R	Renal Dose Adjustments <sup>1</sup>	
NRTIs		
didanosine	≥ 60 kg:  CrCl 30-59: (buffered) 100 mg bid or 200 mg qd, (EC) 200 mg qd;  CrCl 10-29: (buffered) 150 mg qd, (EC) 125 mg qd;  CrCl < 10, HD² or CAPD: (buffered) 100 mg qd, (EC) 125 mg qd < 60 kg:  CrCl 30-59: (buffered) 75 mg bid or 150 mg qd, (EC) 125 mg qd;  CrCl 30-59: (buffered) 100 mg qd, (EC) 125 mg qd;  CrCl 10-29: (buffered) 100 mg qd, (EC) 125 mg qd;  CrCl < 10, HD² or CAPD: (buffered) 75 mg qd	
emtricitabine	CrCl 30-49: 200 mg cap q48h or 120 mg soln. q24h; CrCl 15-29: 200 mg cap q72h or 80 mg soln. q24h; CrCl < 15 or HD <sup>2</sup> : 200 mg cap q96h or 60 mg soln. q24h	
lamivudine	CrCl 30-49: 150 mg qd; CrCl 15-29: 150 mg x 1 then 100 mg qd; CrCl 5-14: 150 mg x 1 then 50 mg qd; CrCl < 5 or HD <sup>2</sup> : 50 mg x 1 then 25 mg qd	
stavudine	$\geq 60$ kg: CrCl 26-50: 20 mg q12h, CrCl $\leq$ 25 or HD²: 20 mg q24h; < 60 kg: CrCl 26-50: 15 mg q12h, CrCl $\leq$ 25 or HD²: 15 mg q24h	
tenofovir	CrCl 30-49: 300 mg q48h; CrCl 10-29: 300 mg twice weekly; CrCl < 10 or HD <sup>2</sup> : 300 mg qweek	
tenofovir + emtricitabine (Truvada <sup>®</sup> )	CrCl 30-49 one tab q48h; CrCl < 30 combo product cannot be used; see dosing for individual agents	
zidovudine	CrCl < 15 or HD <sup>2</sup> : 100 mg TID	

- 1. There are no renal dose adjustment recommendations for ABC, Pls. NNRTIs, and T-20
- 2 Dose after HD on HD days

#### **Creatinine Clearance Calculation:**

CrCl = (140-age) x (IBW in kg) x (0.85 if female) Serum Cr x 72

#### Estimate Ideal Body Weight (IBW) in kg:

IBW = (50 kg of or 45.5 kg Q) + 2.3 kg for each in. > 5 ft. Note: If Actual Body Wt. (ABW) is < IBW, use ABW for calculation

## Dual NRTI, Boosted PI, Dual PI, PI/NRTI, DI/NINDTI Combination Dage Adjustments

PI/NNRTI Combination Dose Adjustments				
Combination	Adjustment			
didanosine + tenofovir 1	≥ 60 kg: ↓ ddl dose to 250 mg qd < 60 kg: ↓ ddl dose to 200 mg qd			
atazanavir + ritonavir	ATV 300 mg qd + RTV 100 mg qd (Pl-exp or naïve)			
atazanavir + tenofovir	ATV 300 mg qd + RTV 100 mg qd + TDF 300 mg qd			
atazanavir + efavirenz	ATV 300 mg qd + RTV 100 mg qd + EFV 600 mg qd			
fosamprenavir + efavirenz	f-APV 700 mg bid + RTV 100 mg bid + EFV 600 mg qd			
fosamprenavir + ritonavir	fos-APV 1400 mg qd + RTV 200 mg qd (PI-naïve) <sup>2</sup> fos-APV 700 mg bid + RTV 100 mg bid (PI-naïve or exp)			
indinavir + ritonavir	IDV 800 mg bid + RTV 100 - 200 mg bid			
indinavir + efavirenz or nevirapine	IDV 1000 mg q8h (or IDV 800 mg bid + RTV 100-200 mg bid) with EFV or NVP standard dose			
lopinavir/ritonavir + efavirenz or nevirapine	KAL dose to 3 tabs bid with EFV or NVP standard dose			
saquinavir + ritonavir 3	SQV 1000 mg bid + RTV 100 mg bid			
saquinavir + lopinavir/ritonavir <sup>3</sup>	SQV 1000 mg bid + KAL 2 tabs bid			

