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Providing state-of-the-art HIV education, consultation, and resource materials to healthcare professionals throughout the region.

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- - - If outside our region, please consult the national services below - - -

National Consultation Services Clinician Consultation Center Online Consultation: nccc.ucsf.edu

Pre-Exposure Prophylaxis 855.448.7737 Advice to clinicians on providing antiretroviral drug therapy to HIV uninfected persons to prevent HIV infection Call 11 am - 6 pm EST, Monday - Friday

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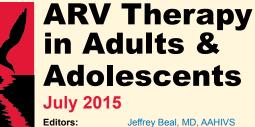
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	Renal Dose Adjustments ⁴ e visit: www.kidney.org/professionals/kdoqi/gfr_calculator.cfm
	glomerular filtration rate calculator to estimate renal function.
Agent(s)	Dose Adjustment
	NRTIS
Zidovudine	CrCL < 15 or HD ⁵ : 100 mg tid or 300 mg every 24 hours
Didanosine	 ≥ 60 kg: CrCL 30-59: (EC) 200 mg every 24 hours; CrCL 10-29: (EC) 125 mg every 24 hours; CrCL < 10, HD⁵ or CAPD: (EC) 125 mg every 24 hours; < 60 kg: CrCL 30-59: (EC) 125 mg every 24 hours; CrCL 10-29: (EC) 125 mg every 24 hours; CrCL < 10, HD⁵ or CAPD: 75 mg every 24 hours (use oral soln)
Emtricitabine	CrCL 30-49: 200 mg cap every 48 hours or 120 mg soln every 24 hours; CrCL 15-29: 200 mg cap every 72 hours or 80 mg soln every 24 hours; CrCL < 15 or HD ⁵ : 200 mg cap every 96 hours or 60 mg soln every 24 hours
Lamivudine	CrCL 30-49: 150 mg every 24 hours; CrCL 15-29: 150 mg x 1 then 100 mg every 24 hours; CrCL 5-14: 150 mg x 1 then 50 mg every 24 hours; CrCL < 5 or HD ⁵ : 50 mg x 1 then 25 mg every 24 hours
Stavudine	 ≥ 60 kg: CrCL 26-50: 20 mg every 12 hours, CrCL ≤ 25 or HD⁵: 20 mg every 24 hours; < 60 kg: CrCL 26-50: 15 mg every 12 hours, CrCL ≤ 25 or HD⁵: 15 mg every 24 hours
Tenofovir ⁶	CrCL < 70: Do not use with cobicistat CrCL 30-49: 300 mg every 48 hours; CrCL 10-29: 300 mg twice weekly every 72-96 hours; CrCL < 10 <u>and</u> not on HD: not recommended; HD ⁵ : 300 mg every week (assumes 3 HD sessions per week of approximately 4 hours each)
	NNRTIS
Nevirapine ⁷	No dosage adjustment for pts with CrCL > 20 HD: Give extra 200 mg dose of immediate release following each HD
Rilpivirine ⁸	Severe renal impairment or HD ⁵ : use with caution and monitor for adverse effects
	Pls
Atazanavir (ATV)	ARV-naïve on HD⁵: ATV 300 mg + RTV 100 mg once daily; ARV-experienced (exp) on HD⁵: ATV not recommended (unboosted or boosted)
Lopinavir/r	HD ⁵ : Avoid once daily dosing
	INSTI
Dolutegravir ⁹	Use with caution in INSTI-exp pts with severe renal impairment as DTG levels may be decreased
	CCR5 Inhibitor
Maraviroc	CrCL < 30 or HD ⁵ : With potent CYP3A inhibitor or inducer: not recommended Without potent CYP3A inhibitor or inducer: 300 mg po bid (↓ to 150 mg po bid if postural hypotension occurs)
	Pharmacokinetic Enhancers
Cobicistat	CrCL < 70: ATV/c or DRV/c use with TDF not recommended
raltegravir, or Dose after he CAUTION: co Viramune [®] [pa Pharmaceutic Edurant [®] [pac Janssen Prod	adj for abacavir, PIs (except ATV, Iopinavir/r), NNRTIs, dolutegravii T20. modialysis (HD) on HD days. nsider tenofovir as possible cause for renal dysfunction. <i>ackage insert]</i> . Ridgefield, CT: Boehringer Ingelheim als, Inc.; Revised April 2014. <i>kage insert]</i> . Titusville, NJ: Janssen Therapeutics, Division of ucts; Revised May 2014. <i>(age insert]</i> . Research Triangle Park, NC: ViiV Healthcare; Revised 14.



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This resource summarizes information from the Department of Health and Human Services (DHHS) guidelines referenced below. Critical information regarding antiretroviral agents currently approved for use in adults and adolescents is included. Information summarized includes adult dosing (including renal dosing recommendations), available dosage forms, side effects, and important patient (pt) counseling points.

Unless otherwise noted, information is adapted from the Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. April 8, 2015. 1-285. Available at: http://aidsinfo.nih.gov/guidelines. Accessed April 9, 2015.

Fact Sheet: Pharmaceutical Company Co-payment Assistance Programs (CAP)

This fact sheet from the National Alliance of State & Territorial AIDS Directors (NASTAD) provides background on what co-payment assistance programs are and an overview of CAP contact information, drugs covered, and assistance offered. (http://www.nastad.org/sites/default/files/121330_HIV_and_PAPs_CAPs_Resource_Document.pdf)

SPECIAL THANKS TO:

Colorado AIDS Education and Training Center for medication images (images are not actual size and colors may vary)

> and www.AIDSmeds.com for phonetic pronunciations

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An up-to-date and downloadable PDF file is available online at www.FCAETC.org/treatment. To order additional printed copies, please email orders@fcaetc.org. If you require an alternate format to accommodate a disability, please email contact@fcaetc.org or call 866.352.2382.

