Antiretroviral Adverse Effects

Agent	Adverse Effects	Monitoring Parameters	Pregnancy Category	Notes
NRTIs	*(ALL)* **Lactic Acidosis and Hepatic Steatosis**			
Abacavir (Ziagen® ABC)	**Potentially Fatal Hypersensitivity Reaction** (**fever**, **rash**, **fatigue**, SOB, **N/V/D/Abd pain, malaise**), HA	HLA-B*5701 test (before initiation), LFTs, CBC, CK	C	Pt will receive info handout at retail pharmacy regarding HSR. Must be HLA-B*5701 negative Not recommended with VL >100K
Didanosine (Videx EC® ddI)	**Peripheral neuropathy, pancreatitis**, anemia, leucopenia, N/V/D/Abd pain, ↑ amylase, rash	CBC, Renal fxn, LFTs, Amylase, weight	B	Dosing based on weight and renal fxn Drug interaction with tenofovir
Emtricitabine (Emtriva® FTC)	Skin hyperpigmentation (palms and soles of feet), N/V/D/HA, dizziness, insomnia, rash	Renal fxn	B	
Lamivudine (Epivir® 3TC)	N/D/HA, fatigue, insomnia, anemia, dizziness	Renal fxn	C	
Stavudine (Zerit® d4T)	**Peripheral neuropathy**, ↑ bilirubin, **lipoatrophy**, ↑ LFTs, rash, **lipodystrophy**, **anemia**, **N**/V/D/HA,↑ lipase/amylase	Renal fxn, LFTs, CBC	C	Dosing based on weight
Tenofovir DF (Viread® TDF)	N/V/D/HA, **renal dysfxn, bloating/abd discomfort,** Fanconi, ↓BMD	Renal fxn, UA, BMD	B	Contains lactose
Tenofovir AF (Vemlidy® TAF)	N/HA, abd discomfort, fatigue, cough	Renal fxn, UA	-	Only approved for Tx of HBV at this time. Not recommended for Crcl <15mL/min
Zidovudine (Retrovir® ZDV, AZT)	**N**/V/HA, **anemia, neutropenia**, **fatigue**, anorexia, constipation	CBC, Renal fxn, LFTs	C	
Combivir® (zidovudine + lamivudine)	See individual components		C	
Truvada® (emtricitabine + tenofovir DF)	See individual components		B	Also indicated for Tx of HBV and for PrEP
Descovy® (emtricitabine + tenofovir AF)	See individual components			
Cimduo® (lamivudine + tenofovir DF)	See individual components			
Epzicom® (lamivudine + abacavir)	See individual components		C	Pt will receive info handout at retail pharmacy regarding HSR. Must be HLA-B*5701 negative Not recommended with VL >100K
Trizivir® (zidovudine + lamivudine + abacavir)	See individual components		C	Pt will receive info handout at retail pharmacy regarding HSR. Must be HLA-B*5701 negative Not recommended with VL >100K
NNRTIs	Lots of drug interactions			
Efavirenz (Sustiva® EFV)	**CNS (drowsiness, insomnia, confusion, vivid dreams, dizziness)**, depression, **rash**, N/V/D, ↑ LFTs, ↑ lipids, teratogenicity in first trimester	LFTs, lipids	D	Administer on empty stomach
Nevirapine (Viramune®, Viramune XR®, NVP)	**Rash, hepatotoxicity**, ↑ LFTs, N/D/HA/Abd pain, fatigue, flu-like ssx,	LFTs, CBC	B	Do not give in women with CD4 >250 or men with CD4 >400
Etravirine (Intelence® ETR)	**Rash**, ↑ LFTs, ↑ lipids	LFTs, lipids	B	Orally dissolving tablets; approved as QD in Europe
Rilpivirine (Edurant® RPV)	**Rash**, depressive disorders, HA, N/V, insomnia	LFTs	B	Drug interaction with acid suppressing agents Not recommended with VL >100K or CD4 < 200 Requires 400-500kcal meal
Doravirine (Pifeltro® DOR)	Nausea, headache, fatigue, diarrhea, abd pain, dizziness, rash, abnormal dreams, insomnia, somnolence, Neuropsychiatric adverse events (depression and SI) reported incidence: 4%)	LFTs	No data	Substrate of CYP3A metabolism
INSTIs				
Raltegravir (Isentress®, Isentress HD®,RAL)	↑ lipids, **fatigue**, rash, ↑ bilirubin, ↑ LFTs, insomnia, ↑ **CPK**, Post-marketing reports of depression, suicidal thoughts/behaviors, and skin rash (including SJS)	Lipids	C	
Dolutegravir (Tivicay® DTG)	**Insomnia**, **headache**, rash, fatigue, abdominal discomfort, weight gain	LFTs, lipids	B	Drug interactions with multi-valent cation-containing meds or administer with food. Mean change in Scr from baseline is 0.15mg/dL. Use with caution in women of child-bearing potential.