- 1. CAUTION: early failure seen with combination of TDF + ddl when used with NVP or EFV
- 2. fosamprenavir + ritonavir qd regimen should not be used in PI-exp patients
- Invirase<sup>®</sup> should only be used in combination with ritonavir or Kaletra<sup>®</sup>

H	Hepatic Dose Adjustments <sup>1</sup>	
NRTIs		
abacavir 2	Mild (Child-Pugh 5-6): 200 mg bid; Moderate/Severe: Contraindicated	
zidovudine	No dose adjustment recommended, monitor for toxicity	
NNRTIs		
delavirdine or efavirenz	Use with caution-no recommendation	
nevirapine	Avoid use with moderate to severe hepatic impairment	
Pis		
amprenavir	Child-Pugh 5-8: 450 mg bid; Child-Pugh 9-12: 300 mg bid	
atazanavir	Child-Pugh Class B: 300 mg qd; Class C: not recommended	
fosamprenavir	Child-Pugh 5-8: 700 mg bid; Child-Pugh 9-12: Not recommended. Ritonavir boosting not advised with hepatic disease	
indinavir	Mild to moderate insufficiency with cirrhosis: 600 mg q8h; no data in severe hepatic impairment	
lopinavir/ ritonavir	Use with caution; no dosing information available	
nelfinavir	Use with caution; no dosing information available	
ritonavir	No adjustment for mild impairment; no data for moderate/severe impairment-use with caution	
saquinavir	Use with caution; no dosing information available	
tipranavir	Use with caution. Contraindicated with moderate/severe impairment (Child-Pugh Class B & C)	

- 1. There are no hepatic dose adjustment recommendations for other NRTIs and T-20
- 2. http://us.gsk.com/products/assets/us ziagen tablets.pdf

Child-Pugh Score (add scores for each category to determine class)

Score	1	2	3
Encephalopathy*	None	Grade 1-2	Grade 3-4
Ascites	None	Mild or controlled by diuretics	Moderate or refractory to diuretics
Albumin	> 3.5 g/dL	2.8-3.5 g/dL	< 2.8 g/dL
Total Bilirubin or	< 2 mg/dL	2-3 mg/dL	> 3 mg/dL
Modified Total Bilirubin**	< 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 1: mild confusion, anxiety, restlessness, fine tremor, slowed coordination; Grade 2: drowsiness, disorientation, asterixis; Grade 3: somnolent but rousable, marked confusion, incomprehensible speech, incontinent, hyperventilation; Grade 4: coma, decerebrate posturing,

\*\*Modified Total Bilirubin used to score patients with Gilbert's Syndrome or taking IDV or ATV Class A: Score 5-6: Class B: Score 7-9: Class C: Score > 9

## **ARV Components Not Recommended** as Part of Initial Therany

as rait of illitial filerapy				
Agent(s)	Comments			
ddC + AZT	Inferior efficacy; higher rates of adverse effects			
TDF + ddl + NNRTI	High rate of early virologic failure and rapid development of resistance			
delavirdine	Inferior efficacy; inconvenient dosing			
amprenavir (boosted or unboosted)	High pill burden			
indinavir (unboosted)	Inconvenient dosing; meal restrictions			
ritonavir as sole PI	High pill burden; GI intolerance			
tipranavir/ritonavir	Lack of data in treatment-naïve patients			
enfuvirtide (T-20)	Lack of data in treatment-naïve patients; requires bid injections			

