FDA Approved Antiretrovirals for the treatment of HIV Infection **Revised April 2008**

Drug	*FDA Adult Dose*	*Dosage Forms*	*Alternative or Adjusted Dose*	*Diet*	*Special Considerations*	*Adverse Effects*
Single Tablet Regimen						
EFV/FTC/TDF Atripla®	1 tablet QHS	• Efavirenz (EFV) 600mg + • Emtricitabine (FTC) 200mg + • Tenofovir (TDF) 300mg		Empty stomach recommended	Do not use if renal function is impaired (must adjust individual components)	Refer to individual agents
Nucleoside and Nucleotide Reverse Transcriptase Inhibitors (NRTI)						
Abacavir Ziagen® (ABC)	300mg BID - or - 600 mg Daily	• 300mg tablet • 20mg/mL oral solution		With or without food	**Abacavir Hypersensitivity** **DO NOT RECHALLENGE** **If hypersensitivity suspected** ▪ No Renal Dosing Adjustments	**Hypersensitivity reaction** Symptoms may include: Fever, Rash, Nausea, Vomiting, Malaise or Fatigue, Respiratory Difficulties*
Didanosine Videx-EC® (ddI)	Didanosine-EC: 400mg Daily ***If weight <60 kg:*** 250mg Daily	• 125mg, 200mg, 250mg, 400mg EC capsules *(check package insert for other formulations)*	**Didanosine + Tenofovir:** ***If weight > 60 kg:*** • ddI-EC 250mg Daily + TDF 300mg Daily; together with or without food ***If weight <60 kg:*** • Appropriate dose not established, probably ddI <250 mg/day	Empty stomach with water **Videx-EC capsule formulation should not be crushed, but swallowed whole**	• **Numerous formulations with different dosing requirements exist – use caution!!** • Dose adjust for impaired renal function	Peripheral neuropathy, Pancreatitis, Nausea, Diarrhea*
Emtricitabine Emtriva® (FTC)	200mg daily	• 200mg capsule		With or without food	• Dose adjust for impaired renal function	Generally well tolerated; Headaches, Fatigue, Nausea*
Lamivudine Epivir® **(**3TC)	150mg BID - or - 300mg daily	• 150mg, 300mg tablet • 10mg/mL oral solution		With or without food	• Dose adjust for impaired renal function	Generally well tolerated; Headaches, Fatigue, Nausea*
Stavudine Zerit® (d4T)	40mg BID ***If weight <60 kg:*** 30mg BID	• 15mg, 20mg, 30mg, 40mg capsule • 1mg/ml for oral solution		With or without food	• Dose adjust for impaired renal function • Co-administration with zidovudine not recommended	Peripheral neuropathy, Pancreatitis, Altered liver function, Lipoatrophy, Hyperlipidemia, Ascending paresis (rare)*
Tenofovir DF Viread® (TDF)	300mg Daily	• 300mg tablet	**Didanosine + Tenofovir** ***If weight >60 kg:*** • ddI-EC 250mg Daily + TDF 300mg Daily; together with or without food ***If weight <60 kg:*** • Appropriate dose not established, probably ddI <250mg/day **Atazanavir + Tenofovir** • ATV 300mg Daily + RTV 100mg Daily + TDF 300mg Daily	With or without food	• Dose adjust for impaired renal function	Generally well tolerated; Nausea, Upset stomach, Vomiting, Fanconi Syndrome (rare)*
Zidovudine Retrovir® (AZT)	300mg BID - or - 200mg TID	• 100mg capsule • 300mg tablet • 10mg/mL oral syrup		With or without food (suggest with food)	• Dose adjust for impaired renal function • Co-administration with stavudine not recommended	Anemia, Neutropenia, Headaches, Nausea, Body aches, Insomnia*
*** Class Adverse Reaction**: lactic acidosis with hepatic steatosis (rare, but potentially life threatening reaction with use of NRTIs)						
NRTI Fixed Dose Combinations						
AZT/3TC Combivir®	1 tablet BID	• Zidovudine (AZT) 300mg + • Lamivudine (3TC) 150mg		With or without food (suggest with food)	• **DO NOT** use if renal function is impaired (must adjust individual components)	Refer to individual agents*
ABC/3TC Epzicom®	1 tablet Daily	• Abacavir (ABC) 600mg + • Lamivudine (3TC) 300mg		With or without food	• **Abacavir hypersensitivity** (see abacavir) • **DO NOT** use if renal function is impaired (must adjust 3TC dose)	Refer to individual agents* Headaches, Fatigue, Nausea **DO NOT RECHALLENGE!**
ABC/AZT/3TC Trizivir®	1 tablet BID	• Abacavir (ABC) 300mg + • Zidovudine (AZT) 300mg + • Lamivudine (3TC) 150mg		With or without food (suggest with food)	• **Abacavir hypersensitivity** (see abacavir) • **DO NOT** use if CrCl < 50mL/min (adjust individual components) • **DO NOT** use in hepatic dysfunction	Refer to individual agents* **DO NOT RECHALLENGE!**
