

FDA Approved Antiretrovirals for HIV

Revised March 2004

<i>Drug</i>	<i>FDA Adult Dose</i>	<i>Dosage Forms</i>	<i>Alternative or Adjusted Dose</i>	<i>Diet</i>	<i>Special Considerations</i>	<i>Adverse Effects</i>
Nucleoside Reverse Transcriptase Inhibitors (NRTI)						
Abacavir Ziagen® (ABC)	300mg BID	<ul style="list-style-type: none"> 300mg tablet 20mg/mL oral suspension 		With or without food	Abacavir Hypersensitivity DO NOT RECHALLENGE if hypersensitivity suspected	Hypersensitivity reaction (fever, rash, N/V, malaise, congestion); Diarrhea
Combivir® (AZT/3TC)	1 tablet BID	<ul style="list-style-type: none"> Zidovudine 300mg + Lamivudine 150mg 		With or without food (suggest with food)	<ul style="list-style-type: none"> DO NOT use if CrCl < 50mL/min (must adjust individual components) 	Refer to individual agents
Didanosine Videx® EC (ddl)	Didanosine EC dose: 400mg QD If weight < 60 Kg: 250mg QD	<ul style="list-style-type: none"> 125mg, 200mg, 250mg, 400mg EC capsule (Check package insert for other formulations) 	Didanosine + Tenofovir Dosing: If weight > 60 Kg: <ul style="list-style-type: none"> DDI EC 250mg QD + TNF 300mg QD <u>together with or without food</u> If wt < 60 Kg: no information available	<u>Empty stomach</u> Videx® EC Capsule formulation should not be crushed, but swallowed whole	<ul style="list-style-type: none"> Numerous formulations with different dosing requirements exist – use caution!! Dose adjust for impaired renal function 	Peripheral neuropathy, Pancreatitis, Nausea, Diarrhea
Emtricitabine Emtriva® (FTC)	200mg QD	<ul style="list-style-type: none"> 200mg capsule 		With or without food	<ul style="list-style-type: none"> Dose adjust for impaired renal function 	Generally well tolerated; Headaches, Nausea
Lamivudine Epivir® (3TC)	150mg BID - or - 300mg QD	<ul style="list-style-type: none"> 150mg, 300mg tablet 10mg/mL oral solution 		With or without food	<ul style="list-style-type: none"> Dose adjust for impaired renal function 	Generally well tolerated; Headaches, Nausea
Stavudine Zerit® (d4T)	40mg BID If weight < 60 Kg: 30mg BID	<ul style="list-style-type: none"> 15mg, 20mg, 30mg, 40mg capsule 		With or without food	<ul style="list-style-type: none"> Dose adjust for impaired renal function 	Peripheral neuropathy, Altered liver function
Trizivir® (ABC/AZT/3TC)	1 tablet BID	<ul style="list-style-type: none"> Abacavir 300mg + Zidovudine 300mg + Lamivudine 150mg 		With or without food (suggest with food)	<ul style="list-style-type: none"> Abacavir Hypersensitivity (see Abacavir) DO NOT use if CrCl < 50mL/min (must adjust individual components) 	Refer to individual agents
Zidovudine Retrovir® (AZT)	300mg BID - or - 200mg TID	<ul style="list-style-type: none"> 100mg capsule 300mg tablet 10mg/mL syrup 		With or without food (suggest with food)	<ul style="list-style-type: none"> Dose adjust for impaired renal function 	Anemia, Neutropenia, Headaches, Nausea, Body aches, Insomnia
Nucleotide Reverse Transcriptase Inhibitor (NtRTI)						
Tenofovir Viread® (TNF)	300mg QD	<ul style="list-style-type: none"> 300mg tablet 	Didanosine + Tenofovir Dosing: If weight > 60 Kg: <ul style="list-style-type: none"> DDI EC 250mg QD + TNF 300mg QD <u>together with or without food</u> If wt < 60 Kg: no information available Atazanavir + Tenofovir Dosing: <ul style="list-style-type: none"> ATV 300mg QD + RTV 100mg QD + TNF 300mg QD 	With or without food	<ul style="list-style-type: none"> Dose adjust for impaired renal function 	Generally well tolerated; Nausea, Vomiting
Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI)						
Delavirdine Rescriptor® (DLV)	400mg TID	<ul style="list-style-type: none"> 100mg, 200mg tablet 	Dosage adjustment: <ul style="list-style-type: none"> DLV 400 TID + IDV 600 Q8H DLV 600mg BID + SQV 1600mg BID 	With or without food (Do not take with antacids)		Rash, Headache, Altered liver function
Efavirenz Sustiva® (EFV)	600mg QHS	<ul style="list-style-type: none"> 600mg tablet 50mg, 100mg, 200mg capsule 	Dosage adjustment: <ul style="list-style-type: none"> IDV 1000mg Q8H RTV 400mg BID + SQV 400-600 BID APV 600mg + RTV 100-200mg BID Lopinavir/R 533/133mg (4 caps BID) 	Avoid taking with high-fat meals– food may increase side effects	<ul style="list-style-type: none"> Minimize alcohol intake 	Rash, Abnormal dreams, Dizziness, Impaired concentration, Altered liver function
Nevirapine Viramune® (NVP)	200 mg/day for first 14 days 200mg BID	<ul style="list-style-type: none"> 200mg tablet 10mg/ml oral suspension 	Dosage adjustment : <ul style="list-style-type: none"> IDV 800mg BID+ RTV 100-200mg BID AMP 600mg BID+ RTV 200mg BID 	With or without food		Rash, Headache, Altered liver function including severe hepatotoxicity