## Please visit our website at www.FAETC.org

## **Antiretroviral Regimens or Components Not Recommended at Any Time**

**Comments** 

Zidovudine monotherapy may be considered

Regimens

Monotherapy	Zidovudine monotherapy may be considered for use in pregnant women to prevent perinatal transmission if pre-treatment VL < 1000 copies/mL; combination therapy preferred		
Two-agent drug combinations	Rapid development of resistance. Inferior to 3 or more drugs. If virologic goals are achieved, some clinicians may choose to continue		
ABC + TDF + 3TC (or FTC)	High rate of early virologic non-response seen in ARV-naïve patients		
TDF + ddl + 3TC (or FTC)	High rate of early virologic non-response seen in ARV-naïve patients		
d4T + AZT	Both thymidine analogs; antagonistic		
ddC + d4T	Additive peripheral neuropathy		
ddC + ddl	Additive peripheral neuropathy		
ddC + 3TC	In vitro antagonism		
d4T + ddl	Increased risk of toxicities such as lactic acidosis and pancreatitis; May be considered when no other options available and potential benefits outweigh the risks. Reports of fatalities when used in pregnancy		
FTC + 3TC	Similar resistance profile; no potential benefit		
amprenavir oral solution	Contains large amounts of propylene glycol; contraindicated in pregnancy, children < 4 years old, renal or hepatic failure, and those taking metronidazole, disulfiram, or ritonavir oral solution		
amprenavir oral solution + ritonavir oral solution	Should not be combined due to propylene glycol content of amprenavir solution/alcohol content of ritonavir solution		
amprenavir + fosamprenavir	Amprenavir is active component of both drugs; no benefit in combination		
atazanavir + indinavir	Potential for additive hyperbilirubinemia		
saquinavir hard gel capsule or tablet (Invirase®) as single PI	Must be combined with other PIs such as ritonavir or lopinavir/ritonavir due to poor bioavailability		
efavirenz in 1st trimester of pregnancy or in women with pregnancy potential	Teratogenic - consider use only when no other options available and potential benefits outweigh risks		
nevirapine initiation in women with CD4 > 250 or in men with CD4 > 400	Higher incidence of symptomatic hepatic events; use only if potential benefits outweigh risks		



Produced by the Florida/Caribbean AIDS Education and Training Center

Special thanks to the NCCC for their editorial contributions



# Antiretroviral **Therapy** in Adults and **Adolescents**

## February 2006

Content Editors:

Jeffrey Beal, MD

Managing Editor: Layout:

Kim Alfonso, MAcc Michael Ikeya

Joanne J. Orrick, PharmD, BCPS

Paid for in part by DHHS-HAB Grant No. 6 H4A HA 00049-04-01

Unless otherwise noted, tables and information adapted from Department of Health and Human Services. Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents October 6, 2005. www.aidsinfo.nih.gov

## **Antiretroviral Regimens Recommended for Treatment of HIV-1 in Antiretroviral Naïve Patients**

## NNRTI - Based Regimens Preferred efavirenz<sup>1</sup> + (3TC<sup>2</sup> or FTC<sup>3</sup>) + (AZT<sup>2</sup> or TDF<sup>3</sup>) efavirenz<sup>1</sup> + (3TC<sup>4</sup> or FTC) + (ddl or ABC<sup>4</sup> or d4T<sup>5</sup>)

nevirapine<sup>6</sup> +  $(3TC^{2,4} \text{ or } FTC^3)$  +  $(AZT^2 \text{ or } d4T^5 \text{ or } ddl \text{ or } ABC^4 \text{ or } TDF^3$ PI - Based Regimens Preferred Iopinavir/ritonavir + (3TC<sup>2</sup> or FTC) + AZT<sup>2</sup> atazanavir<sup>7</sup> + (3TC<sup>2,4</sup> or FTC<sup>3</sup>) + (AZT<sup>2</sup> or d4T<sup>5</sup> or ABC<sup>4</sup> or ddl or Alternative TDF<sup>3,7</sup>) osamprenavir ± ritonavir<sup>8</sup> + (3TC<sup>2,4</sup> or FTC<sup>3</sup>) + (AZT<sup>2</sup> or d4T<sup>5</sup> or ABC4 or ddl or TDF3) indinavir + ritonavir8 + (3TC2,4 or FTC3) + (AZT2 or d4T5 or ABC4 or ddl or TDF3) lopinavir/ritonavir + (3TC<sup>4</sup> or FTC<sup>3</sup>) + (d4T<sup>5</sup> or ABC<sup>4</sup> or ddl or TDF<sup>3</sup>)

nelfinavir + (3TC<sup>2,4</sup> or FTC<sup>3</sup>) + (AZT<sup>2</sup> or d4T<sup>5</sup> or ABC<sup>4</sup> or ddI or TDF<sup>3</sup>

saguinavir (HGC or tablets) + ritonavir<sup>8</sup> + (3TC<sup>2,4</sup> or FTC<sup>3</sup>) + (AZT<sup>2</sup> or d4T<sup>5</sup> or ABC<sup>4</sup> or ddI or TDF<sup>3</sup>)