Renal Dosing for Combo Products				
Agent(s)		Dose Adjustment		
EFV/FTC/TDF (Atri	pla®) ⁶			
ZDV/3TC (Combivir	·®)	1		
RPV/FTC/TDF (Cor	mplera®) ⁶	These fixed-dose combo products should not be used in pts with CrCL < 50. See dosing		
ABC/3TC (Epzicom	®)	for individual agents.		
DTG/ABC/3TC (Triu	umeq®)			
ABC/ZDV/3TC (Triz	:ivir®)			
FTC/TDF (Truvada®	⁹)6	CrCL 30-49: One tab every 48 hours; CrCL < 30: Combo product cannot be used; see dosing for individual agents		
ATV/c (Evotaz [™]) CrCL < 70: Use with TDF not recommen ARV-exp on HD: ATV/c not recommended				
DRV/c (Prezcobix [™]))	CrCL < 70: Use with TDF not recommended		
EVG/c/FTC/TDF (S	tribild®) ⁶	ribild®) ⁶ CrCL < 70: do not initiate CrCL < 50: discontinue		
Hepatic Dosing of ARVs See DHHS Guidelines (Appendix B, Table 7) for recommendations for dosing ARVs in pts with hepatic insufficiency. See Child-Pugh Score Calculation table below to assist in determining severity of hepatic insufficiency.				
Child-Pugh (CP) Score Calculation ¹⁰				
Score	1	2	3	
Encephalopathy ¹¹	None	Grade 1 - 2	Grade 3 - 4	

Regimens below assume no baseline resistance. Resistance testing recommended for all pts upon entry into care and prior to starting ARVs. Regimens within classes are in alphabetical order. (/r) indicates low-dose ritonavir and (/c) indicates cobicistat for boosting. See detailed information in this resource and in the guidelines for dosing and other important points.			
Recommended Initial Regimen Options, Regardless of pre-ART Viral Load or CD4 Cell Count: (All Al) ¹			
INSTI-Based			
Dolutegravir + abacavir + lamivudine ² (available as Triumeq®) - Only if HLA-B*5701 negative			
Dolutegravir (Tivicay [®]) + tenofovir + emtricitabine ² (available as Truvada [®])			
Elvitegravir/c + tenofovir + emtricitabine (available as Stribild [®]) - Only if pre-ART estimated CrCL ≥ 70 mL/min			
Raltegravir (Isentress®) + tenofovir + emtricitabine ²			
PI-Based			
Darunavir (Prezista®)/r once daily + tenofovir + emtricitabine ²			
Alternative Regimen Options: Effective/tolerable but have potential disadvantages compared to recommended regimens listed above, have limitations for use in certain patient populations, or have less randomized clinical trial data. May be preferred in some pts.			
NNRTI-Based: (All BI)			
Efavirenz + tenofovir + emtricitabine ² (available as Atripla®)			
Rilpivirine + tenofovir + emtricitabine ² (available as Complera [®]) - Only if pre-ART viral load < 100,000 copies/mL and CD4 > 200 cells/mm ³			
PI-Based			
Atazanavir/c (Evotaz [™]) + tenofovir + emtricitabine ² - Only if pre-ART estimated CrCL ≥ 70 mL/min (BI)			
Atazanavir (Reyataz [®])/r + tenofovir + emtricitabine ² (BI)			
[Darunavir/c (BIII, Prezcobix [™]) or darunavir/r (BII)] + abacavir + lamivudine² (available as Epzicom [®]) - Only if HLA-B*5701 negative			
Darunavir/c + tenofovir + emtricitabine ² - Only if pre-ART estimated CrCL ≥ 70 mL/min (BII)			
Other Regimen Options: When compared to Recommended or Alternative options, may have ↓ virologic efficacy, limited data from large comparative clinical trials, more toxicities, higher pill burden, drug interaction potential or limitations for use in certain pt populations.			
INSTI-Based			
Raltegravir + abacavir + lamivudine ² - Only if HLA-B*5701 negative (CII)			
NNRTI-Based			
Efavirenz (Sustiva®) + abacavir + lamivudine ² - Only if HLA-B*5701 negative and pre-ART viral load < 100,000 copies/mL (CI)			
PI-Based			
Atazanavir/c (CIII) or atazanavir/r (CI) + abacavir + lamivudine ² - Only if HLA-B*5701 negative and pre-ART viral load < 100,000 copies/mL			
Lopinavir/r (Kaletra [®]) once or twice daily ³ + abacavir + lamivudine ² - Only if HLA-B*5701 negative (CI)			
Lopinavir/r once or twice daily ³ + tenofovir + emtricitabine ² (CI)			
Other Regimens When Tenofovir or Abacavir Cannot be Used			
Darunavir/r once daily + Raltegravir - Only if pre-ART viral load < 100,000 copies/mL and CD4 > 200 cells/mm3 (Cl)			
Lopinavir/r twice daily + lamivudine twice daily (CI)			
. See <i>Table 2 of DHHS guidelines</i> for rating scheme for strength of recommendations/quality of evidence. 2. Emtricitabine may replace lamivudine and vice versa (co-formulation is major determining factor).			

Regimens for Treatment of HIV-1 in Antiretroviral-Naïve Patients

3. Once daily lopinavir/r not recommended in pregnant Q. See Perinatal Guidelines (www.aidsinfo.nih.gov/ContentFiles/PerinatalGL.pdf) for detailed recommendations for treating HIV in pregnancy.

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The information contained in this publication is intended for medical professionals, as a quick reference to the national guidelines. This resource does not replace nor represent the comprehensive nature of the published guidelines. Recognizing the rapid changes that occur in this field, clinicians are encouraged to consult with their local experts or research the literature for the most up-to-date information to assist with individual treatment decisions for their patient. If your patient should experience a serious adverse event, please report the event to the FDA (www.fda.gov/Safety/MedWatch/HowToReport/default.htm) to help increase patient safety.
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Visit www.FCAETC.org/treatment for the most up-to-date version of this resource.

