

## Report Adverse Events and Pregnancy Exposures

- FDA MedWatch:**  
Report unusual or severe toxicity to antiretrovirals  
[www.fda.gov/Safety/MedWatch/HowToReport/default.htm](http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm)  
800-FDA-1088 (332-1088)
- Antiretroviral Pregnancy Registry:**  
A voluntary prospective, exposure-registration, observational study designed to collect and evaluate data on the outcomes of pregnancy exposures to antiretroviral products.  
Web: [www.apregistry.com](http://www.apregistry.com)  
Phone: 800-258-4263  
E-mail: [registries@kendle.com](mailto:registries@kendle.com)

**REMEMBER: Protect yourself. Report all exposures to employee health and/or your supervisor.**

To order additional copies or request an alternate format of this card:  
**866-352-2382**

The up-to-date PDF is available online:  
**[www.FCAETC.org/Treatment](http://www.FCAETC.org/Treatment)**

### ALSO AVAILABLE FOR ORDER AND DOWNLOAD:

- ARV Therapy in Adults & Adolescents**
- ARV Therapy in Pediatrics**
- Hepatitis C and HIV/AIDS**
- Opportunistic Infections (OIs) in HIV/AIDS**
- Oral Manifestations Associated with HIV/AIDS**
- Post-Exposure Prophylaxis (PEP) in Pediatrics/Adolescents**
- Treatment of STDs in HIV-Infected Patients**
- Treatment of Tuberculosis (TB) in HIV/AIDS**

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### SPECIAL THANKS TO:

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### National Clinicians' Post-Exposure Prophylaxis Hotline

**888-HIV-4911 (448-4911)**

Treatment Guideline Resources  
HIV CareLink Newsletter • HIV Updates  
Online Training Modules • Preceptorships  
F/C AETC - Project ECHO™ • Chart Reviews  
Annual Conference • Specialty Conferences  
Perinatal HIV Prevention Program  
Routine HIV Testing Program

**F/C AETC - Project ECHO™**  
**[www.FCAETC.org/ECHO](http://www.FCAETC.org/ECHO)**

**Clinical Consultation**  
**[www.FCAETC.org/Consultation](http://www.FCAETC.org/Consultation)**

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

**National HIV Telephone Consultation Service**  
**800-933-3413**

**National Perinatal HIV Consultation and Referral Service**  
**888-HIV-8765 (448-8765)**

**Perinatal HIV Prevention Community**  
**[www.USFCenter.org/Perinatal](http://www.USFCenter.org/Perinatal)**



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

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## Post-Exposure Prophylaxis (PEP) Pre-Exposure Prophylaxis (PrEP)

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This card summarizes the guidelines for the management of occupational and non-occupational exposures to HIV, hepatitis B, and hepatitis C, including recommendations for post-exposure prophylaxis (PEP). Pre-exposure prophylaxis (PrEP) for the prevention of HIV in men who have sex with men is also summarized. This card is intended to guide initial decisions about PEP/PrEP and should be used in conjunction with other guidance provided in the full reports. View the full reports at websites listed throughout card.

### Management of Occupational Exposures

Requires immediate reporting so health care worker (HCW) can be evaluated, tested, and provided with appropriate post-exposure prophylaxis if indicated.

- Treatment of Exposure Site**
  - Wash wounds and skin sites with soap and water
  - Flush mucous membranes with water
  - Use of antiseptics-not contraindicated but no evidence that it will further reduce risk of transmission. Avoid use of caustic agents (e.g. bleach)
- Evaluate Exposure - See inside of card**
- Start PEP if indicated**

### Management of Non-Occupational Exposures

- Evaluate Exposure - See inside of card**
- Start nPEP if indicated**
- If sexual exposure requires evaluation for STDs**
- Women at risk for unintended pregnancy should be offered emergency contraception**
- Refer as appropriate to counseling for risk-reduction, mental health, substance abuse, and domestic violence**
- Victims of sexual assault should be referred for additional evaluation and counseling [National Sexual Assault Online Hotline 1-800-656-HOPE (656-4673)]**

Clients should be counseled to initiate or resume preventive behaviors to prevent additional exposure and to prevent possible secondary transmission while receiving PEP or nPEP.