#### Triple NRTI Regimen - Only when an NNRTI- or PI-based regimen cannot or should not be used as first line therapy

Alternative ABC + 3TC + AZT9

- 1. Except for women in first trimester of pregnancy or women with high pregnancy potential due to teratogenic possibility
- 2. Lamivudine (3TC) + Zidovudine (AZT) available in combination as Combivir
- 3. Emtricitabine (FTC) + Tenofovir (TDF) available in combination as Truvada®
- 4. Abacavir (ABC) + Lamivudine (3TC) available in combination as Epzicom®
- 5. Higher incidence of lipoatrophy, hyperlipidemia, and mitochondrial toxicities with stavudine (d4T)
- 6. Note: Higher incidence of hepatotoxicity in women with pre-nevirapine CD4+ cell counts > 250 cells/mm3 and in men with pre-nevirapine CD4+ cell counts > 400 cells/mm3
- 7. Boosted atazanavir regimen (300 mg qd + ritonavir 100 mg qd) recommended with tenofovir (TDF) or in PI-experienced patients
- 8. See Combination Table for dose recommendations
- 9. Abacavir (ABC) + Lamivudine (3TC) + Zidovudine (AZT) available in combination as Trizivir®

## Warmline:

National HIV Telephone Consultation Services

1-800-933-3413

**PEPline:**National Clinicians' Post-Exposure Prophylaxis Hotline 1-888-HIV-4911 (448-4911)

> **Perinatal Hotline** 1-888-448-8765

## **NUCLEOSIDE/NUCLEOTIDE REVERSE** TRANSCRIPTASE INHIBITORS (NRTIs)

Class adverse effects: Lactic acidosis with hepatic steatosis

Abacavir (Ziagen®, ABC)

Dosage form: 300 mg tab. 20 mg/mL solution Adult dose: 300 mg po bid or 600 mg po qd

**Patient Counseling Points:** 

Alcohol ↑ ABC levels 41%; potential for adverse effects

 AEs: Hypersensitivity reaction occurs in 2-9% of patients, characterized by a sign or symptom from 2 or more of the following groups: G1: fever; G2: rash; G3: nausea, vomiting, diarrhea, or abdominal pain; G4: malaise, fatigue, or achiness; G5: dyspnea, cough, or pharyngitis. Onset is usually in 1st 4-6 weeks

Discontinue drug promptly and DO NOT RECHALLENGE!

Didanosine (Videx®, Videx EC®, ddl) ® R G

25, 50, 100, 150, 200 mg Videx® buffered tab Dosage form:

(no longer available in U.S.)

Pediatric powder for oral solution 10 mg/mL (2g or 4g bottle)

125, 200, 250, 400 mg cap (Videx EC®, generic

available)

Adult dose:  $\geq$  60 kg: 200 mg po bid or 400 mg po gd < 60 kg: 125 mg po bid or 250 mg po qd

Dose with tenofovir: ≥ 60 kg: ↓ ddl dose to 250 mg gd < 60 kg: ↓ ddl dose to 200 mg gd

## **Patient Counseling Points:**

• Must chew tabs or dissolve in non-acidic liquid (Videx® only)

 Take on empty stomach. 30 min ac or 2 hr pc (Videx® and Videx EC®) - except when given with tenofovir-can be with or without food

Drug interactions with non-enteric coated formulation due to buffer

Swallow Videx EC<sup>®</sup> capsules whole: do not crush, chew or break open

 AEs: peripheral neuropathy, pancreatitis, diarrhea (less with Videx EC®) nausea

Emtricitabine (Emtriva®, FTC) (N) (R)