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G = Generic Available				
S = Take with food S = Take without food S = Take with or without food				
R = Renal Adjustment (See table)				
10C = ↑ Combination Oral Contraceptive Level				
JOC = U Combination Oral Contraceptive Level; Use alternate/additional form of birth control				
C = Do not coadminister with Combination Oral Contraceptive				
B,C,D = Pregnancy Category				
= See Treatment of Tuberculosis (TB) in HIV/AIDS Pocketcard for drug interactions. Located at www.FCAETC.org/Treatment				
♦ = Dosage in photo, when multiple dosage forms are available				
Note: Medication images are NOT actual size, and colors may vary.				

Regimens/ Components	Comments
Monotherapy (AII)	Rapid development of resistance; inferior to ≥ 3 drugs
Dual-NNRTI (AI)	Adverse events and drug-drug interactions prevent benefit
Dual-NRTI (AI)	Rapid development of resistance; inferior to ≥ 3 drugs
Triple NRTI (AI) <u>exceptions</u> : ABC/ZDV/3TC (BI) and possibly TDF/ZDV/3TC (BII)	Consider exceptions when preferred/alternati not feasible; † early virologic non-response w ABC/TDF/3TC or TDF/ddl/3TC
d4T + ZDV (AII)	Both thymidine analogs; antagonistic
d4T + ddl (All)	Toxicities: pancreatitis, neuropathy, ↑ lactate. Fatalities (lactic acidosis with hepatic steatosi with or without pancreatitis) in pregnancy.
ddl + TDF (All)	↑ ddl levels and toxicity, ↑ virologic failure/resistar potential for immunologic nonresponse/CD4 ↓. Consider altering regimen even if clinically stable ddl/TDF containing regimen.
FTC + 3TC (AIII)	Similar resistance profile; no benefit
EFV in 1 st trimester or if pregnancy potential (AIII)	Teratogenic (in nonhuman primates) use only if other options and potential benefits > risks (BIII)
EFV + (ATV/c or DRV/c)	Do not combine
EVG + (EFV or NVP)	Do not combine
ETR + (all unboosted PIs, ATV/r, ATV/c, DRV/c, FPV/r, or TPV/r) (AII)	Do not combine
NVP + (ATV/r, ATV/c, or DRV/c)	Do not combine
NVP in ARV-naïve $\stackrel{\circ}{2}$ with CD4 > 250 cells/mm ³ or $\stackrel{\circ}{O}$ with CD4 > 400 cells/mm ³ (BI)	↑ symptomatic hepatic events; use only if potential benefits > risks
ATV + IDV (AIII)	Potential for additive hyperbilirubinemia
RTV as sole PI ¹³	Pill burden; GI intolerance
Unboosted DRV, SQV, TPV (AII)	Should only be used with low-dose RTV

	Statin Intera	ctions with ARVs ¹⁴			
	Protease Inhibitor (PI) Interactions				
NOTE: Interacti	NOTE: Interactions with indinavir and nelfinavir are not included since these are rarely used				
Statin	Interacting PI(s)	Prescribing Recommendation			
	ATV, ATV/c, ATV/r, DRV/c	Titrate atorvastatin dose carefully and use the lowest dose necessary			
Atorvastatin	DRV/r FPV or FPV/r SQV/r	Titrate atorvastatin dose carefully and use lowest dose necessary (not to exceed 20 mg daily)			
	LPV/r	Use with caution and with the lowest atorvastatin dose necessary			
	TPV/r	DO NOT COMBINE			
Fluvastatin	All HIV PIs	No data available			
Lovastatin Simvastatin	All HIV PIs	CONTRAINDICATED			
Pitavastatin	All HIV PIs	No dosage adjustments necessary			
	ATV/c or ATV/r	Use lowest starting dose of pravastatin and monitor for efficacy and toxicity			
Pravastatin	DRV/c or DRV/r	Use lowest possible starting dose of pravastatin with careful monitoring			
	LPV/r SQV/r	No dosage adjustments necessary			
	ATV/r LPV/r	Titrate rosuvastatin dose carefully and use lowest dose necessary (not to exceed 10 mg daily)			
Rosuvastatin	ATV/c DRV/c or DRV/r SQV/r	Titrate rosuvastatin dose carefully and use lowest dose possible while monitoring for toxicities			
	FPV or FPV/r TPV/r	No dosage adjustments necessary			
St	tribild® (EVG + CO	BI + TDF + FTC) Interactions			
Statin	Interacting Agent	Prescribing Recommendation			
Atorvastatin Rosuvastatin	COBI	Titrate atorvastatin or rosuvastatin dose carefully and use the lowest dose necessary			
Fluvastatin Pitavastatin Pravastatin	СОВІ	No data or dosage recommendation			
Lovastatin Simvastatin	COBI	CONTRAINDICATED			

Albumin	> 3.5 g/dL	2.8 - 3.5 g/dL	< 2.8 g/dL	
Total Bilirubin <u>or</u>	< 2 mg/dL	2 - 3 mg/dL	> 3 mg/dL	
Modified Total Bilirubin ¹²	< 4 mg/dL	4 - 7 mg/dL	> 7 mg/dL	
Prothrombin Time	< 4	4 - 6	> 6	
or INR	< 1.7	1.7 - 2.3	> 2.3	
Grade 2: drowsine marked confusion, 4: coma, decerebr	usion, anxiety ss, disorienta incomprehen ate posturing,	, restlessness, fine tre tion, asterixis; Grade sible speech, incontin flaccidity.	re > 9. emor, slowed coordination; 3: somnolent but rousable, ient, hyperventilation; Grade yndrome or taking IDV or ATV.	