FTC/TDF Truvada®	1 tablet Daily	• Emtricitabine (FTC) 200mg + • Tenofovir (TDF) 300mg		With or without food	• **DO NOT** use if renal function is impaired (must adjust individual components)	Refer to individual agents*

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Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI)						
Delavirdine Rescriptor® (DLV)	• 400mg TID • 600mg BID	• 100mg, 200mg tablet		With or without food ***(Do not take with antacids)***	• Older agent; not commonly used	Rash, Headache, Altered liver function
Efavirenz Sustiva® (EFV)	600mg PO QHS	• 600mg tablet • 50mg, 100mg, 200mg capsule	Dosage adjustment: EFV standard dose + • ATV 300mg Daily + RTV 100mg Daily • FPV 700mg BID + RTV 100mg BID • FPV 1,400mg Daily + RTV 300mg Daily (not recommended for tx exp pts) • LPVr 600mg/150mg (3 tabs) BID • IDV 800mg BID + RTV 100-200mg BID	Empty stomach recommended Avoid taking with high-fat meals – food may increase side effects	• Minimize alcohol intake • False + cannabinoid test	Rash, CNS effects x 2-3 weeks (Abnormal dreams, Dizziness, Impaired concentration, Insomnia, Drowsiness), Altered liver function
Etravirine Intelence® (ETR)	200mg BID	• 100mg tablet	Do not co-administer etravirine with the following ARVs: • TPV/RTV, FPV/RTV, ATV/RTV • Protease inhibitors administered without RTV • NNRTIs	Take following a meal (empty stomach ↓'s absorption)	• Indicated for tx-experienced patients with resistant HIV-1, including K103N mutation • Caution is warranted when co-administered with 3A4, 2C9, and 2C19 substrates (drug levels may be altered) • Dose adjustment not required for renal dysfunction, mild/moderate hepatic dysfunction, or Hep B or C co-infection	Rash (most common in weeks 2-4, typically resolved x 1-2 weeks), Nausea
Nevirapine Viramune® (NVP)	200mg Daily x first 14 days, then 200mg BID	• 200mg tablet • 10mg/ml oral suspension	Dosage adjustment: NVP standard dose + • ATV 300mg Daily + RTV 100mg Daily • FPV 700mg BID + RTV 100mg BID • FPV 1,400mg Daily + RTV 300mg Daily (not recommended for tx exp pts) • IDV 800mg BID + RTV 100-200mg BID • LPVr 600mg/150mg (3 tabs) BID	With or without food *(with food if with RTV)*		Rash, Hepatitis, Hepatic necrosis (50% with rash) – especially in women with a baseline CD4 >250 or in men with a baseline CD4 >400
Fusion Inhibitors						
Enfuvirtide Fuzeon® (T-20)	**Administered dose: 90mg/mL SQ BID** (108mg vial diluted with 1.1 mL sterile water)	• Available as kit containing 60 doses w/ syringes, diluent & alcohol pads • Also available as biojector device			• Rotate injection sites • Store at controlled room temperature (59–86° F) • Visit www.fuzeon.com for ordering information	**Injection site reaction:** Pain/discomfort, induration, Erythema, Nodules **Other:** Diarrhea, Nausea, Vomiting, Fatigue, Insomnia, Nerve pain & Bruising with biojector device
CCR5 Receptor Antagonist						
Maraviroc Selzentry® (MVC)	300mg BID *(See alternative or adjusted dose)*	• 150mg, 300mg tablets	When given with strong CYP3A inhibitors (with or w/o a CYP3A inducer) including PIs (except tipranavir/ritonavir), delavirdine: • 150mg BID With NRTIs, tipranavir/ritonavir, nevirapine: • 300mg BID When given with CYP3A inducers (w/o a strong CYP3A inhibitor) including efavirenz: • 600mg BID	With or without food	• Only indicated in tx-experienced pts with CCR5-tropic-HIV-1, with evidence of viral replication and HIV-1 strains resistant to multiple ARV agents	**Hepatotoxicity, Systemic allergic reaction prior to hepatotoxicity,** Cough, Pyrexia, URI, Rash, Musculoskeletal Symptoms, Abdominal Pain, Dizziness
Integrase Inhibitors						
Raltegravir Isentress® (RAL)	400mg BID	• 400mg tablet		With or without food	• Indicated for tx-experienced pts with evidence of viral replications and HIV-1 strains resistant to multiple ARV agents • Caution in patients with an increased risk of myopathy or rhabdomyolysis.	Nausea, Headache, Diarrhea, Pyrexia

