food PK in Pregnancy: • Plasma PK not significantly altered in pregnancy.	Low placental transfer to fetus.[b] Insufficient data to assess for teratogenicity in humans. No evidence of teratogenicity in rats. Renal function should be monitored because of potential for renal toxicity.	December 7, 2018

Table 10. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 5 of 21)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
Tenofovir Alafenamide, continued		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., BIC, COBI. DRV, EVG, FTC, RPV).		
Tenofovir Disoproxil Fumarate (TDF) *Viread* (TDF/EFV/FTC) *Atripla* (TDF/3TC) *Cimduo* (TDF/FTC/RPV) *Complera* (TDF/DOR/3TC) *Delstrigo* (TDF/EVG/COBI/FTC) *Stribild* (TDF/EFV/3TC) *Symfi* (TDF/EFV/3TC) *Symfi Lo* (TDF/3TC) *Temixys* (TDF/FTC) *Truvada* **Note:** Generic available for some formulations	TDF (Viread) *Tablet:*[d] • 300 mg *Powder:* • 40 mg/1 g oral powder TDF/EFV/FTC (Atripla): • TDF 300 mg plus EFV 600 mg plus FTC 200 mg tablet TDF/3TC (Cimduo): • TDF 300 mg plus 3TC 300 mg tablet TDF/FTC/RPV (Complera): • TDF 300 mg plus FTC 200 mg plus RPV 25 mg tablet TDF/DOR/3TC (Delstrigo): • TDF 300 mg plus DOR 100 mg plus 3TC 300 mg tablet TDF/EVG/COBI /FTC (Stribild): • TDF 300 mg plus EVG 150 mg plus COBI 150 mg plus FTC 200 mg tablet TDF/EFV/3TC (Symfi): • TDF 300 mg plus EFV 600 mg plus 3TC 300 mg tablet TDF/EFV/3TC (Symfi Lo): • TDF 300 mg plus EFV 400 mg plus 3TC 300 mg tablet	Standard Adult Doses *TDF (Viread)* *Tablet:* • TDF 300 mg once daily without regard to food *Powder:* • TDF 8 mg/kg (up to a maximum of TDF 300 mg). Take with food. *TDF/EFV/FTC (Atripla):* • 1 tablet once daily at or before bedtime. Take on an empty stomach to reduce side effects. *TDF/3TC (Cimduo):* • 1 tablet once daily without regard to food *TDF/FTC/RPV (Complera):* • 1 tablet once daily with food *TDF/DOR/3TC (Delstrigo):* • 1 tablet once daily without regard to food. *TDF/EVG/COBI/FTC (Stribild):* • 1 tablet once daily with food *TDF/EFV/3TC (Symfi or Symfi Lo):* • 1 tablet once daily on an empty stomach and preferably at bedtime *TDF/3TC (Temixys):* • 1 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). Studies in monkeys (at doses approximately 2-fold higher than those for human therapeutic use) show decreased fetal growth and reduction in fetal bone porosity within 2 months of starting maternal therapy. Human studies demonstrate no consistent link to low birth weight, but data are conflicting about potential effects on growth outcomes later in infancy. If patient is HBV coinfected, it is possible that an HBV flare may occur if TDF is stopped; see HIV/Hepatitis B Virus Coinfection. Renal function should be monitored because of potential for renal toxicity.	December 7, 2018

Table 10. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 6 of 21)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
Tenofovir Disoproxil Fumarate, continued	TDF/3TC (Temixys): • TDF 300 mg plus 3TC 300 mg tablet TDF/FTC (Truvada): • TDF 300 mg plus FTC 200 mg tablet	*TDF/FTC (Truvada):* • 1 tablet once daily without regard to food PK in Pregnancy: • AUC is lower in third trimester than postpartum, but trough levels are adequate. Dosing in Pregnancy: • No change in dose is indicated. • For guidance about use of combination products in pregnancy, please see the specific sections on other components (i.e., 3TC, COBI, DOR, EFV, EVG, FTC, RPV)		
Zidovudine (ZDV) *Retrovir* (ZDV/3TC) *Combivir* (ZDV/ABC/3TC) *Trizivir* **Note:** Generic available for all formulations.	ZDV (Retrovir) *Capsule:* • 100 mg *Tablet:* • 300 mg *Oral Solution:* • 10 mg/mL *Intravenous Solution:* • 10 mg/mL ZDV/3TC (Combivir): • ZDV 300 mg plus 3TC 150 mg tablet ZDV/ABC/3TC (Trizivir): • ZDV 300 mg plus 3TC 150 mg plus ABC 300 mg tablet	Standard Adult Dose *ZDV (Retrovir):* • ZDV 300 mg BID or ZDV 200 mg TID without regard to food *Active Labor:* • ZDV 2 mg/kg IV loading dose, followed by ZDV 1 mg/kg/hour continuous infusion from beginning of active labor until delivery *Combivir:* • 1 tablet twice daily without regard to food *Trizivir:* • 1 tablet twice daily without regard to food Dosing in Pregnancy: • No change in dose is indicated. PK in Pregnancy: • PK is not significantly altered in pregnancy. • For guidance about 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).	December 7, 2018