The information contained in this publication is intended for medical professionals. If a serious adverse event occurs please report the event to the FDA ([www.fda.gov/Safety/MedWatch/HowToReport/default.htm](http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm)), to help increase pt safety. 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 tx decisions for their pt.

## CDC Interim Guidance: Preexposure Prophylaxis for the Prevention of HIV Infection in Men Who Have Sex with Men

Centers for Disease Control and Prevention. (2011, January 28). Interim Guidance: Preexposure Prophylaxis for the Prevention of HIV Infection in Men Who Have Sex with Men. MMWR, 60(3), 60-92. Retrieved from [www.cdc.gov/mmwr/pdf/wk/mm6003.pdf](http://www.cdc.gov/mmwr/pdf/wk/mm6003.pdf)

### BEFORE INITIATING PrEP

Determine Eligibility

- Document negative HIV antibody test(s) immediately before starting PrEP medication
- Test for acute HIV infection if patient has symptoms consistent with acute HIV infection
- Confirm that patient is at substantial, ongoing, high risk for acquiring HIV infection
- Confirm that calculated creatinine clearance is  $\geq 60$  mL per minute (via Cockcroft-Gault formula)

Other Recommended Actions

- Screen for hepatitis B infection: vaccinate against hepatitis B if susceptible, or treat if active infection exists, regardless of decision about prescribing PrEP
- Screen and treat as needed for STIs

### BEGINNING PrEP MEDICATION REGIMEN

- Prescribe 1 tablet of Truvada® (300 mg TDF/200 mg FTC) daily<sup>1</sup>
- Prescribe no more than a 90-day supply, renewable after HIV testing confirms that patient is HIV-uninfected
- Consider using TDF/FTC for both treatment of active hepatitis B infection and HIV prevention
- Provide risk-reduction and PrEP medication adherence counseling and condoms

1. These recommendations do not reflect current Food and Drug Administration-approved labeling for TDF/FTC

### FOLLOW UP WHILE PrEP MEDICATION IS TAKEN

- Every 2-3 months, perform an HIV antibody test: document negative result
- Evaluate and support PrEP medication adherence at each follow-up visit, more often if inconsistent adherence is identified
- Every 2-3 months, assess risk behaviors and provide risk-reduction counseling and condoms. Assess STI symptoms and, if present, test and treat for STI as needed
- Every 6 months, test for STI even if patient is asymptomatic and treat as needed
- Three months after initiation, then yearly while on PrEP medication, check blood urea nitrogen and serum creatine

### ON DISCONTINUING PrEP

- Perform HIV test(s) to confirm whether HIV infection has occurred
- If HIV positive, order and document results of resistance testing and establish linkage to care
- If HIV negative, establish linkage to risk-reduction support services as indicated
- If active hepatitis B is diagnosed, consider appropriate medication for continued treatment

## Post-Exposure Prophylaxis for Hepatitis B Virus

Centers for Disease Control and Prevention. (2001, June 29). Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. MMWR, 50(RR-11), 1-53. Retrieved from [www.cdc.gov/mmwr/pdf/rr/rr5011.pdf](http://www.cdc.gov/mmwr/pdf/rr/rr5011.pdf)

### Management of Exposures to HBV

- Any blood or body fluid exposure to an unvaccinated person should lead to the initiation of the hepatitis B vaccine series
  - Recombivax HB® 10 mcg or Energix-B® 20 mcg IM at 0, 1, and 6 months
- When Hepatitis B Immune Globulin (HBIG) is indicated, it should be administered as soon as possible after the exposure (preferably within 24 hours, but is recommended up to 1 week following an occupational exposure)
  - Hepatitis B vaccine can be administered simultaneously with HBIG but at a separate site
- Test for Hepatitis B surface antibody (anti-HBs) 1-2 months after last dose of vaccine<sup>2</sup>