Mild or controlled

by diuretics

None

Ascites

Moderate or refractory

to diuretics

ARV Compone	nts Not Recommend	led as Part of Initial Therapy
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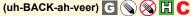
Agent(s)	Comments	Agent(s)	Comments	
ABC/ZDV/3TC ± TDF	\downarrow virologic efficacy	ATV (unboosted)	Less potent than boosted ATV	
d4T + 3TC	Lipoatrophy, peripheral neuropathy, symptomatic lactic acidosis, hepatic steatosis, and pancreatitis	FPV (± RTV)	Unboosted FPV virologic failure may \rightarrow DRV resistance mutations; less data with FPV/r than for other boosted PIs	
ddl + (3TC or FTC)	↓ virologic efficacy; limited clinical trial data in ART-naïve; ddl toxicity	IDV (± RTV)	Nephrolithiasis, meal/fluid requirements	
ZDV/3TC	More toxicities (e.g., bone marrow suppression, GI toxicity, lipoatrophy, symptomatic lactic acidosis, hepatitis steatosis, and pancreatitis) than recommended NRTIs	NFV	↓ virologic efficacy; ↑ diarrhea	
DLV	↓ virologic efficacy; inconvenient dosing	SQV/r	High pill burden; QT and PR prolongation possible and requires ECG monitoring	
ETR	Insufficient data in ARV-naïve	TPV/r	↓ virologic efficacy	
NVP	Serious and potentially fatal toxicities (e.g., hepatic events, severe rash including SJS, TEN); did not meet non-inferiority criteria compared to EFV	ENF, T20	T20 Insufficient data in ARV-naïve, T20 requires bid SQ injections	
		MVC	CCR5 tropism testing required prior to use; no virologic benefit compared to recommended regimens; requires bid dosing	

 See DHHS Guidelines (*Table 19b*) for statin interaction with NNRTIs. Generally no dosage adjustments needed but there may be decreased statin response depending on agents used.

NUCLEOSIDE/NUCLEOTIDE REVERSE TRANSCRIPTASE INHIBITORS (NRTIs)

Class adverse effects: Lactic acidosis and hepatic steatosis

Abacavir (Ziagen[®], ABC)



GX 623

Dosage form: 300 mg tab, 20 mg/mL soln (240 mL/bottle) Also available in combination products: Epzicom[®], Trizivir[®], Triumeq[®]; see Combination Products for more detail

Adult dose: 300 mg po bid or 600 mg po once daily NOTE: Perform HLA-B*5701 test prior; only use if negative Important Points:

- Use with caution in pts with ↑ CVD risk. Use with caution if pre-ART viral load >100,000 copies/mL unless combined with dolutegravir.
- Alcohol ↑ ABC levels 41%; potential for adverse effects
- AEs: Hypersensitivity reaction (2-9%), characterized by sign/symptom from ≥ 2 groups: G1: fever; G2: rash; G3: nausea, vomiting, diarrhea, or abdominal pain; G4: malaise, fatigue, or achiness; G5: dyspnea, cough, or pharyngitis (onset 4-6 weeks). Discontinue drug promptly and DO NOT RECHALLENGE!