Table 10. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 7 of 21)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
NNRTI NNRTIs are recommended for use in combination regimens with 2 NRTI drugs. Hypersensitivity reactions, including hepatic toxicity and rash, more common in women; unclear if increased in pregnancy.				
Doravirine (DOR) *Pifeltro* (DOR/3TC/TDF) *Delstrigo*	DOR (Pifeltro): • 100 mg tablet DOR/3TC/TDF (Delstrigo): • DOR 100 mg plus 3TC 300 mg plus TDF 300 mg tablet	Standard Adult Dose *DOR (Pifeltro):* • 100 mg once daily with or without food *DOR/3TC/TDF (Delstrigo):* • 1 tablet once daily with or without food PK in Pregnancy: • No PK studies in human pregnancy. Dosing in Pregnancy: • Insufficient data to make dosing recommendation. • For guidance about use of combination products in pregnancy, please see the specific sections on other components (i.e., 3TC, TDF)	No human data are available on placental transfer of DOR, but animal studies suggest that DOR crosses the placenta. Insufficient data to assess for teratogenicity in humans. No evidence of teratogenicity in rats or rabbits.	December 7, 2018
Efavirenz (EFV) *Sustiva* (EFV/FTC/TDF) *Atripla* (EFV/3TC/TDF) *Symfi* (EFV/3TC/TDF) *Symfi Lo* **Note:** Generic available for some formulations.	EFV (Sustiva)[d] *Capsules:* • 50 mg • 200 mg *Tablet:* • 600 mg EFV/FTC/TDF (Atripla): • EFV 600 mg plus FTC 200 mg tablet TDF 300 mg plus EFV/3TC/TDF (Symfi): • EFV 600 mg plus 3TC 300 mg plus TDF 300 mg tablet EFV/3TC/TDF (Symfi Lo): • EFV 400 mg plus 3TC 300 mg plus TDF 300 mg tablet	Standard Adult Doses *EFV (Sustiva):* • EFV 600 mg once daily at or before bedtime, on an empty stomach to reduce side effects *EFV/FTC/TDF (Atripla):* • 1 tablet once daily at or before bedtime, on an empty stomach to reduce side effects *EFV/3TC/TDF (Symfi or Symfi Lo):* • 1 tablet once daily on an empty stomach and preferably at bedtime 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.	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, as fetal harm may occur. Although the limited data on first-trimester EFV exposure cannot rule out a 2-fold or 3-fold increased incidence of a rare outcome such as NTDs, the available data from a meta-analysis of >2,000 births suggest that there is no large increase in the risk of neural tube defects with first-trimester exposure (e.g., a 10-fold increase to a rate of 1%). 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.	December 7, 2018

Table 10. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 8 of 21)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
Efavirenz, continued		• For guidance about use of combination products in pregnancy, please see the specific sections on other components (i.e., 3TC, FTC, TDF)	EFV should be continued in pregnant women who are on a virologically 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 Pregnant Women Living with HIV Who are Currently Receiving Antiretroviral Therapy).	
Etravirine (ETR) *Intelence*	ETR (Intelence) *Tablets:* • 25 mg • 100 mg • 200 mg For patients unable to swallow tablets whole, the tablets may be dispersed in a glass of water.	Standard Adult Dose *ETR (Intelence):* • 200 mg twice daily with food PK in Pregnancy: • PK data in pregnancy (n = 26) suggest that etravirine exposure during pregnancy increases 1.2-fold to 1.6-fold. Dosing in Pregnancy: • No change in dose indicated.	Variable placental transfer, usually in the moderate to high categories, ranging from 0.19–4.25 (data from 19 mother-infant pairs).[b] Insufficient data to assess for teratogenicity in humans. No evidence of teratogenicity in rats or rabbits.	December 7, 2018
Nevirapine (NVP) *Viramune Viramune XR (Extended Release)* **Note:** Generic available for some formulations	NVP (Viramune) *Tablets:* • 200 mg[d] *Oral Suspension:* • 50 mg/5 mL Viramune XR Tablets: • 100 mg • 400 mg[d]	Standard Adult Dose: • 200 mg once-daily Viramune (immediate release) for 14 days (lead-in period); thereafter, 200 mg twice daily or 400 mg (Viramune XR tablet) once daily, without regard to food. • Repeat lead-in period if therapy is discontinued for >7 days. • In patients who develop mild-to-moderate rash without constitutional symptoms during lead-in period, continue lead-in dosing until rash resolves, but administer for ≤28 days total. PK in Pregnancy: • PK of immediate release tablets is not significantly altered in pregnancy.	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. Increased risk of symptomatic, often rash-associated, and potentially fatal liver toxicity among women with CD4 cell counts ≥250/mm^3 when first initiating therapy; pregnancy does not appear to increase risk. NVP should be initiated in pregnant women with CD4 cell counts ≥250 cells/mm^3 only when benefit clearly outweighs risk because of potential increased risk of	December 7, 2018