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PIs	*(ALL)* **Hyperglycemia, Lipodystrophy/Fat redistribution, Lipid abnormalities**	Lots of drug interactions		
Atazanavir (Reyataz® ATV)	↑ **Bili**, nausea, nephrolithiasis, **rash**, ↑ LFTs, ↑ amylase, ↑ PR interval	Bilirubin, LFTs, lipids	B	Drug interaction with acid suppressing agents "Lipid neutral"
Darunavir (Prezista® DRV)	**Rash**, **N**/V/D/HA, ↑ lipids, ↑ LFTs	LFTs, lipids	C	*Sulfa moiety Boxed warning for hepatotoxicity
Fosamprenavir (Lexiva® FPV)	**Rash**, N/D, ↑ LFTs, ↑ **TG**	LFTs, lipids	C	*Sulfa moiety
Indinavir (Crixivan® IDV)	**Nephrolithiasis**, ↑ bilirubin↓, ↑ LFTs, N/V/D/HA/Abd pain	Fluid status, LFTs, UA, lipids	C	
Lopinavir/ritonavir (Kaletra® LPV/r)	**N/V/D/Abd pain**, ↑ LFTs, rash, ↑ **lipids**, ↑ amylase, ↑**TG**	LFTs, lipids	C	
Nelfinavir (Viracept® NFV)	**Diarrhea**, rash, nausea, ↑ LFTs	LFTs, lipids	B	Does not require RTV
Saquinavir (Invirase® SQV)	N/V/D/HA, rash, ↑ LFTs, fatigue	LFTs, lipids,	B	
Tipranavir (Aptivus® TPV)	↑ LFTs, rash, ↑ lipids, N/V/D, intracranial hemorrhage	LFTs, lipids,	C	*Sulfa moiety Boxed warning for ICH
Prezcobix® (darunavir + cobicistat)	See individual components		C	Not recommended with multiple ART that require boosting Not recommended to start in patients with Crcl < 70mL/min
Evotaz® (atazanavir + cobicistat)	See individual components		B	Not recommended with multiple ART that require boosting Not recommended to start in patients with Crcl < 70mL/min
EIs				
Enfuvirtide (Fuzeon® T-20, ENF)	**Injection site reactions**, fatigue, insomnia, N/D, eosinophilia	HSR and injection site reactions	B	Admin in upper arm, abdomen, or anterior thigh. Rotate injection sites. Reconstituted vials are only good for 24h. Store reconstituted vials in refrigerator. To reconstitute, mix with 1mL SWFI, tap vial and roll gently between hands.
Fostemsavir (Rukobia®)	N/D/HA, abd pain, dyspepsia, fatigue, rash, sleep disturbances, **QTc prolongation, transaminitis,** elevated Scr (19%)	LFTs	Insufficient data	Causal association with increased Scr has not been established; DDI with ethinyl estradiol – EE should not exceed 30mcg daily.