See Tables 17, 18, 19,	and 20 of the DHHS guidelines and www.hiv-druginterad	ctions.org for drug interaction information before prescrib	ing any ARV regimen.
NRTIs (Continued) Didanosine (Videx [®] EC, ddl) ¹⁵	Rilpivirine (Edurant®, RPV) (ril-pih-VIGH-reen) (R H B TB	Nelfinavir (Viracept [®] , NFV) ³¹ (nell-FIH-nuh-veer) () (10 C B B) Rarely used	COMBINATION PRODUCTS NRTI Combinations (see individual drug components for important points)
(dye-DAH-no-seen) (() () () () () () () () ()	Dosage form: 25 mg tab Also available in combination product: Complera®; see Combination Products for more detail Adult dose ²³ : 25 mg once daily	 See Viracept[®] Prescribing Information available online at www.viivhealthcare. com/our-medicines for dosage forms, dosing, adverse effects and other important points. 	Combivir® (COM-bih-veer) C ((((((((((((((((((
Emtricitabine (Emtriva®, FTC) (em-trih-SIGH-ta-been) ((R) (R) B Dosage form: 200 mg cap, 10 mg/mL soln (170 mL/bottle)	Important Points: Take with a meal Interacts with acid-reducing agents PPIs (e.g., omeprazole, lansoprazole): contraindicated 	Saquinavir (Invirase®, SQV) ³² (sa-KWIH-nuh-veer) () 100 B B Rarely used	Adult dose: 1 tab po bid Epzicom [®] (EP-zih-com) (R ³⁸ C (C)
Also available in combination products: Truvada®, Atripla®, Complera®, Stribild®; see Combination Products for more detail Adult dose: 200 mg cap or 240 mg (24 mL) soln po once daily	 H2-receptor blockers (e.g., famotidine, ranitidine) should be taken at least 12 hours before or 4 hours after RPV Antacids (e.g., aluminum or magnesium hydroxide, calcium carbonate) should be taken at least 2 hours before or 4 hours after RPV 	 See Invirase[®] Prescribing Information available online at www.gene.com/medical- professionals/medicines for dosage forms, dosing, adverse effects and other important points. 	Each tab contains: 300 mg 3TC + 600 mg ABC Adult dose: 1 tab po once daily NOTE: Perform HLA-B*5701 test prior; only use if negative
 Important Points: Abrupt withdrawal can cause chronic active hep B flares AEs: Generally well-tolerated, ↑ pigmentation of palms/soles (> in black and Hispanic pts) 	 Caution with drugs that prolong the QT interval AEs: Depression, insomnia, headache, rash 23. Not recommended if pretreatment HIV RNA > 100,000 copies/mL († risk for virologic failure). † rate of virologic failure with use of RPV + 2 NRTI when pre- 	Tipranavir (Aptivus®, TPV) ³³ (ti-PRAN-a-veer) (*) (*) ³⁴ (*) JOC (*) (*) Rarely used 33. See Aptivus® Prescribing Information available online at http://us.boehringer-	Trizivir® (TRY-zih-veer) G () () (R) 38 H C Each tab contains: 300 mg ZDV + 150 mg 3TC + 300 mg ABC
 Refrigerate soln or room temp if used within 3 months Lamivudine (Epivir[®], 3TC) (la-Ml-vue-deen) C (k) (R) C 	ART CD4 < 200 cells/mm ³ . PROTEASE INHIBITORS (PIS) <i>Class adverse effects:</i> ↑ glucose, ↑ lipids (less with ATV and DRV),	 <i>ingelheim.com/our_products/prescription-medication-products.html</i> for dosage forms, dosing, adverse effects and other important points. 34. Take with food with RTV tabs. Take without regard to meals with RTV caps or soln. 	Adult dose: 1 tab po bid NOTE: Perform HLA-B*5701 test prior; only use if negative Truvada®
Dosage form: 150 mg, ◆300 mg tab, 10 mg/mL soln (240 mL) Also available in combination products: Combivir®, Epzicom®, Trizivir®, Triumeq®; see Combination Products for more detail Adult dose: 300 mg po once daily or 150 mg po bid	lipodystrophy, ↑ LFTs, ↑ bleeding in hemophiliacs. All undergo hepatic metabolism mostly via CYP3A4 - Many drug interactions. See DHHS Guidelines and www.hiv-druginteractions.org.	ENTRY INHIBITORS Fusion Inhibitor	(true-VAH-duh) (R ³⁹ B Each tab contains: 200 mg FTC + 300 mg TDF Adult dose: 1 tab po once daily 38. Do not use these combo products if CrCL is < 50 mL/min.
Important Points: Abrupt withdrawal can cause chronic active hep B flares AEs: Generally well-tolerated Stavudine (Zerit [®] , d4T) ¹⁶	Atazanavir (Reyataz [®] , ATV) (ah-ta-ZA-na-veer) (() (R) (1) OC ²⁴ (B) (10) Dosage form: 100, 150, 200, +300 mg cap, 50 mg oral powder packets	Enfuvirtide (Fuzeon®, T20, ENF) ³⁵ (en-FEW-ver-tide) B Rarely used 35. See Fuzeon® Prescribing Information available online at www.gene.com/medical-	 39. Do not use this combo product if CrCL is < 30 mL/min. PI Combinations (see individual drug components for important points)
(STA-vue-deen) G & R C Rarely used 16. See Zerit [®] Prescribing Information available online at www.bms.com/products for	Also available in combination product: Evotaz [™] ; see Combination Products for more detail Adult dose: - 400 mg po once daily (ARV-naïve only) <u>or</u>	professionals/medicines for dosage forms, dosing, adverse effects and other important points. CCR5 Inhibitor	Evotaz [™] (EV-oh-taz) (R ⁴⁰ C OC ⁴¹ C C C B Each tab contains: 300 mg ATV + 150 mg COBI
dosage forms, dosing, adverse effects and other important points. Tenofovir (Viread®, TDF) (ten-OH-foh-veer) (()) (()) 17 (R) B	- 300 mg + (COBI 150 mg or RTV 100 mg) po once daily (naïve, exp, or with TDF) Atazanavir Dosing with Acid-reducing Agents	Maraviroc (Selzentry®, MVC) (mah-RAV-er-rock) (() (() () () () () () () () () () ()	Adult dose: 1 tab po once daily 40. Do not combine with TDF in pts with estimated CrCL < 70 mL/min.
Nucleotide RTI Dosage form: 150, 200, 250, ◆300 mg tab 40 mg/1 g oral powder (60 g multi-use bottle) Also available in combination products: Truvada®, Atripla®, Complera®,	Acid-reducing Agents ARV-naïve ARV-exp Antacids or buffered after antacid or buffered after antacid or buffered medication • ATV, ATV/c, ATV/r: Give ≥ 2 hours before or 1 to 2 hours after antacid or buffered medication	Note: Do not use in pts with dual/mixed tropic or CXCR4-tropic virus. Perform tropism assay prior to use and if virologic failure is suspected. A phenotypic tropism assay is preferred over a genotypic assay to predict co-receptor usage. Many drug interactions. See table below, DHHS	Prezcobix [™] (prez-koe-bix) (()) (R) ⁴⁰ (C) (C) (C) (C) (C) Each tab contains: 800 mg DRV + 150 mg COBI
Stribid [®] ; see Combination Products for more detail Adult dose: 300 mg po once daily (1 tab or 7.5 scoops of powder) Important Points:	ARV-naïve with or without TDF ARV-exp without TDF	Guidelines, and www.hiv-druginteractions.org. Maraviroc Dosing Concomitant Medications Adult Dose	Adult dose: 1 tab po once daily Kaletra [®] (KAL, LPV/r) (Io-PIN-uh-veer/rih-TAH-nuh-veer) (() (2 ²⁹ [] JOC C []
 Take tabs with or without food; take powder with food. Mix powder in ¼ - ½ cup of soft food (e.g., applesauce, baby food, yogurt) and take entire dose ASAP to avoid bad taste. Interacts with ATV (see ATV for dosing) Document urine glucose and protein at baseline and perform routine 	 ATV: Give ≥ 2 hours before or 10 hours after H2RA. Max dose of famotidine 20 mg ATV/r or ATV/c: Give simultaneously with or ≥ 10 hours after H2RA. Max dose of famotidine 20 mg bid [or 	CYP3A inhibitors (with or without a CYP3A inducer): protease inhibitors (except TPV/r), DLV cobicistat ketoconazole, itraconazole, clarithromycin 150 mg po bid	Dosage Form:•200 mg LPV + 50 mg RTV, 100 mg LPV + 25 mg RTV, liquid form 400 mg LPV + 100 mg RTV per 5 mL soln (160 mL/bottle)Adult dose30:- 2 tabs (400/100 mg) po bid (PI-naïve or PI-exp) or