Table 10. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 9 of 21)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
Nevirapine, continued		• No data are available on extended release formulations in pregnancy. Dosing in Pregnancy: • No change in dose indicated.	life-threatening hepatotoxicity in women with high CD4 cell counts. Elevated transaminase levels at baseline may increase the risk of NVP toxicity. Women who become pregnant while taking NVP-containing regimens and who are tolerating their regimens well can continue therapy, regardless of CD4 cell count.	
Rilpivirine (RPV) *Edurant* (RPV/FTC/TDF) *Complera* (RPV/DTG) *Juluca* (RPV/FTC/TAF) *Odefsey*	RPV (Edurant) *Tablets:* • 25 mg RPV/FTC/TDF (Complera): • RPV 25 mg plus FTC 200 mg plus TDF 300 mg tablet RPV/DTG (Juluca): • RPV 25 mg plus DTG 50 mg tablet RPV/FTC/TAF (Odefsey): • RPV 25 mg plus FTC 200 mg plus TAF 25 mg tablet	Standard Adult Dose *RPV (Edurant):* • RPV 25 mg once daily with food *RPV/FTC/TDF (Complera):* • 1 tablet once daily with food *RPV/DTG (Juluca):* • 1 tablet once daily with food *RPV/FTC/TAF (Odefsey):* • 1 tablet once daily with food PK in Pregnancy: • RPV PK highly variable during pregnancy. RPV AUC and trough concentration reduced 20% to 50% lower in pregnancy than postpartum. While most pregnant women exceeded target exposure, those with detectable viral loads had lower RPV troughs. Dosing in Pregnancy: • While RPV plasma concentration is reduced during pregnancy, higher-than-standard doses have not been studied. Insufficient data are available to recommend a dosing change in pregnancy. With standard dosing, viral loads should be monitored more frequently. • For guidance about use of combination products in pregnancy, please see the specific sections on other components (i.e., DTG, FTC, TAF, TDF).	Moderate to high placental transfer to fetus.[b] No evidence of human teratogenicity (can rule out 2-fold increase in overall birth defects). 2-drug regimens (e.g., RPV/DTG FDC) **are not recommended** in pregnancy.	December 7, 2018

Table 10. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 10 of 21)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
PIs PIs are recommended for use in combination regimens with 2 NRTI drugs. Hyperglycemia, new onset or exacerbation of diabetes mellitus, and diabetic ketoacidosis reported with PI use; unclear if pregnancy increases risk. Conflicting data regarding preterm delivery in women receiving PIs (see Combination Antiretroviral Drug Regimens and Pregnancy Outcomes).				
Atazanavir (ATV) *Reyataz* **Note:** Generic available for some formulations. **Note:** ATV must be combined with low-dose RTV boosting in pregnancy. (ATV/COBI) *Evotaz*	ATV (Reyataz) *Capsules*: • 100 mg (generic product only) • 150 mg[d] • 200 mg[d] • 300 mg[d] *Oral Powder:* • 50 mg packet ATV/COBI (Evotaz): • ATV 300 mg plus COBI 150 mg tablet	Standard Adult Doses *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. *With RTV Boosting:* • ATV 300 mg plus RTV 100 mg once daily with food • When combined with EFV in ARV-naive patients: ATV 400 mg plus RTV 100 mg once daily with food *ARV-Experienced Patients:* • ATV 300 mg plus RTV 100 mg once daily with food • Do not use with PPIs or EFV *If Combined with an H2-Receptor Antagonist:* ATV 300 mg plus RTV 100 mg once daily with food *If Combined with an H2-Receptor Antagonist and TDF:* • ATV 400 mg plus RTV 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/COBI (Evotaz): • 1 tablet once daily with food PK in Pregnancy *ATV (Reyataz):* • ATV concentrations reduced during pregnancy; further reduced when given concomitantly with TDF or H2-receptor antagonist. *ATV/COBI (Evotaz):* • No PK studies in human pregnancy. • For guidance about use of combination products in pregnancy, please see the specific sections on other components (i.e., COBI).	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 as low-dose RTV-boosted regimen in pregnancy. Effect of *in utero* ATV exposure on infant indirect bilirubin levels is unclear. Nonpathologic elevations of neonatal hyperbilirubinemia 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. ATV/COBI **is not recommended** for use in pregnancy. For women who become pregnant while taking ATV/COBI, consider switching to a more effective, recommended regimen. If an ATV/COBI regimen is continued, doses should be administered with food; viral load should be monitored frequently.	December 7, 2018