VACCINATION/AB RESPONSE OF WORKER	TREATMENT		
	Source HBsAg (+)	Source HBsAg (-)	Source unknown or not available for testing
Unvaccinated	HBIG (0.06 mL/kg IM) x 1 and vaccinate	Vaccinate	Vaccinate
Vaccinated-responder <sup>2</sup>	No PEP	No PEP	No PEP
Vaccinated-nonresponder	HBIG (0.06 mL/kg IM) x 1 and revaccinate or HBIG (0.06 mL/kg IM) x 2 (at time of exposure and 1 month after exposure)	No PEP	If known high risk treat as HBsAg (+)
Vaccinated-Ab response unknown	Test exposed person for anti-HBs 1. If adequate, no PEP necessary 2. If inadequate, administer HBIG x 1 and vaccine booster	No Treatment	Test exposed person for anti-HBs 1. If adequate, no PEP necessary 2. If inadequate, give vaccine booster and recheck titer in 1-2 months

2. Adequate anti-HBs > 10 mIU/mL (>0.99 index value)

## Post-Exposure Management for Hepatitis C Virus

Centers for Disease Control and Prevention. (2001, June 29). Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. MMWR, 50(RR-11), 1-53. Retrieved from [www.cdc.gov/mmwr/pdf/rr/rr5011.pdf](http://www.cdc.gov/mmwr/pdf/rr/rr5011.pdf)

### Management of Exposures to HCV

- Perform testing for anti-HCV for the source
- Perform baseline testing for anti-HCV and ALT activity for the exposed person
- Perform follow-up testing
  - Anti-HCV and ALT activity at 4-6 months or
  - HCV RNA by PCR at 4-6 weeks for earlier detection
- Confirm anti-HCV results reported positive by enzyme immunoassay with supplemental test [e.g. recombinant immunoblast assay (RIBA) or HCV RNA by PCR]

### Post-Exposure Management for HCV

- No regimens proven beneficial for PEP
- Early identification of chronic disease and referral for management
- Immediately refer HCW to hepatitis C specialist for management

Post-Exposure Prophylaxis (PEP) for both non-occupational and occupational exposures should be started **IMMEDIATELY** (ideally within 1-2 hours) after HIV exposure and continued for 28 days. PEP can be considered after 24-36 hours of the exposure with expert consultation. PEP is not recommended >72 hours after HIV exposure.

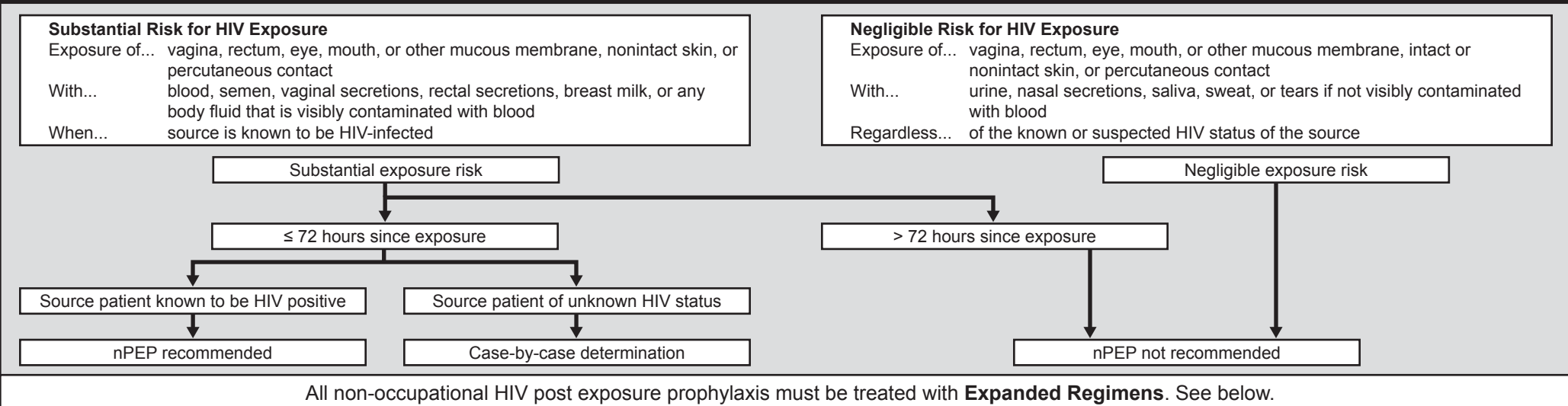
The National Clinicians' Post-Exposure Prophylaxis Hotline (PEpline) **888-448-4911** offers treating clinicians up-to-the-minute advice on managing occupational exposures (e.g. needlesticks, splashes, etc.) to HIV, hepatitis and other blood-borne pathogens. **PEpline clinicians will respond to your call 24 hours a day, 7 days a week.**