Drug	FDA Adult Dose	Dosage Forms	Alternative or Adjusted Dose	Diet	Special Considerations	Adverse Effects
Protease Inhibitors (PI)						
Amprenavir Agenerase® (APV)	For capsules: • APV 1200mg BID • APV 600mg BID + RTV 100mg BID • APV 1200mg QD + RTV 200mg QD	• 50mg, 150mg capsule • 15mg/ml oral solution	Dosage adjustment of Amprenavir when used with Efavirenz or Nevirapine: • APV 600 + RTV 100-200mg BID • APV 1200mg TID Dosage adjustment of Amprenavir when used with Lopinavir/Ritonavir (Kaletra): • APV 750mg BID + LPV/r 533/133mg (4 capsules BID)	May be taken with or without food (high fat meals decreases drug absorption) (Do not take with antacids)	• Capsule and oral solution dosages are not interchangeable • Vitamin E 109 IU in <u>each</u> capsule	Diarrhea, Nausea, Headache, Altered liver function
Atazanavir Reyataz® (ATV)	• ATV 400mg QD • ATV 300mg QD + RTV 100mg QD	• 100mg, 150mg, 200mg capsules	Dosage adjustment of Atazanavir when used with Efavirenz, Nevirapine, or Tenofovir: • ATV 300mg QD + RTV 100mg QD	Take with light meal for better absorption (Do not take with antacids or Proton Pump Inhibitors)	• Avoid combining atazanavir and indinavir due to possible hyperbilirubinemia	Diarrhea, Nausea, Abdominal Discomfort, Hyperbilirubinemia
Fosamprenavir Lexiva® (F-APV)	PI-naïve patients: • F-APV 1400mg BID • F-APV 1400mg QD + RTV 200mg QD • F-APV 700mg BID + RTV 100mg BID PI-experienced patients: ▪ F-APV 700mg BID + RTV 100mg BID	• 700mg tablet	For PI-experienced patients, use BID dosing with Ritonavir: • F-APV 700mg BID + RTV 100mg BID When combining QD regimen with Efavirenz or Nevirapine use: • F-APV 1400mg QD + RTV 300mg QD <i>Do NOT coadminister with Lopinavir/Ritonavir (Kaletra)</i>	May be taken with or without food (Do not take with antacids)	• Caution in patients with known sulfonamide allergy (refer to package insert)	Diarrhea, Nausea, Headache, Altered liver function
Indinavir Crixivan® (IDV)	• IDV 800mg <u>Q8H</u> • IDV 800mg BID + RTV 100-200mg BID • IDV 400mg BID + RTV 400mg BID	• 100mg, 200mg, 333mg, 400mg capsule	Dosage adjustment of IDV when used with Efavirenz or Nevirapine: • IDV 1000mg Q8H • IDV 800mg + RTV 200mg BID	Empty stomach <u>unless combined with ritonavir</u> (Do not take with antacids)	• If intolerance, take with light, non-fat snack • Drink at least 1.5 liters of fluids daily (water, fruit juice, non-caffeinated) • No grapefruit juice (decreased Indinavir level)	Nausea, Vomiting, Kidney stone formation, Heartburn, Hyperbilirubinemia
Lopinavir/r Kaletra® (LPV/r)	• LPV 400mg + RTV 100mg BID (3 caps BID) (combination capsule)	• 133mg Lopinavir/33mg Ritonavir capsule • 80mg/20mg per ml oral solution	Dosage adjustment of Lopinavir/r when used with Efavirenz or Nevirapine: • LPV 533mg + RTV 133mg (4 caps BID)	Take with food for enhanced absorption (Do not take with antacids)	• Refrigerate capsules - may store at room temperature for up to 60 days	Diarrhea, Nausea, Headache, Abnormal stools
Ritonavir Norvir® (RTV)	• RTV 600mg BID • (may start with 300mg BID and increase by 100mg every 2 or 3 days)	• 100mg capsule • 80mg/mL oral solution	• RTV 400mg + SQV 400mg BID • Numerous other combinations use Ritonavir for pharmacokinetic enhancement	Take with food for enhanced absorption (Do not take with antacids)	• Refrigerate capsules - may store at room temperature for up to 30 days • DO NOT refrigerate oral solution (may crystallize)	Nausea, Vomiting, Numbness around the mouth, Altered taste
Saquinavir Fortovase® (SQV-SGC)	• SQV-SGC 1200mg TID • SQV-SGC 1000mg BID + RTV 100mg BID	• 200mg <u>soft</u> gel capsule	• SQV 1600mg BID • SQV 400mg + RTV 400mg BID	Take with food for enhanced absorption (Do not take with antacids)	• Refrigerate capsules - may store at room temperature for up to 90 days	Diarrhea, Nausea, Headache, Altered liver function
Invirase® (SQV-HGC)	• SQV-HGC 1000mg BID + RTV 100mg BID	• 200mg <u>hard</u> gel capsule			• Do not use Invirase without RTV • Store at room temperature	
Nelfinavir Viracept® (NFV or NLF)	• NFV 1250mg BID • NFV 750mg TID	• 250mg tablet • Pediatric powder available, 50mg/scoop		Take with food for enhanced absorption	• Important to provide <u>antidiarrheal</u> agent	Diarrhea, Nausea, Vomiting, Abdominal pain
Fusion Inhibitor						
Enfuvirtide Fuzeon® (ENF/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			• 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, Nodule Other: Diarrhea, Nausea, Vomiting, Fatigue, Insomnia