Ibalizumab (Trogarzo®)	Infusion-related reactions, dizziness, rash, N/D, ↑serum creatinine (1.8x ULN or 1.5x baseline), ↑serum lipase (>3x ULN), serum bilirubin (>2.6x ULN)	CBC, renal fxn, LFTs, HSR and injection site reactions	Insufficient data	Requires loading dose (10 vials) then maintenance dose (4 vials) every 14 days. Loading dose required again if miss dose by ≥3 days. Infuse over 30 min – 1h and observe 1h after initial dose then may decrease infusion and observation time to 15 min each. Store vials in refrigerator. Protect from light.
Maraviroc (Selzentry® MVC)	↑ **LFTs**, fever, **URI**, cough, dizziness, insomnia, abd pain	LFTs, Tropism test (before initiation)	B	Lots of drug interactions
Pharmacokinetic Enhancers	Lots of drug interactions			
Cobicistat (Tybost® COB)	Nausea, ↑ LFTs	Renal fxn, LFTs, UA	B	Not recommended with multiple ART that require boosting Not recommended to start in patients with Crcl < 70mL/min. May increase Scr up to 0.4mg/dL from baseline
Ritonavir (Norvir® RTV)	**N/V/D**/Abd pain, anorexia **paresthesias**, ↑ LFTs, taste perversion, ↑ **lipids**, insulin resistance	LFTs, lipids, glucose, amylase, lipase	B	Take with food

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Fixed-Dose Combination Products				
Atripla® (emtricitabine + tenofovir DF + efavirenz)	See individual components		D	Administer on empty stomach
Symfi® Symfi Lo® (lamivudine + tenofovir DF + efavirenz)	See individual components			Administer on empty stomach
Complera® (emtricitabine + rilpivirine + tenofovir DF)	See individual components		B	Drug interaction with acid suppressing agents Not recommended with VL >100K or CD4 < 200 Requires 400-500kcal meal
Odefsey® (emtricitabine + rilpivirine + tenofovir AF)	See individual components			Drug interaction with acid suppressing agents. Not recommended with VL >100K or CD4 <200. Not recommended with Crcl <30mL/min. Take "with meal"
Delstrigo® (doravirine + lamivudine + tenofovir DF)	See individual components Sleep disorders & disturbances (12%), dizziness (9%), and altered sensorium (4%)	Renal fxn, UA, LFTs, BMD	Insufficient data	Not recommended with Crcl < 50mL/min.
Stribild® (cobicistat + elvitegravir + emtricitabine + tenofovir DF)	**N**/D**, renal dysfxn**, decreased BMD, abnormal dreams, rash, insomnia, HA See individual components	Renal fxn, UA LFTs, fLP	B	Not recommended with Crcl < 70mL/min
Genvoya® (cobicistat + elvitegravir + emtricitabine + tenofovir AF)	**N**, decreased BMD, abnormal dreams, rash, insomnia, HA	Renal fxn, UA LFTs, fLP		Not recommended with Crcl < 30mL/min
Triumeq® (abacavir + dolutegravir + lamivudine)	See individual components	HLA-B*5701 test (before initiation), LFTs	C	Pt will receive info handout at retail pharmacy regarding HSR. Must be HLA-B*5701 negative. Use with caution in women of child-bearing potential.
Biktarvy® (bictegravir + emtricitabine + tenofovir AF)	HA, fatigue, dizziness, insomnia, N/D, ↑serum bilirubin, ↑CPK	Renal fxn, LFTs, UA		Mean change in Scr from baseline is 0.10mg/dL. Use with caution in women of child-bearing potential.
Juluca® (dolutegravir + rilpivirine)	See individual components	LFTs		Option for switch Tx if pt undetectable on ART for ≥6 months with no h/o Tx failure or resistance to DTG or RPV. Requires 400-500kcal meal. Drug interaction with acid suppressing agents and multi-valent cation-containing meds. Mean change in Scr from baseline is 0.15mg/dL Use with caution in women of child-bearing potential.
Dovato® (dolutegravir + lamivudine)	See individual components	Renal fxn, LFTs		For ART-naïve patients with no known resistance. Mean change in Scr from baseline is 0.15mg/dL. Use with caution in women of child-bearing potential. Not recommended with Crcl <50 mL/min and if VL > 500k.