### Non-Occupational HIV Post-Exposure Prophylaxis (nPEP)

Centers for Disease Control and Prevention. (2005, January 1). Antiretroviral Postexposure Prophylaxis After Sexual, Injection-Drug Use, or Other Nonoccupational Exposure to HIV in the United States: Recommendations from the U.S. Department of Health and Human Services. MMWR, 54(No. RR-2). Retrieved from [www.aidsinfo.nih.gov/contentfiles/NonOccupationalExposureGL.pdf](http://www.aidsinfo.nih.gov/contentfiles/NonOccupationalExposureGL.pdf)

The guidelines recommend offering non-occupational post-exposure prophylaxis (nPEP) to persons presenting within 72 hours of unanticipated sexual or injection-drug use HIV exposure to prevent transmission. It is most cost-effective following highest risk exposures (e.g. when sex partner is known to be HIV-infected or after receptive anal intercourse with a homosexual or bisexual man of unknown serostatus). Guidelines emphasize the importance of providing counseling on risk-avoidance and risk-reduction to decrease future exposures to HIV. Exposed person should have a baseline HIV antibody test performed and repeat antibody testing at 4-6 weeks, 3 months, and 6 months. Testing for other sexually transmitted diseases, hepatitis B and C, and pregnancy should be offered. When given, nPEP should be continued for 28 days.

#### Algorithm for Evaluation and Treatment of Possible Non-occupational HIV Exposures



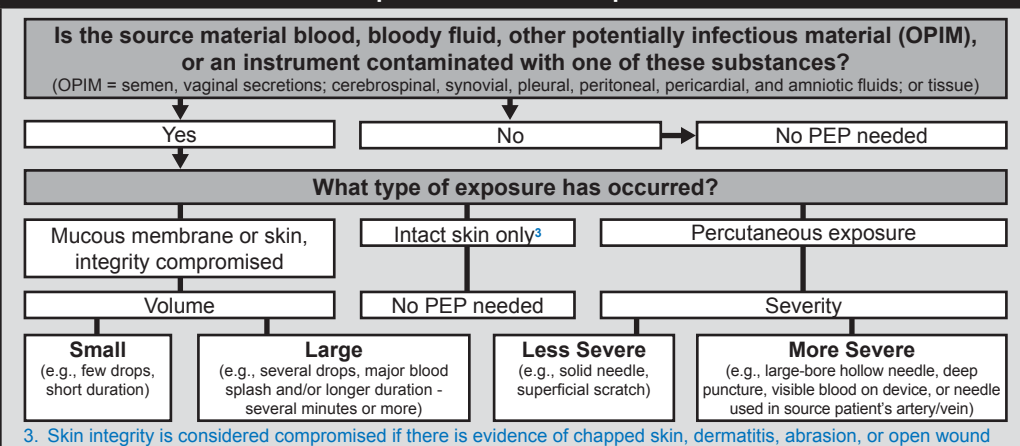
All non-occupational HIV post exposure prophylaxis must be treated with **Expanded Regimens**. See below.