Table 10. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 11 of 21)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
Atazanavir, continued		Dosing in Pregnancy *ATV (Reyataz):* • Use of unboosted ATV **is not recommended** during pregnancy. • Use of ATV **is not recommended** for ARV-experienced pregnant women taking TDF *and* an H2-receptor antagonist. • Use of an increased dose (ATV 400 mg plus RTV 100 mg once daily with food) during the second and third trimesters results in plasma ATV concentrations equivalent to those seen in nonpregnant adults on standard dosing. Although some experts recommend increased ATV dosing in all women during the second and third trimesters, the package insert recommends increased ATV dosing only for ARV-experienced pregnant women in the second and third trimesters who are also receiving either TDF or an H2-receptor antagonist. *ATV/COBI (Evotaz):* • Insufficient data to make dosing recommendation in pregnancy (see Cobicistat section).		
Darunavir (DRV) *Prezista* **Note:** Must be combined with low-dose RTV or COBI boosting. (DRV/COBI) *Prezcobix* (DRV/COBI/FTC/TAF) *Symtuza*	DRV (Prezista): *Tablet:* • 75 mg • 150 mg • 600 mg • 800 mg *Oral Suspension:* • 100 mg/mL DRV/COBI (Prezcobix): • DRV 800 mg plus COBI 150 mg tablet DRV/COBI/FTC/TAF (Symtuza): • DRV 800 mg plus COBI 150 mg plus FTC 200 mg plus TAF 10 mg tablet	**Standard Adult Doses** ARV-Naive Patients: • DRV 800 mg plus RTV 100 mg once daily with food • DRV 800 mg plus COBI 150 mg once daily with food ARV-Experienced Patients: *If Patient Has No DRV Resistance Mutations:* • DRV 800 mg plus RTV 100 mg once daily with food • DRV 800 mg plus COBI 150 mg once daily with food *If Any DRV Resistance Mutations Are Present:* • DRV 600 mg plus RTV 100 mg twice daily with food *DRV/COBI (Prezcobix):* • 1 tablet once daily with food *DRV/COBI/FTC/TAF (Symtuza):* • 1 tablet once daily with food 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 600 mg plus RTV 100 mg with food) is	Low placental transfer to fetus.[b] No evidence of teratogenicity in mice, rats, or rabbits. No evidence of human teratogenicity. Must be boosted with low-dose RTV. The Panel **does not recommend** once-daily dosing with DRV/COBI during pregnancy or the use of DRV/COBI during pregnancy. If a DRV/c regimen is continued during pregnancy, viral load should be monitored frequently.	December 7, 2018

Table 10. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 12 of 21)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
Darunavir, continued		recommended for all pregnant women. Increased twice-daily DRV dose (DRV 800 mg plus RTV 100 mg with food) during pregnancy does not result in an increase in darunavir exposure and **is not recommended**. PK in Pregnancy: • Decreased exposure in pregnancy with use of DRV/r. • For guidance about use of combination products in pregnancy, please see the specific sections on other components (i.e., COBI, FTC, TAF)		
Fosamprenavir (FPV) *Lexiva (a prodrug of amprenavir)* **Note:** Must be combined with low-dose RTV boosting in pregnancy.	FPV (Lexiva) *Tablets:* • 700 mg *Oral Suspension:* • 50 mg/mL	Standard Adult Doses *FPV (Lexiva)* *ARV-Naive Patients:* • FPV 1400 mg twice daily without food, *or* • FPV 1400 mg plus RTV 100 or 200 mg once daily without food, *or* • FPV 700 mg plus RTV 100 mg twice daily without food *PI-Experienced Patients:* • Once-daily dosing **is not recommended** • FPV 700 mg plus RTV 100 mg twice daily without food *Coadministered with EFV:* • FPV 700 mg plus RTV 100 mg twice daily without food; *or* • FPV 1400 mg plus RTV 300 mg once daily without food PK in Pregnancy: • With RTV boosting, AUC is reduced during the third trimester. However, exposure is greater during the third trimester with boosting than in nonpregnant adults without boosting, and trough concentrations achieved during the third trimester were adequate for patients without PI resistance mutations. Dosing in Pregnancy: • Use of unboosted FPV or once-daily FPV with RTV boosting **is not recommended** during pregnancy. No change is indicated in standard boosted twice-daily dose (FPV 700 mg plus RTV 100 mg twice daily without food).	FPV **should not** be used during pregnancy. Low placental transfer to fetus.[b] Insufficient data to assess for teratogenicity in humans. Increased fetal loss in rabbits, but no increase in defects in rats and rabbits.	December 7, 2018