200 mg cap, 10mg/mL oral solution Dosage form:

200 mg cap or 240 mg (24mL) solution po qd Adult dose: Patient Counseling Points:

 AEs: Generally well-tolerated, hyperpigmentation of palms/soles seen in up to 6% of patients (more common in Black and Hispanic patients)

 Solution should be refrigerated or used within 3 mos. if stored at room temperature

Lamivudine (Epivir®, 3TC) (N) (R)

Dosage form: 150 mg tab. 300 mg tab. 10 mg/mL solution Adult dose: 150 ma po bid or 300 ma po ad

**Patient Counseling Points:** 

· AEs: Generally well-tolerated

Stavudine (Zerit®, d4T) N R Dosage form: 15, 20, 30, 40 mg caps, 1 mg/mL solution

Adult dose:  $\geq$  60 kg: 40 mg po bid < 60 kg: 30 mg po bid

### **Patient Counseling Points:**

· AEs: peripheral neuropathy, pancreatitis (especially with didanosine), lipoatrophy, hyperlipidemia, rapidly progressing ascending neuromuscular weakness

· Refrigerate solution and shake well

## Tenofovir (Viread®, TDF) RG A nucleotide reverse transcriptase inhibitor

Dosage form: 300 mg tab 300 mg po qd Adult dose:

Patient Counseling Points:

Interacts with ddl and ATV (see combo table for dosing)

· AEs: nausea, vomiting, diarrhea, flatulence, renal insufficiency, Fanconi Syndrome, hypophosphatemia, asthenia, headache

**NRTIs (Continued)** Zidovudine (Retrovir®, AZT, ZDV) 🔊 🔊 🤻

**Patient Counseling Points:** 

neutropenia, myopathy

**Combination Products:** 

Combivir® (N) (R)

Epzicom® N N R

Each tablet contains:

Trizivir® N R

Each tablet contains:

Truvada® N R

Each tablet contains:

Each tablet contains:

Dosage form:

Adult dose:

Adult dose:

Adult dose:

Adult dose:

Adult dose:

Dosage form:

Dosage form:

Dosage form:

Adult dose:

Adult dose:

Patient Counseling Points:

degree AV block can occur

Patient Counseling Points:

**Patient Counseling Points:** 

low fat/protein snack

OK with Videx EC®)

Renal Adjustment

Adult dose:

300 mg tab, 100 mg cap, 10 mg/mL syrup,

10mg/mL IV soln.

cord clamping

300 mg po bid, 200 mg po tid

1 tablet po bid

1 tablet po qd

1 tablet po bid

These combo products should not be used if CrCl is < 50 mL/min.

1 tablet po qd

Class adverse effects: Hyperglycemia, hyperlipidemia (except

bleeding episodes in hemophiliacs. All undergo hepatic

Atazanavir (Reyataz®, ATV) \( \bigcit{\text{L} \text{C} \text{OC}} \\ \text{Note} \end{array}

hours), and proton pump inhibitors (do not use together)

alternate/additional form of contraception

OCs 
 ↓ Fos-APV levels; do not coadminister

Indinavir (Crixivan®, IDV) 🔊 🖫 🕞

• IDV + RTV can be taken with meals

· AEs: nephrolithiasis, hyperbilirubinemia

· Store in original container with desiccant

Must be boosted when used with TDF

¹ Use OC with lower estrogen dose; RTV boosted ↓ OC, use

metabolism mostly by CYP3A4 - Many drug interactions!

atazanavir), lipodystrophy, increased transaminases, increased

• Interacts with antacids (separate by 2 hrs), H-2 blockers (separate by 12

· AEs: Increases unconjugated bilirubin levels (common), jaundice or

scleral icterus (less common), does not adversely affect lipid profile

Fosamprenavir (Lexiva®, fos-APV-prodrug of amprenavir)

AEs: Skin rash (19%), nausea, vomiting, diarrhea, caution with sulfa allergy

• Drink 48 ounces (6 eight oz glasses) of fluid each day (water preferred)