### Occupational HIV Post-Exposure Prophylaxis (PEP)

Centers for Disease Control and Prevention. (2005, September 30). Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis. MMWR, 54(RR-9). Retrieved from [www.aidsinfo.nih.gov/contentfiles/HealthCareOccupExpoGL.pdf](http://www.aidsinfo.nih.gov/contentfiles/HealthCareOccupExpoGL.pdf)

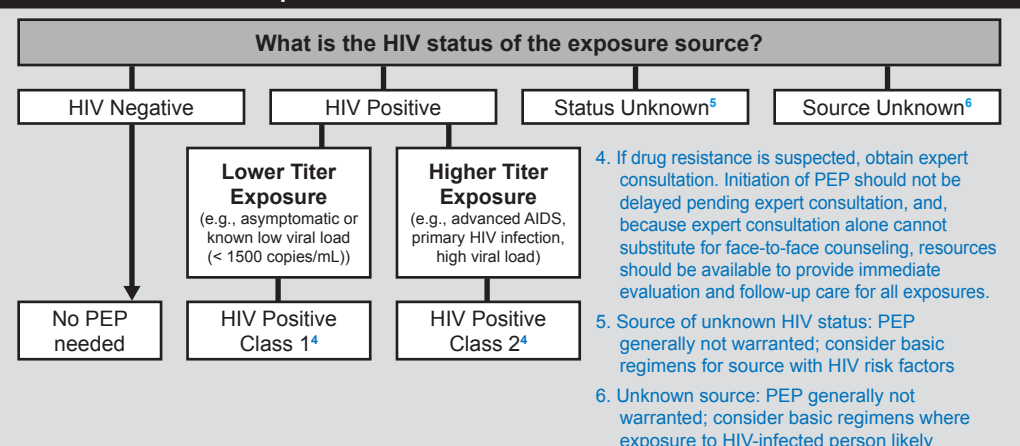
Consider exposure to hepatitis B or C in addition to HIV. Regardless of whether PEP given, test exposed health care provider for HIV using an antibody test at baseline, 6 weeks, 3 months, 6 months.

#### Step 1: Evaluation of Exposure



3. Skin integrity is considered compromised if there is evidence of chapped skin, dermatitis, abrasion, or open wound

#### Step 2: Determine the HIV Status of the Source



4. If drug resistance is suspected, obtain expert consultation. Initiation of PEP should not be delayed pending expert consultation, and, because expert consultation alone cannot substitute for face-to-face counseling, resources should be available to provide immediate evaluation and follow-up care for all exposures.  
5. Source of unknown HIV status: PEP generally not warranted; consider basic regimens for source with HIV risk factors  
6. Unknown source: PEP generally not warranted; consider basic regimens where exposure to HIV-infected person likely

#### Step 3: Determine the Post-Exposure Prophylaxis Recommendation

EXPOSURE TYPE	HIV POSITIVE CLASS 1	HIV POSITIVE CLASS 2
Percutaneous - Less Severe	Recommend Basic Regimen	Recommend Expanded Regimen
Percutaneous - More Severe	Recommend Expanded Regimen	Recommend Expanded Regimen
Mucous Membrane/Nonintact Skin - Small Volume	Consider Basic Regimen	Recommend Basic Regimen
Mucous Membrane/Nonintact Skin - Large Volume	Recommend Basic Regimen	Recommend Expanded Regimen

### Basic and Expanded Post-Exposure Prophylaxis Regimens (All regimens are for 28 days)

Given that new advances and data regarding antiretroviral therapy have occurred since the release of the 2005 U.S. Public Health Service Guidelines, below find the F/C AETC 2011 authors' recommendations for **Preferred Basic** and **Expanded Regimens** based upon review of current literature and clinical experience. Please see Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis, September 30, 2005, <http://www.cdc.gov/mmwr/pdf/rr/rr5409.pdf>, Management of Possible Sexual, Injection-Drug-Use, or Other Nonoccupational Exposure to HIV, Including Considerations Related to Antiretroviral Therapy - January 21, 2005 <http://www.cdc.gov/mmwr/PDF/rr/rr5402.pdf>, and Regimens for 28-day Postexposure Prophylaxis for HIV Infection, Landovitz RJ, Currier JS. New England Journal of Medicine. 2009, 361(18), 1768-75. [www.nejm.org/doi/full/10.1056/NEJMcp0904189](http://www.nejm.org/doi/full/10.1056/NEJMcp0904189) for further recommendations. Other considerations when choosing antiretroviral agents include pregnancy and exposure to virus known or suspected to be resistant to the antiretroviral drugs. Use of daily regimens may improve adherence to PEP.