Table 10. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 13 of 21)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
Indinavir (IDV) *Crixivan* **Note:** Must be combined with low-dose RTV boosting in pregnancy	IDV (Crixivan) *Capsules:* • 200 mg • 400 mg	Standard Adult Dose *Without RTV Boosting:* • IDV 800 mg every 8 hours, taken 1 hour before or 2 hours after meals; may be taken with skim milk or a low-fat meal. *With RTV Boosting:* • IDV 800 mg plus RTV 100 mg twice daily without regard to meals PK in Pregnancy: • IDV exposure markedly reduced when administered without RTV boosting during pregnancy. IDV exposure is low with IDV 400 mg/RTV 100 mg dosing during pregnancy; no PK data available on alternative boosted dosing regimens in pregnancy. Dosing in Pregnancy: • Use of unboosted IDV **is not recommended** during pregnancy.	Minimal placental transfer to fetus.[b] No evidence of human teratogenicity in cases reported to the Antiretroviral Pregnancy Registry (can rule out 2-fold increase in overall birth defects). Must be given as low-dose, RTV-boosted regimen in pregnancy. Theoretical concern regarding increased indirect bilirubin levels, which may exacerbate physiologic hyperbilirubinemia in neonates. Minimal placental passage mitigates this concern. Given the available alternative ARVs, IDV **is not recommended** for treatment of pregnant women in the United States.	December 7, 2018
Lopinavir/ Ritonavir (LPV/r) *Kaletra*	LPV/r (Kaletra) *Tablets (Coformulated):* • LPV/r 200 mg/50 mg • LPV/r 100 mg/25 mg *Oral Solution:* • LPV/r 400 mg/100 mg/5 mL	Standard Adult Dose: • LPV/r 400 mg/100 mg twice daily, *or* • LPV/r 800 mg/200 mg once daily *Tablets:* • Take without regard to food. *Oral Solution:* • Take with food. With EFV or NVP (PI-Naive or PI-Experienced Patients): • LPV/r 500 mg/125 mg tablets twice daily without regard to meals (use a combination of 2 LPV 200-mg plus RTV 50-mg tablets and 1 LPV 100-mg plus RTV 25-mg tablet), *or* • LPV/r 520 mg/130 mg oral solution (6.5 mL) twice daily with food	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	December 7, 2018

Table 10. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 14 of 21)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
Lopinavir/ Ritonavir, continued		PK in Pregnancy: • With twice-daily dosing, LPV exposure is reduced in pregnant women receiving 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. If standard dosing is used, monitor virologic response and, if available, LPV drug levels.		
Nelfinavir (NFV) *Viracept*	NFV (Viracept): *Tablets:* • 250 mg • 625 mg (tablets can be dissolved in a small amount of water) *Powder for Oral Suspension:* • 50 mg/g	Standard Adult Dose: • NFV 1250 mg twice daily, *or* • NFV 750 mg 3 times daily with food PK in Pregnancy: • Lower NFV exposure was observed during the third trimester than postpartum in women receiving NFV 1250 mg twice daily; however, adequate drug levels are generally achieved during pregnancy, although levels are variable in late pregnancy. Dosing in Pregnancy: • NFV 750 mg 3 times daily with food **is not recommended** during pregnancy. No change in standard dose (NFV 1250 mg twice daily with food) indicated.	NFV **should not** be used during pregnancy. Minimal to low 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 risk of cardiovascular and genitourinary birth defects. Contains aspartame; should not be used in individuals with phenylketonuria.	December 7, 2018