 monitoring (at least every 6 months) of eGFR Monitor serum phosphorus in pts with or at risk for renal impairment when used with TDF Avoid TDF if concomitant or recent use of nephrotoxic agent 	H2 Receptor Antagonists (H2RAs) bid (not to exceed 20 mg in single dose) [or equivalent]. equivalent]. • ATV/r or ATV/c: Give • ATV/r (400/100 mg) or	other strong CYP3A inhibitors (e.g., nefazodone, telithromycin) CYP3A inducers (without a strong CYP3A inhibitor) including: EFV, ETR	- 4 tabs (800/200 mg) po once daily (PI-naïve or PI-exp with ≤ 3 significant mutations) Full Regimen Combinations (see individual drug components for important points)
 Abrupt withdrawal can cause chronic active hep B flares AEs: Flatulence, headache, renal insufficiency, Fanconi Syndrome (rare), ↓ PO₄, osteopenia (rare, multifactorial) 17. Tabs are with or without food; powder is with food. 	simultaneously with or ≥ 10 hours after H2RA. Max dose of famotidine 40 mg bid [or equivalent]. ATV/c (400/150 mg): Give simultaneously with or ≥ 10 hours after H2RA. Max dose of famotidine 20 mg bid [or equivalent].	CEP, ETR, ETR, 600 mg po bid rifampin carbamazepine, phenobarbital, and phenytoin Other concomitant medications, including: TPV/r, NVP, RPV, all NRTIs, T20, RAL, DTG 300 mg po bid	Atripla® (uh-TRIP-luh) (R) ³⁸ (OC ⁴²) (C ⁴²) Each tab contains: 600 mg EFV + 200 mg FTC + 300 mg TDF
Zidovudine (Retrovir [®] , AZT, ZDV) (zye-DOE-vue-deen) C (2) (2) (2) (2) (2) (2) (2) (2) (2) (2)	Proton Pump ATV/c: Max dose of omeorazole ATV/r or ATV/c: not	 Important Points AEs: Hepatotoxicity: may be preceded by a systemic allergic reaction (↑ LFTs, pruritic rash, ↑ eos, other systemic symptoms), dizziness/postural 	Adult dose: 1 tab po once daily at bedtime Important Points: • • Take at bedtime without food to ↓ CNS side effects 42. ♀ with child-bearing potential, should use 2 forms of birth control since EFV is
10 mg/mL syrup (240 mL/bottle) Also available in combination products: Combivir®, Trizivir®; see Combination Products for more detail Adult dose: 300 mg po bid or 200 mg po tid	Inhibitors (PPIs) Component of a line for a line line for a line for a line for a line line for a line line line	hypotension, cough, pyrexia, URI, rash, musculoskeletal symptoms, abdominal pain, ↑ CV events (MI, ischemic events) INTEGRASE STRAND TRANSFER	teratogenic; consider pregnancy test prior to use. Complera® (com-PLAIR-uh) ((R) (R) (R) (R) (R) (R) (R) (R) (R) (
Intrapartum: 2 mg/kg IV over 1 hour then 1 mg/kg/hour until cord clamping Important Points: • AEs: Headache, nausea, ↑ pigmentation skin/nails, ↓ hemoglobin/	 Take with food AEs: ↑ unconjugated bilirubin (common), jaundice or scleral icterus (less common); less adverse effects on lipid profile; prolonged PR interval, asymptomatic 1st degree AV block (rare); nephrolithiasis (rare), cholelithiasis 	INHIBITORS (INSTIS) Dolutegravir (Tivicay®, DTG) (Doe-loo-teg'-ra-vir) (() (() (R) (R) (R) (R) (R) (R) (R) (R	Each tab contains: 25 mg RPV + 200 mg FTC + 300 mg TDF Adult dose: 1 tab po once daily Important Points: • Take with food
hematocrit, ↓ WBC, ↑ MCV, myopathy NON-NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITORS (NNRTIS)	24. ATV/r: OC dose <u>minimum</u> 35 mcg ethinyl estradiol (EE); ATV: OC dose <u>maximum</u> 30 mcg EE. Alternative contraception recommended. OCs with < 25 mcg EE, progestins other than norethindrone or norgestimate, and other hormonal contraceptives have not been studied. ATV/c: No data available	Dosage form: 50 mg tab Also available in combination product: Triumeq®; see Combination Products for more detail Adult dose ³⁶ : - 50 mg po once daily (ART-naïve or exp but	Stribild® (STRY-bild) (STRY-bild) (STRY-bi
Class adverse effects: rash (rarely Stevens-Johnson Syndrome), ↑ LFTs, many drug interactions. See DHHS Guidelines and www. hiv-druginteractions.org.	regarding coadministration with oral or other hormonal contraceptive. Consider alternative nonhormonal contraception. Darunavir (Prezista®, DRV)	INSTI-naïve) or - 50 mg po bid (ART-naïve or exp but INSTI-naïve when given with potent UGT1A/CYP3A inducers [e.g., EFV, FPV/r, TPV/r or rifampin]) or	200 mg FTC + 300 mg TDF Adult dose: 1 tab po once daily Important Points: • Take with food 43. Do not initiate in pts with baseline CrCL < 70 mL/min. Discontinue if CrCL < 50
Delavirdine (Rescriptor®, DLV) ¹⁸ (deh-LAH-ver-deen) () Rarely used	(da-ROO-nuh-veer) () ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓	- 50 mg po bid (pts with clinically suspected INSTI resistance or INSTI mutations) See the Viking-3 trial data in the Tivicay [®] package insert (<i>https://www.viv/healthcare.com/media/58599/us_tivicay.pdf</i>) for predicted efficacy response in the setting	 43. Do not initiate in pis with baseline CrCL < 70 mi2/min. Discontinue in CrCL < 50 mi2/min. 44. ↑ norgestimate ↓ ethinyl estradiol. See package insert for potential risks/ benefits associated with this interaction. Interactions with alternative hormonal contraception not fully studied. Consider use of nonhormonal contraceptives.
 See Rescriptor[®] Prescribing Information available online at www.vivhealthcare. com/our-medicines for dosage forms, dosing, adverse effects and other important points. 	see Combination Products for more detail Adult dose: - 800 mg + (COBI 150 mg or RTV 100 mg) po once daily (ARV-naïve or ARV-exp if no DRV mutations [V111, V32I, L33F, I47V, I50V, I54L, I54M, T74P, L76V, I84V, L89V]) ²⁵ or	of certain INSTI resistance mutations. ³⁷ Refer to: http://hivdb.stanford.edu/DR/ INIResiNote.html for a complete list of INSTI mutations. In the setting of suspected or known INSTI resistance, consider a regimen that does not include metabolic inducers.	Triumeq [®] (TRI-u-meck) ((R) (R) (R) (C) (R) Each tab contains: 50 mg DTG + 600 mg ABC + 300 mg 3TC
Efavirenz (Sustiva [®] , EFV) (eh-FAH-vih-rehnz) (C ¹⁹) (Empire C ¹⁹) Dosage form: 50, +200 mg cap, +600 mg tab Also available in combination product: Atripla [®] ;	 - 600 mg + RTV 100 mg po bid (ARV-naïve or ARV-exp) Important Points: Take with food AEs: Rash (10%), abdominal pain, headache, hepatotoxicity, caution with 	 Important Points: Take DTG ≥ 2 hours before or 6 hours after antacids or laxatives containing cations, sucralfate, oral iron or calcium supplements, or buffered medications. Alternatively, DTG and calcium or iron supplements are betaken aimultaneously with feed. Cuidelineous recommend aiming 	Adult dose: 1 tab po once daily NOTE: Perform HLA-B*5701 test prior; only use if negative PHARMACOKINETICS (PK) ENHANCERS
see Combination Products for more detail Adult dose: 600 mg po once daily at bedtime Important Points: • Take at bedtime without food to ↓ CNS side effects	sulfa allergy (not contraindicated) 25. Prezista® [package insert]. Titusville, NJ: Janssen Pharmaceuticals; Revised April 2014. Fosamprenavir (Leviva®- FPV)	 can be taken simultaneously with food. Guidelines recommend giving DTG ≥ 2 hours before or 6 hours after medications containing other polyvalent cations (e.g., Al, Mg, Zn) including multivitamins with minerals and sucralfate. AEs: Headache and insomnia most common. Hypersensitivity reaction 	Cobicistat (Tybost®, COBI) ⁴⁵ (koe-BIK-i-stat) (COBI) ⁴⁵ (koe-BIK-i-stat) (COBI) ⁴⁵ Dosage form: 150 mg tab