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Protease Inhibitors (PI)						
Atazanavir Reyataz® (ATV)	Un-boosted: 400mg Daily Boosted: 300mg Daily + RTV 100mg Daily	• 100mg, 150mg, 200mg, 300mg capsule	**Use boosted dose** of Atazanavir when used with Efavirenz, Nevirapine, or Tenofovir: • ATV 300mg Daily + RTV 100mg Daily • **Do not take with antacids, H2 blockers or proton pump inhibitors without consulting the prescribing information.**	Take with a light meal for better absorption.	• **In PI-experienced patients, the combination of Atazanavir + Ritonavir should be used** • Dose adjust for hepatic impairment	Generally well tolerated; Diarrhea, Nausea, Abdominal discomfort, Rash, Hyperbilirubinemia++
Darunavir Prezista™ (DRV)	Boosted only: DRV 600mg BID + RTV 100mg BID	• 300mg tablet	DRV requires RTV boosting	Take with food for enhanced absorption	• Caution in patients with known sulfonamide allergy	Diarrhea, Nausea, Headache, Rash, and Cold Symptoms++
Fosamprenavir Lexiva® (f-APV)	Un-boosted: 1400mg BID Boosted: - 700mg BID + RTV 100mg BID - 1400mg QD + RTV 100mg-200mg QD	• 700mg tablet	When combining with Efavirenz or Nevirapine: • f-APV 1400mg Daily + RTV 300mg Daily (not recommended for tx exp pts) • f-APV 700mg BID + RTV 100mg BID	May be taken with or without food (with food if with RTV)	• Caution in patients with known sulfonamide allergy • Dose adjust for hepatic impairment	Rash, Diarrhea, Nausea, Headache++
Indinavir Crixivan® (IDV)	Un-boosted: 800mg Q8H Boosted: 800mg BID + RTV 100-200mg BID	• 100mg, 200mg, 333mg, 400mg capsule	Dosage adjustment of Indinavir when used with NNRTIs (except DLV): • IDV 1000mg Q8H • IDV 800mg BID + RTV 100-200mg BID	Un-boosted IDV: Empty stomach or low fat snack Ritonavir boosted IDV: take with food	• If intolerable, take with light, non-fat snack • Drink at least 1.5 liters of fluids daily • No grapefruit juice (decreased IDV level)	Nausea, Vomiting, Kidney stone formation, Heartburn, Hyperbilirubinemia++
Lopinavir/ Ritonavir Kaletra® (LPVr)	This combination is boosted (contains RTV)	• Lopinavir 200mg/Ritonavir 50mg tablet • LPV 80mg/RTV 20mg per ml oral solution	Can be given 2 tabs BID or 4 tabs Daily Dosage adjustment of LPVr when used with NNRTIs (except DLV): • LPVr 600mg/150mg (3 tabs) BID	With or without food	• RTV has multiple drug interactions via CYP450 and P-glycoprotein • Refrigerate oral solution	Diarrhea, Nausea, Headache, Asthenia (lack of strength) ++
Nelfinavir Viracept® (NFV)	• 1250mg BID • 750mg TID	• 250mg, 625mg tablet • 50mg/1g scoop, powder for solution		Take with food for enhanced absorption	• Important to provide anti-diarrheal agent	Diarrhea, Nausea, Vomiting, Abdominal pain++
Ritonavir Norvir® (RTV)	**Ritonavir is primarily used in low doses to boost drug levels of other protease inhibitors**	• 100mg capsule • 80mg/mL oral solution	• Numerous combinations use ritonavir for pharmacokinetic enhancement • Most use 100-200mg RTV Daily	Take with food for enhanced absorption	• Refrigerate capsules. May store at room temperature up to 30d. • **DO NOT** refrigerate oral solution (may crystallize) • Multiple drug interactions via CYP450 and P-glycoprotein	Diarrhea, Nausea, Headache, Numbness around the mouth, Altered taste, Asthenia++
Saquinavir Invirase® (SQV)	Boosted only: 1000mg BID + RTV 100mg BID	• 200mg hard gel capsule • 500mg tablet	SQV requires RTV boosting	Take with food for enhanced absorption	• Store at room temperature	Diarrhea, Nausea, Headache++
Tipranavir Aptivus® (TPV)	Boosted only: 500mg BID + RTV 200mg BID	• 250mg soft gel capsule	Separate Videx EC from TPV/RTV by at least 2 hours	Take with food for enhanced absorption **DO NOT** take with antacids	• Caution in patients with known sulfonamide allergy • Contraindicated in patients with moderate to severe hepatotoxicity • Refrigerate capsules – may store at room temp up to 60 days	Diarrhea, Nausea, Vomiting, Stomach cramps, Rash, Intracranial Hemorrhage++

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Updated by Kaddin Moretsky (April 2008)