100, 200, 333, 400 mg cap

700 mg tab

(even with low-dose ritonavir), prolonged PR interval, asymptomatic 1st

\* See individual components on Renal Dose Adjustment Table

**PROTEASE INHIBITORS (PIs)** 

Intrapartum dose: 2 mg/kg IV over 1 hour followed by 1 mg/kg/hr IV until

· AEs: headache, nausea, hyperpigmentation of the skin and nails, anemia,

300 mg AZT + 150 mg 3TC

300 mg 3TC + 600 mg ABC

200 mg FTC + 300 mg TDF

100 mg, 150 mg, 200 mg cap

400 mg po qd (PI-naïve only), often boosted

with ritonavir, see combo table for dosing

1400 mg bid (PI-naïve), often boosted

with ritonavir, see combo table for dosing

800 mg po g8h, rarely used unboosted, see

combo table for dosing with ritonavir

300 mg AZT + 150 mg 3TC + 300 mg ABC

\_ Hepatic Adjustment

· Take on empty stomach; 1 hr ac or 2 hr pc. Can be taken with

Combination, Dual, or **Boosted Adjustment** (See table other side)

(N) (N) [H] (G) [DC

↑ Combination Oral

Combination Oral Contraceptive Level: Use alternate/additional

Do not coadminister OC with Combination Oral Contraceptive

800/200 mg 4 tabs, 6 caps or 10 mL po qd (PI-naïve)

nevirapiné, efavirenz, amprenavir, fosamprenavir,

## NON-NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITORS (NNRTIs)

## Delavirdine (Rescriptor®, DLV) N C TOC

Dosage form: 100, 200 mg tab Adult dose:

(DLV bid dose not FDA-approved)

### Patient Counseling Points:

· AEs: rash - mild to severe, usually within 1st six weeks. D/C drug if severe rash (with blistering, desquamation, muscle involvement or

 Tablets must be swallowed whole and cannot be chewed, broken, or crushed

Tablets can be taken without food, solution and caps should be taken with

· Oral solution contains 42% alcohol

· Take ddl 1.5 hr apart from LPV

Patient Counseling Points:

Pls (Continued)

Dosage form:

Adult dose:

· AEs: GI intolerance (nausea, vomiting, diarrhea), asthenia

Lopinavir/Ritonavir (Kaletra®, KAL) 🖫 😉 💵

or nelfinavir

200/50 mg tab

133.3/33/3 mg cap

400/100 mg per 5 mL solution

400/100 mg 2 tabs, 3 caps or 5 mL po bid

Once daily dosing should not be used with

In treatment experienced patients where decreased susceptibility to lopinavir is clinically

suspected. 3 tabs po bid may be considered

Refrigerate solution or store at room temp (up to 77°) for up to 60 days

Tablets do not require refrigeration; caps OK at room temp up to 60 days

• Store in original container: exposure to high humidity for > 2 weeks is not recommended

## Nelfinavir (Viracept®, NFV) NFC LOC

Dosage form: 250 mg tab, 625 mg tab, 50 mg/scoop powder 750 mg po tid, 1250 mg po bid Adult dose:

Patient Counseling Points:

· AEs: diarrhea (can use OTC loperamide to treat diarrhea; calcium carbonate 1-2 tabs with each dose may lessen diarrhea)

## Ritonavir (Norvir®, RTV) 🔊 🖫 🕒 🗤 С

Dosage form: 100 mg cap, 600 mg / 7.5 mL solution Adult dose: Rarely used as sole PI-mainly used in minidoses to boost other PIs

### Patient Counseling Points:

Take with food (may not be required with all PI/RTV combinations)

Take ddl 2 hr apart from RTV

· Oral solution contains 43% alcohol

· AEs: Gl intolerance (nausea, vomiting, diarrhea), asthenia, taste disturbances, paresthesias, pancreatitis-adverse effects less common/severe when used in low doses with other PIs (i.e. boosting)

 Refrigerate caps, may be stored at room temp. (up to 77°) for up to 30 days

## Saguinavir (Invirase®-HGC or tab, SQV) The HGC LOC

Dosage form: 200 mg cap or 500 mg tab (Invirase®) Unboosted SQV not recommended; Adult dose: SQV 1,000 mg + RTV 100 mg bid

**Patient Counseling Points:** 

 Grapefruit juice ↑ SQV level, Garlic supplements ↓ SQV level (potential) interaction with all PIs/NNRTIs)

AEs: Gl intolerance (nausea, diarrhea, abdominal pain, dyspepsia)

## Tipranavir (Aptivus®, TPV) 🔊 💾 🗤 🗀

Dosage Form: 250 mg capsule

Adult Dose: 500 mg po bid with ritonavir 200 mg po bid

#### Patient Counseling Points: · High fat meal preferred

 Antacids may decrease TPV/RTV absorption (25-29%), consider separating dosing

 AEs: Hepatotoxicity-monitor LFTs closely; See Hepatic Dose Adjustment table: Rash-8-14% of patients (may be more common in women taking estrogen-containing medications), diarrhea, nausea, vomiting, caution with sulfa allergy

Keep in refrigerator or store at room temperature for up to 60 days

400 mg po tid or 600 mg po bid

· Separate antacids and bufferred ddl (Videx®) by approx 1 hour

Potential for ↑ in ethinyl estradiol levels; clinical significance unknown

fever), ↑ transaminases, headaches

## Efavirenz (Sustiva®, EFV) N N C 100

50, 100, 200 mg cap, 600 mg tab Dosage form: Adult dose: 600 mg po gd at bedtime

#### Patient counseling points:

Capsules: empty stomach advised, avoid high fat meal

Take at bedtime and without food to lessen CNS side effects

 Teratogenic-use with caution in women of child-bearing potential Interacts with OCs-OC levels increased but since EFV is terotegenic,

an alternate/additional form of contraception is recommended. AEs: CNS - drowsinesss, dizziness, insomnia, abnormal dreaming. agitation, hallucinations. Begins 1st or 2nd day and generally resolves in 2-4 weeks: Rash - usually mild to moderate, onset usually 1-2 weeks. D/C if severe rash (with blistering, desquamation, muscle involvement or fever). ↑ transaminases, false positive cannabinoid test

## Nevirapine (Viramune®, NVP) Nevirapine (Viramune®, NVP)



200 mg tab, 10 mg/mL suspension Dosage form: Adult dose: 200 mg po qd x 14d, then (200 mg po bid OR 400 mg po gd) NVP gd dose not

FDA-approved

## **Patient Counseling Points:**

· AEs: rash - mild to severe, usually within 1st six weeks. D/C drug if severe rash (with blistering, desquamation, muscle involvement or fever), ↑ transaminases, hepatitis (Monitor LFTs at baseline. 2 wks. then q4wks for first 3 months, then q3months). Hepatotoxicity is often rash-associated. Check LFTs in any patient presenting with rash on nevirapine. Women with CD4+ cell counts > 250, men with CD4+ cell counts > 400, and pts with Hep B or C co-infection are at greater risk for hepatic events with nevirapine

## **FUSION INHIBITOR**

## Enfuvirtide (Fuzeon®, T-20)

Dosage form: Powder for SC injection, mix with 1.1 mL of

sterile water for injection for final concentration of 90 mg/mL

90 ma SC bid

### **Patient Counseling Points:**

Adult dose:

Must instruct patient on reconstitution and administration techniques

· Administer SC in upper arm, upper leg, or stomach (do not inject into naval area, scar tissue, bruise, mole, or area with injection site reaction)

· Rotate injection sites

· AEs: injection site reactions (usually mild to moderate, can be severe)itching, swelling, redness, pain or tenderness, induration, nodules and cysts; bacterial pneumonia occurred more frequently in T-20 treated patients; injection site infections (must be instructed on aseptic technique!); Hypersensitivity reactions (< 1%) - sxs. may include rash, fever, nausea, vomiting, chills, rigors, hypotension, or elevated transaminases; rechallenging is not recommended

· Reconstituted soln. should be refrigerated and used within 24 hours



To order additional copies, visit www.FAETC.org/Products or call (866) 352-2382

Funded in part by DHHS-HAB Grant No. 6 H4A HA 00049-04-01









Separate at least 1 hour from doses of ddl (Videx® only,