Table 10. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 15 of 21)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
Saquinavir (SQV) *Invirase* **Note:** Must be combined with low-dose RTV for PK boosting	SQV (Invirase) *Tablet:* • 500 mg *Capsule:* • 200 mg	Standard Adult Dose: • SQV 1000 mg plus RTV 100 mg twice a day with food or within 2 hours after a meal PK in Pregnancy: • Based on limited data, SQV exposure may be reduced in pregnancy, but this effect is not sufficient to warrant a dose change. Dosing in Pregnancy: • No change in dose indicated.	SQV **should not be used** during pregnancy. **Contraindicated** in patients with pre-existing cardiac conduction system disease. Baseline ECG recommended before starting, because PR and/or QT interval prolongations have been observed. Low placental transfer to fetus.[b] Insufficient data to assess for teratogenicity in humans. No evidence of teratogenicity in rats or rabbits. Must be boosted with low-dose RTV.	December 7, 2018
Tipranavir (TPV) *Aptivus* **Note:** Must be combined with RTV for PK boosting	TPV (Aptivus) *Capsules:* • 250 mg *Oral Solution:* • 100 mg/mL	Standard Adult Dose: • TPV/r 500 mg/200 mg twice daily *With RTV Tablets:* • Take with food. *With RTV Capsules or Solution:* • Take without regard to food; however, administering with food may help make the dose more tolerable. Dosing in Pregnancy: • Insufficient data to make dosing recommendation PK in Pregnancy: • Limited PK data in human pregnancy	TPV **should not be used** during pregnancy. Moderate placental transfer to fetus reported in 1 patient.[b] Insufficient data to assess teratogenicity in humans. No evidence of teratogenicity in rats or rabbits. Must be given as low-dose, RTV-boosted regimen.	December 7, 2018

Table 10. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 16 of 21)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
Entry and Attachment Inhibitors				
Enfuvirtide (T-20) *Fuzeon*	T-20 (Fuzeon) *Injectible:* • Supplied as lyophilized powder. Each vial contains 108 mg of T-20; reconstitute with 1 mL of sterile water for injection for SQ delivery of approximately 90 mg/1 mL.	T-20 is indicated for advanced HIV disease and must be used in combination with other ARV drugs to which the patient's virus is susceptible, as determined by resistance testing. Standard Adult Dose: • T-20 90 mg (1 mL) twice daily without regard to meals PK in Pregnancy: • No PK data in human pregnancy. Dosing in Pregnancy: • Insufficient data to make dosing recommendation.	Minimal to low placental transfer to fetus.[b] No data on human teratogenicity.	December 7, 2018
Ibalizumab (IBA) *Trogarzo*	IBA (Trogarzo) *Solution:* • Solution for IV infusion is available in single-dose vials	Standard Adult Dose *IBA (Trogarzo):* • IBA 2000-mg loading dose, followed by IBA 800-mg maintenance doses administered every 2 weeks Dosing in Pregnancy: • Insufficient data are available to make dosing recommendation. PK in Pregnancy: • No PK studies have been reported in human pregnancy.	No data are available, but placental transfer of IBA, a monoclonal antibody, is possible. Insufficient data are available to assess for teratogenicity in humans.	December 7, 2018
Maraviroc (MVC) *Selzentry*	MVC (Selzentry) *Tablets:* • 150 mg • 300 mg	Standard Adult Dose: • MVC 300 mg twice daily with or without food • MVC should only be used for patients with CCR5-tropic virus (and no X4-tropic virus). Dose Adjustments: • Increase to MVC 600 mg BID when used with potent CYP3A inducers: EFV, ETR, and rifampin. • Decrease to MVC 150 mg BID when used with CYP3A inhibitors: all PIs except TPV/r, itraconazole.	No evidence of teratogenicity in rats or rabbits; insufficient data to assess for teratogenicity in humans. MVC placental passage category should be moderate.[b]	December 7, 2018

Table 10. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 17 of 21)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
Maraviroc, continued		PK in Pregnancy: • A PK study in human pregnancy demonstrated a 20% to 30% overall decrease in AUC, but C_{trough} exceeded the recommended minimal concentration of 50 ng/mL. Dosing in Pregnancy: • Standard adult dosing adjusted for concomitant ARV use appears appropriate.		
Integrase Inhibitors				
Bictegravir/ Emtricitabine/ Tenofovir Alafenamide (BIC/FTC/TAF) *Biktarvy* **Note:** BIC is not available as a single-entity formulation.	BIC/FTC/TAF (Biktarvy): • BIC 50 mg plus FTC 200 mg plus TAF 25 mg tablet	Standard Adult Dose *BIC/FTC/TAF (Biktarvy):* • 1 tablet once daily with or without food Dosing in Pregnancy: • There is insufficient data to make a dosing recommendation. PK in Pregnancy: • No PK studies have been reported in human pregnancy. • For guidance about use of combination products in pregnancy, please see the specific sections on other components (i.e., FTC, TAF).	No data are available on placental transfer of BIC. Insufficient data to assess for teratogenicity in humans. No evidence of teratogenicity in rats or rabbits. To maximize BIC absorption, doses should not be administered within 2 hours of ingestion of any preparation containing minerals such as iron or calcium, including prenatal vitamins.	December 7, 2018

Table 10. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 18 of 21)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
Dolutegravir (DTG) *Tivicay* (DTG/RPV) *Juluca* (DTG/ABC/3TC) *Triumeq*	DTG (Tivicay) *Tablet:* • DTG 50 mg tablet DTG/RPV (Juluca): • DTG 50 mg plus RPV 25 mg tablet DTG/ABC/3TC (Triumeq): • DTG 50 mg plus ABC 600 mg plus 3TC 300 mg tablet	Standard Adult Doses *In ARV-Naive or ARV-Experienced (but Integrase Inhibitor-Naive) Patients* *DTG (Tivicay):* • 1 tablet once daily, without regard to food *DTG/RPV (Juluca):* • 1 tablet once daily with food *DTG/ABC/3TC (Triumeq):* • 1 tablet once daily, without regard to food *ARV-Naive or ARV-Experienced (but Integrase Inhibitor-Naive) if Given with EFV, FPV/r, TPV/r, or Rifampin; or Integrase Inhibitor-Experienced* *DTG (Tivicay):* • 1 tablet twice daily, without regard to food PK in Pregnancy: • AUC may be decreased during the third trimester compared with postpartum, but good viral suppression observed in third-trimester recipients. 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., ABC, 3TC, RPV)	High placental transfer to fetus.[b] No evidence of teratogenicity in mice, rats, or rabbits. Preliminary data suggest a possible increased risk of NTDs in infants born to women who initiated DTG prior to pregnancy and were receiving it at the time of conception. Dolutegravir **should not be initiated** during the first trimester of pregnancy (less than 14 weeks [up to 13 6/7 weeks] gestational age by LMP.) For more information see Interim Guidance about the Use of Dolutegravir in Pregnancy in Recommendations for Use of Antiretroviral Drugs During Pregnancy. To maximize DTG absorption, doses should not be administered within 2 hours of ingestion of any preparation containing minerals such as iron or calcium, including prenatal vitamins.	December 7, 2018
Elvitegravir (EVG) **Note:** As of October 2017, Vitekta (i.e., EVG as a single-entity formulation) is no longer available (EVG/COBI/FTC/TAF) *Genvoya* (EVG/COBI/FTC/TDF) *Stribild*	EVG/COBI/FTC/TAF (Genvoya): • EVG 150 mg plus COBI 150 mg plus FTC 200 mg plus TAF 10 mg tablet EVG/COBI/FTC/TDF (Stribild): • EVG 150 mg plus COBI 150 mg plus FTC 200 mg plus TDF 300 mg tablet	Standard Adult Dose (Genvoya and Stribild): • 1 tablet once daily with food Dosing in Pregnancy: • Insufficient data to make dosing recommendation PK in Pregnancy: • PK studies in women who received EVG/c demonstrated significant reduction in EVG plasma exposure during pregnancy.	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/COBI **is not recommended** for use in pregnancy. For women who become pregnant while taking EVG/c, consider switching to a more effective, recommended regimen. If an EVG/COBI regimen is continued, doses should not be administered within 2	December 7, 2018

Table 10. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 19 of 21)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
Elvitegravir, continued			hours of ingestion of any preparation containing minerals such as iron or calcium, including prenatal vitamins.	
Raltegravir (RAL) *Isentress* *Isentress HD*	RAL (Isentress) *Film-Coated Tablets:* • 400 mg *Chewable Tablets:* • 25 mg • 100 mg RAL (Isentress HD) *Film-Coated Tablets:* • 600 mg	Standard Adult Doses: • RAL 400-mg, film-coated tablets twice daily without regard to food • Two RAL 600-mg, film-coated tablets (1200 mg) once daily for ARV-naive patients or patients who are already virologically suppressed on an initial regimen of RAL 400 mg twice daily without regard to food • Chewable and oral suspension doses are not interchangeable with either film-coated tablets or each other *With Rifampin:* • Two RAL 400-mg, film-coated tablets (800 mg) twice daily without regard to food PK in Pregnancy: • Decreased drug concentrations in third trimester not of sufficient magnitude to warrant a change in dosing. Dosing in Pregnancy: • No change in dose is indicated. • Once-daily dosing (i.e., two RAL 600-mg, film-coated tablets) **should not be used** in pregnant women until more information is available.	High placental transfer to fetus.[b] No evidence of human teratogenicity (can rule out 1.5-fold increase in overall birth defects). Case report of markedly elevated liver transaminases with RAL use in late pregnancy. Severe, potentially life-threatening, and fatal skin and HSRs have been reported in nonpregnant adults. 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.	December 7, 2018

Table 10. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 20 of 21)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
Pharmaco-Enhancers				
Cobicistat (COBI) *Tybost* (ATV/COBI) *Evotaz* (EVG/COBI/FTC/TAF) *Genvoya* (DRV/COBI) *Prezcobix* (EVG/COBI/FTC/TDF) *Stribild* (DRV/COBI/FTC/TAF) *Symtuza*	COBI (Tybost) *Tablet:* • COBI 150 mg ATV/COBI (Evotaz): • ATV/COBI 300 mg/50 mg tablet EVG/COBI/FTC/TAF (Genvoya): • EVG 150 mg plus COBI 150 mg plus FTC 200 mg plus TAF 10 mg tablet DRV/COBI (Prezcobix): • DRV/COBI 800 mg/150 mg tablet EVG/COBI/FTC/TDF (Stribild): • EVG 150 mg plus COBI 150 mg plus FTC 200 mg plus TDF 300 mg tablet DRV/COBI/FTC/TAF (Symtuza): • DRV 800 mg plus COBI 150 mg plus FTC 200 mg plus TAF 10 mg tablet	Standard Adult Doses *COBI (Tybost):* • As an alternative PK booster with ATV or DRV: 1 tablet (150 mg) once daily with food *ATV/COBI (Evotaz):* • 1 tablet once daily with food *EVG/COBI/FTC/TAF (Genvoya):* • 1 tablet once daily with food *DRV/COBI (Prezcobix):* • 1 tablet once daily with food *EVG/COBI/FTC/TDF (Stribild):* • 1 tablet once daily with food *DRV/COBI/FTC/TAF (Symtuza):* • 1 tablet once daily with food PK in Pregnancy: • Based on limited data, COBI exposure and pharmaco-enhancing effect on DRV and EVG are markedly reduced in pregnancy. • No data are available on the pharmaco-enhancing effect of COBI on ATV. • When coadministered with COBI, TAF exposure is not significantly different between pregnancy and the postpartum period. Dosing in Pregnancy: • While COBI exposure is markedly reduced 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).	Low placental transfer to fetus.[b] Insufficient data to assess for teratogenicity in humans. No evidence of teratogenicity in rats or rabbits. Use of COBI-boosted ATV, DRV, or EVG **is not recommended** in pregnancy.	December 7, 2018

Table 10. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 21 of 21)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
Ritonavir (RTV) *Norvir*	RTV (Norvir) *Capsules:* • 100 mg *Tablets:* • 100 mg *Oral Solution:* • 80 mg/mL *Powder:* • 100 mg/sachet	Standard Adult Dose as PK Booster for Other PIs: • RTV 100–400 mg per day in 1–2 divided doses (refer to other PIs for specific dosing recommendations.) *Tablet:* • Take with food. *Capsule or Oral Solution:* • To improve tolerability, take with food if possible. PK in Pregnancy: • Lower levels seen during pregnancy than during postpartum. Dosing in Pregnancy: • No dosage adjustment necessary when used as booster.	Low placental transfer to fetus.[b] No evidence of human teratogenicity (can rule out 1.5-fold increase in overall birth defects). Should only be used as low-dose booster for other PIs. Oral solution contains 43% alcohol and is therefore not recommended during pregnancy, because there is no known safe level of alcohol exposure during pregnancy.	December 7, 2018

[a] 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).

[b] 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

[c] Only indicated for use in chronic HBV virus infection in adults.

[d] Generic formulation available

[e] WHO recommends maximum dose of 30 mg twice daily regardless of weight.

Key to Acronyms: 3TC = lamivudine; ABC = abacavir; ART = antiretroviral therapy; ARV = antiretroviral; ATV = atazanavir; ATV/r = atazanavir/ritonavir; AUC = area under the curve; BIC = bictegravir; CD4 = CD4 T lymphocyte; COBI = cobicistat; d4T = stavudine; ddI = didanosine; DOR = doravirine; DRV = darunavir; DRV/r = darunavir/ritonavir; DTG = dolutegravir; EFV = efavirenz; ETR = etravirine; EVG = elvitegravir; FDA = Food and Drug Administration; FDC = fixed-dose combination; FPV = fosamprenavir; FPV/r = fosamprenavir/ritonavir; FTC = emtricitabine; HBV = hepatitis b virus; HSR = hypersensitivity reaction; IBA =ibalizumab; IDV = indinavir; IDV/r = indinavir/ritonavir; INSTI = integrase strand transfer inhibitor; LPV/r = lopinavir/ritonavir; MVC = maraviroc; NFV = nelfinavir; 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; SQV = saquinavir; SQV/r = saquinavir/ritonavir; T-20 = enfuvirtide; TAF = tenofovir alafenamide; TDF = tenofovir disoproxil fumarate; TID = 3 times a day; TPV = tipranavir; TPV/r = tipranavir/ritonavir; WHO = World Health Organization; ZDV = zidovudine