- Important Points:
- Take at bedtime without food to ↓ CNS side effects False + cannabinoid or benzodiazepine test (usually on screening confirmatory test should be negative)
- Use with caution in pts with unstable psych disorder AEs: Drowsiness, dizziness, insomnia, abnormal dreaming, agitation
- (Usually resolves in 2-4 weeks), hallucinations (rare), ↑ lipids 19. Consider alternative agent in **Q** with childbearing potential not using adequate birth control due to the risk of teratogenicity during the first 5-6 weeks of pregnancy. If pregnancy occurs while on EFV, EFV can be continued if the pt is rologically suppresse

Etravirine (Intelence®, ETR)

- Tabs with or without food; susp without food 1200 OCs ↓ FPV levels; do not coadminister Acid-reducing Agents: PPI coadministration allowed; H2RA use with caution due to \downarrow APV levels; separate administration · AEs: Rash (19%), nausea, vomiting, diarrhea, caution with sulfa allergy (not contraindicated) · Susp. refrigeration not required; improves taste. Shake well before use. 26. Suspension: adults without food; peds with food.
- Important Points:

Fosamprenavir (Lexiva®, FPV)

- (foss-am-PREH-nah-veer) 🔊 🔊 🕫 🔣 💽 🕻 🌆
- Prodrug of amprenavir
- Dosage form: Adult dose:

700 mg tab, 50 mg/mL susp (225 mL/bottle) - 1400 mg po bid <u>or</u> - 1400 mg + RTV 100-200 mg po once daily (ARV-naïve only) or - 700 mg + RTV 100 mg po bid (PI-exp or PI-naïve)

injury) have been reported.
36. Do not combine with NVP. Do not combine with ETR unless ATV/r, DRV/r, or LPV/r included in regimen as ETR may L DTG levels. Note: DHHS Guidelines do not recommend combing ETR with ATV (± RTV).
37. Tivicay[®] [package insert]. Research Triangle Park, NC: ViiV Healthcare; Revised December 2014 Elvitegravir (Vitekta®, EVG)

(el-vye-TEG-ra-veer) 📎 🖁 😡 Dosage form: \$85, \$150 mg tab

- 5 mL soln Pl-exp) or
- ïve or

- ce EFV is
- if CrCL < 50
- risks/ e hormonal aceptives

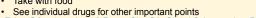
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Also available in combination products: Evotaz[™], Prezcobix[™], and Stribild®

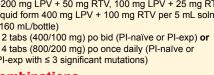
see Comb nation Products for more detail

- COBI 150 mg + ATV 300 mg po once daily (ARV-naïve Adult dose48 or ARV-exp) or
 - COBI 150 mg + DRV 800 mg po once daily (ARV-naïve
 - or ARV-exp without DRV mutations. See Darunavir
- section of resource.) Important Points:
- Take with food









- 25 mg RTV,

(eh-truh-VIGH-reen) 📎 💾 ↑OC 🖪 🎹

100, **♦**200 mg tab Dosage form: Adult dose 20. 200 mg po bid **Important Points:**

- Take following a meal
- May disperse tabs in 5mL of water, stir well. If desired mix with additional water, orange juice or milk (no warm or carbonated drinks) and then drink immediately. Rinse glass several times with water, milk, or orange juice and drink rinse.²¹
- AEs: Nausea, hypersensitivity reactions with rash, constitutional findings, hepatic failure have been reported
- 20. Do not use ETR with unboosted PIs, ATV/c, ATV/r, DRV/c, FPV/r, TPV/r. Standard dosing with DRV/r, LPV/r, SQV/r.
- Intelence[®] [package insert]. Titusville, NJ: Janssen Therapeutics, Division of Janssen Products, LP; Revised August 2014.

Nevirapine (Viramune®,

Viramune XR[®], NVP)

(nah-VAIR-ah-peen) G 📎 🛞 🖁 🗤 🛛 🖪 🃷

- Dosage form:
- 100 mg tab (XR), +200 mg tab, +400 mg tab (XR), 10 mg/mL susp (240 mL bottle) Adult dose²²:
 - 200 mg po once daily for 14 days, then [200 mg po bid or 400 mg (XR) po once daily]

Important Points:

- XR tabs should not be crushed, chewed, or broken AEs: Rash mild to severe, usually within 1st 6 weeks, discontinue if severe; \uparrow LFTs (Monitor LFTs - baseline, 2 weeks after dose escalation, then monthly for the 1st 18 weeks); hepatotoxicity often rash-associated, check LFTs in any pt with rash; Q and 3 with pre-ART CD4 > 250 and > 400, respectively and pts with chronic active hep B or C co-infection are at ↑ risk for ↑ LFTs
- 22. If NVP discontinued \geq 7 days, restart at lower dose for 14 days; pts taking NVP immediate release (200 mg bid or 400 mg once daily) can switch to XR 400 mg once daily without 200 mg daily lead-in dosing; if mild rash occurs and hepatotoxicity ruled out, can continue 200 mg once daily lead-in dose for up to 28 days.

Indinavir (Crixivan[®], IDV)²⁷ (in-DIH-nuh-veer) 🔊 🛞 🕫 💾 🕻 🌃 Rarely used



- 27. See Crixivan® Prescribing Information available online at www.merck.com/
- product/prescription-products for dosage forms, dosing, adverse effects and other important points
- 28. If given without RTV (rarely, if ever, done), take 1 hour before or 2 hours after a meal or with low fat/protein snach

Lopinavir/ritonavir (Kaletra®, KAL, LPV/r) (Io-PIN-uh-veer/rih-TAH-nuh-veer) 🔊 🚳 😕 📕 JOC 🕻 🎹

- Dosage form: ♦200/50 mg, 100/25 mg tab
 - 400/100 mg per 5 mL soln (160 mL/bottle)
- 2 tabs (400/100 mg) po bid (PI-naïve or PI-exp) or Adult dose³⁰ - 4 tabs (800/200 mg) po once daily (PI-naïve or PI-exp with ≤ 3 significant mutations)

Important Points:

- Swallow tabs whole; cannot be chewed, broken, or crushed
- · May take tabs without food, soln should be taken with food
- Oral soln contains 42% alcohol
- AEs: GI intolerance (N/V/D); asthenia; prolonged PR, rare cases of 2nd/3rd degree AV block; prolonged QT interval, rare cases of torsade de pointes (causality not established)
- Do not take tabs out of container for > 2 weeks especially in areas of ↑ humidity
- · Refrigerate soln (stable until label date) or store at room temp (max

25°C/77°F) for up to 60 days 29. Tabs are with or without food; soln is with food. 30. Once daily dosing should not be used in pregnant ♀. Dose LPV/r bid in pts with ≥ 3 of the following PI mutations: L10F/I/R/V, K20M/N/R, L24I, L33F, M36I, I47V, G48V, I54L/T/V, V82A/C/F/S/T, and I84V.

Also available in combination product: Stribild® see Combination Products for more detail

- Adult dose: Indicated for ARV-exp adults. Use in combination with a boosted PI (options listed below) and \geq 1 other ARV
- 85 mg po once daily: Regimens containing ATV 300/RTV 100 mg po once daily <u>or</u> LPV/RTV 400/100 mg po bid • 150 mg po once daily: Regimens containing DRV/RTV 600/100 mg po bid <u>or</u>

AEs: Headache and insomnia most common. Hypersensitivity reaction

including rash, constitutional symptoms and organ dysfunction (e.g. liver

FPV /RTV 700/100 mg po bid or TPV/RTV 500/200 mg po bid

Important Points

- Take with food
- No data available re: COBI + EVG as single agents compared to Stribild[®]
- Not recommended for use with regimens containing PI + cobicistat since dosing recommendation have not been established
- Evidence suggests polyvalent cations may ↓ EVG levels. Take ≥ 2 hours before or 2 hours after antacids containing Ca, Al, or Mg. Guidelines recommend giving EVG ≥ 2 hours before or 6 hours after other medications containing polyvalent cations (e.g., Al, Ca, Fe, Mg, Zn) including multivitamins with minerals and sucralfate.
- Some experts would recommend taking EVG 2 hours before or 6 hours after other medications containing polyvalent cations (e.g., Mg, Al, Fe, Ca) pending more data regarding interactions
- AEs: Diarrhea, nausea, headache

Raltegravir (Isentress[®], RAL)

(ral-TEG-ra-veer) 🔌 🚫 💾 🗲 🎹 Dosage form:

+400 mg tab, 25 mg, 100 mg chewable tabs, 100 mg packet for oral suspension

400 mg po bid

Adult dose Important Points:

- Evidence suggests polyvalent cations may \downarrow RAL levels. Do not combine with antacids containing AI or Mg. No separation needed when given with CaCO₃ antacids. Guidelines recommend taking RAL \ge 2 hours before or 6 hours after medications containing other polyvalent cations (e.g., Fe, Zn) including multivitamins with minerals.
- AEs: Diarrhea, nausea, headache, and pyrexia; ↑ ALT, AST, CPK; myopathy and rhabdomyolysis have been reported, rare severe skin reactions (SJS/ TEN) and systemic HSR with rash and constitutional symptoms +/- hepatitis

- 45. Tybost[®] [package insert]. Foster City, CA: Gilead Sciences, Inc; Re September 2014.
- de Do not combine with TDF in pts with estimated CrCL < 70 mL/min.
 47. No data to make recommendation on use with oral or other hormonal
- contraceptives. Use alternate/additional form of birth control. 48. FDA approved only in combination with the PIs ATV or DRV or the INSTI EVG
- when used in Stribild

Ritonavir (Norvir[®], RTV)



(rih-TAH-nuh-veer) 📎 🚫 49 🔣 🖪 🔢 Dosage form: ♦100 mg tab, ♦100 mg cap, 80 mg/mL soln (240 mL/bottle) Used only at low doses with other PIs (see primary PI for dosing, food requirements and adverse effects)

Important Points:

Store tabs at room temp; refrigerate caps (stable until label date), can store caps at room temp (max 25°C/77°F) for up to 30 days; do not refrigerate soln 49. Food require end on cor resource