REGIMENS	DOSAGE FORM	COMMENTS
<b>Preferred Basic Regimen</b>		
<b>NOTE: All non-occupational exposures and most occupational exposures require expanded regimen (See Below)</b>		
Tenofovir/Emtricitabine (300/200 mg): 1 tab once daily <b>OR</b>	Tenofovir (Viread®, TDF): 300 mg tab Emtricitabine (Emtriva®, FTC): 200 mg caps and 10 mg/mL oral soln Tenofovir/Emtricitabine (Truvada®, TDF/FTC): 300 mg TDF/200 mg FTC	Well tolerated, once daily dosing, nephrotoxicity potential, combo (Truvada®) should not be used if CrCl <30 mL/min. See TDF and FTC renal dosing <sup>5</sup> . See guidelines for dosing of FTC soln <sup>7</sup> .
Zidovudine/Lamivudine (300/150 mg): 1 tab twice a day	Zidovudine (Retrovir®, AZT,ZDV): 100 mg caps, 300 mg tabs, 10 mg/mL syrup Lamivudine (EpiVir®, 3TC): 150 mg or 300 mg tabs and 10 mg/mL oral soln Zidovudine/Lamivudine (Combivir®, AZT/3TC): 300 mg AZT/150 mg 3TC	Preferred in pregnancy, twice daily dosing, nausea/anemia/fatigue common, combo (Combivir®) should not be used if CrCl <50 mL/min. See AZT and 3TC renal dosing <sup>7</sup> .
<b>Preferred Expanded Regimen: Basic Regimen Plus One of the Following</b>		
Atazanavir 300 mg once daily <b>PLUS</b>	Atazanavir (Reyataz®, ATV): 300 mg cap	Well tolerated, ↑ bilirubin (common), possible asymptomatic jaundice (rare), renal stones (rare), ↑ liver enzymes. See dosing instructions with acid-reducing agents (i.e. PPIs, antacids, H-2 blockers <sup>7</sup> ).
Ritonavir 100 mg once daily	Ritonavir (Norvir®, RTV): 100 mg tabs, 100 mg caps, 80mg/mL oral soln	Generally well tolerated when used at this ↓ dose. Store tabs at room temp; refrigerate caps or store at room temp for ≤ 30 days. Do not refrigerate soln.
Darunavir 800 mg once daily <b>PLUS</b>	Darunavir (Prezista®, DRV): 400 mg, 600 mg tabs	Well tolerated, either once or twice daily dosing, high genetic barrier to resistance. May cause rash, GI side effects, hepatotoxicity, caution with sulfa allergy (not contraindicated).
Ritonavir 100 mg once daily	See Ritonavir above	See Ritonavir above
<b>OR alternative dosing (if daily dosing is not tolerated)</b>		
Darunavir 600 mg twice a day <b>PLUS</b>	See Darunavir above	See Darunavir above
Ritonavir 100 mg twice a day	See Ritonavir above	See Ritonavir above
Lopinavir/Ritonavir (200/50 mg): 4 tabs once daily	Lopinavir/Ritonavir (Kaltera®, KAL, LPV/r): LPV/r 200/50 mg tabs, LPV/r 100/25 mg tabs, LPV/r 400/100 mg per 5 mL oral soln	Preferred in pregnancy, either once or twice daily dosing, high genetic barrier to resistance. Commonly causes GI side effects.
<b>OR alternative dosing (if daily dosing is not tolerated)</b>		
Lopinavir/Ritonavir (200/50 mg): 2 tabs twice a day	See Lopinavir/Ritonavir above	See Lopinavir/Ritonavir above

7. Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents October 14, 2011, [www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf](http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf).