

Recommended antiretroviral chemoprophylaxis is for 3 antiretroviral agents for a total of 28 days (4 weeks). The starter pack in RGH & PH night cupboards consists of the follows: (Check expiry dates prior to use)

*Ensure the patient has sufficient supply of medications until the community pharmacy can fill the outpatient prescription. MUST call the Saskatchewan Drug Plan for EDS coverage - Ph: 787-3317 or 1-800-667-7581 (24-h message system) for all non-RQHR persons.*

Refer to HIV Post-Exposure Prophylaxis "PEP Kit" Patient Information enclosed with the PEP kits.

<http://rhdintranet/ps/public/ClinicalInformation/HIV/PEP-HIV%20Post-Exposure%20Prophylaxis%20Pt%20Info.pdf> (Note: It's the same medication as for adults except Combivir® is used instead of separate 3TC and AZT or ZDV products)

### Oral Pediatric Dosing Recommendations

(Note: q12h means every 12 hours, not twice daily; q8h must be every 8 hours, q6h = every 6 hours)

Antiretroviral for HIV Prophylaxis	Premature Infants	Term Infants - 12 years	>12 years - Adult
Lamivudine 10 mg/mL (3TC®) Oral Solution (Also available: 150 & 300mg tabs)	No data	< 1 month of age: 2 mg/kg/dose TWICE daily  >1 month of age: 4 mg/kg/dose TWICE daily (Max. 150 mg TWICE daily)	150 mg TWICE daily* <i>or,</i> If ≥16 years: 300mg ONCE daily
Zidovudine 10mg/mL Syrup (ZDV, AZT, RETROVIR®) (Also available: 100mg cap, 300mg tab, 100mg/20mL IV solution)	0-2 weeks of age: 2 mg/kg/dose <b>q12h</b>  >2weeks of age: ↑ to <b>q8h</b> for <i>gestational age ≥30 weeks, or at 4 weeks of age for neonates &lt;30 weeks gestational age</i>	<6 weeks of age: 2 mg/kg/dose <b>q6h</b>  6 weeks - 12 years: 180 - 240 mg/m <sup>2</sup> <b>q12h</b> (or, 160mg/m <sup>2</sup> q8h)	300 mg TWICE daily*  ( <i>or,</i> 200 mg THREE times/day)
Kaletra® (80mg Lopinavir + 20mg Ritonavir per mL) Oral Solution (LPV/RTV) (Also available: 200mg/50mg yellow hard tablet. NOTE: Orange soft gel capsule = 133.3mg LPV + 33.3mg RTV may also still be available)	Neonates/Term Infants <6 months of age ( <i>Investigational only</i> ): 300mg LPV/75mg RTV/m <sup>2</sup> TWICE daily  6 months - 12 years: See tables below (both mg/kg and mg/m <sup>2</sup> dosing)		

- *Instead of separate 3TC & ZDV products, may give Combivir® i tablet (= ZDV 300mg + 3TC 150mg) TWICE daily*

Any PRINTED version of this document is only accurate up to the date this document was developed. RQHR can not guarantee the currency or accuracy of any printed policy. RQHR accepts no responsibility for use of this material by any person or organization not associated with RQHR. No part of this document may be reproduced in any form for publication without permission of RQHR.

**Kaletra® Pediatric Dosing Guidelines By Weight (kg)** (Ref. e-CPS Kaletra® extracted September, 2007)

- Oral Solution (80mg lopinavir/20mg ritonavir per mL or 200mg/50mg yellow hard tablet)
- **CAUTION:** Orange soft gel capsule = 133.3mg/33.3mg may also still be available!

*\*Administer using a calibrated oral dosing syringe\**

Weight	Dose	Volume of Oral Solution <b>Twice Daily</b>
7 to 10 kg	12 mg/kg b.i.d.	1.25 mL b.i.d.
>10 to <15 kg		1.75 mL b.i.d.
15 to 20 kg	10 mg/kg b.i.d.	2.25 mL b.i.d.
>20 to 25 kg		2.75 mL b.i.d.
>25 to 30 kg		3.5 mL b.i.d.
>30 to 35 kg		4 mL b.i.d.
>35 to 40 kg		4.75 mL b.i.d.
>40 kg	Adult Dose	5 mL (or 2 tablets = 400mg/100mg) b.i.d.

**Kaletra® Pediatric Dosing Guidelines by meters<sup>2</sup>** (based on 230mg LPV/RTV 57.5 mg/m<sup>2</sup>)

Body Surface Area (m <sup>2</sup> ) <sup>a</sup>	Volume of lopinavir/ritonavir (80 mg/20 mg per mL) Oral Solution <b>Twice Daily</b>
0.25m <sup>2</sup>	0.7 mL (57.5/14.4 mg)
0.5	1.4 mL (115/28.8 mg)
0.75	2.2 mL (172.5/43.1 mg)
1	2.9 mL (230/57.5 mg)
1.25	3.6 mL (287.5/71.9 mg)
1.5	4.3 mL (345/86.3 mg)
1.75	5 mL (or 2 tablets = 400mg/100 mg)

$$BSA (m^2) = \sqrt{\frac{\text{Height (cm)} \times \text{Weight (kg)}}{3600}}$$

a.

Additional information below from: PEDIATRICS Vol. 111 No. 6 June 2003, pp. 1475-1489.

Webpage: <http://www.pediatrics.org/cgi/content/full/111/6/1475>

*Exposure to Human Immunodeficiency Virus Postexposure Prophylaxis in Children and Adolescents for Nonoccupational Exposure to Human Immunodeficiency Virus*

- Peter L. Havens and Committee on Pediatric AIDS

**NOTE:** Sept 2007 - *Since Health Canada warning re: nelfinavir (Viracept®), Kaletra® (Lopinavir/ritonavir) will be the protease inhibitor (PI) used instead.*

Any PRINTED version of this document is only accurate up to the date this document was developed. RQHR can not guarantee the currency or accuracy of any printed policy. RQHR accepts no responsibility for use of this material by any person or organization not associated with RQHR. No part of this document may be reproduced in any form for publication without permission of RQHR.

Although PEP may be considered in many circumstances, it is only recommended for high-risk exposures to persons known to be infected with HIV (Table 8). No PEP is given if the exposure occurred more than 72 hours previously, if the exposed person refuses PEP, or if the exposed person is unwilling or unable to commit to 28 days of therapy and appropriate follow-up (Table 7).

A careful discussion of the risks and benefits of therapy guides the decision-making regarding PEP and allows appropriate postexposure care (Table 9). If PEP is begun, it should be started as soon as possible after the exposure (within hours, and definitely within 72 hours), and therapy should be continued for 28 days. If consultation with a clinician experienced in the care of children and adolescents with HIV is not immediately possible, a supply of medications sufficient to last until consultation occurs could be dispensed to the patient.

### Sexual Exposure

Sexual exposure can result in HIV infection (Tables 3 and 4), and sexual abuse has resulted in HIV transmission to children. Of 9136 children with HIV infection or AIDS reported to the CDC from 1981 through 1997, 26 were sexually abused, with confirmed HIV exposure in 17 and suspected HIV exposure in 9.<sup>104</sup> Of the 17 children with confirmed HIV exposure, 14 had no other risk of HIV infection, and 3 had multiple risk factors. Sexual abuse may be more likely to result in HIV transmission in girls than in women because of thin vaginal epithelium in children and cervical ectopy in adolescents and because children may be repeatedly abused by the same person over a long period.<sup>24</sup> In proven cases of sexual assault by a person known or suspected to have HIV infection, PEP may be considered up to 72 hours after the exposure but is likely to be most effective if given sooner, preferably within a few hours after exposure.<sup>105-107</sup> If the exposure source has genital ulcer disease or another sexually transmitted disease or if the exposure included tissue damage, the risk of HIV transmission is greater (Tables 3 and 4), increasing the potential benefit of PEP relative to the burden of therapy and risks of drug toxicity. Such modifying factors might strengthen the force of the recommendation in a given clinical setting.

For adolescents with a history of a single sexual exposure, PEP can be considered, and if given should be started as soon as possible after the exposure but certainly within 72 hours.<sup>108,109</sup> Such exposure might occur from sexual abuse or by accidental exposure in a consensual relationship (eg, a broken condom). For persons with ongoing consensual sexual exposure to HIV, PEP is not indicated, and behavioral interventions to decrease repeated exposure probably are more appropriate.<sup>110,111</sup>

### Percutaneous Exposures

Risk of HIV transmission from a puncture wound from a needle found in the community is significantly lower than the 0.3% HIV transmission risk after needlestick injury in a health care professional from a person with HIV infection. Although it is unlikely that a true estimate of risk can be established, transmission will be related to:

- The probability that the person who used the needle has HIV infection (Table 5);
- The time interval since the needle was in contact with blood of the source;
- The initial concentration of HIV on the needle, presence of blood or tissue that might delay drying (and, therefore, killing of the virus), or the presence of fresh blood or material that might contain viable virus; and
- The severity of the injury (skin contact without skin breakage, abrasion without bleeding, deeper skin penetration) in the exposed individual.

In evaluating a puncture wound, the following factors are considered in assessing potential for HIV transmission (presented as lower risk category followed by higher risk category for each attribute): the depth of the wound (superficial scratch or deep puncture); the presence of blood on the needle (no visible blood or visible blood); the characteristics of the blood on the needle (dried or fresh); the type of needle (solid or hollow bore); and the location the needle was used in the source patient's body (not in artery or vein; or in artery or vein).

The risk of HIV transmission from a discarded needle in public places (often referred to as a "found" needle) seems to be low. Because data are not available on the efficacy of PEP in this circumstance for adults or children, the USPHS is unable to recommend for or against PEP in this circumstance. Furthermore, PEP is not without risk and often is associated with significant adverse effects. Therefore, PEP is not routinely recommended in this situation. However, if the needle and/or syringe are found to have visible blood and the source is known to be HIV infected, some experts recommend that PEP be considered. Testing the syringe for HIV is not practical or reliable and is not recommended.

Any PRINTED version of this document is only accurate up to the date this document was developed. RQHR can not guarantee the currency or accuracy of any printed policy. RQHR accepts no responsibility for use of this material by any person or organization not associated with RQHR. No part of this document may be reproduced in any form for publication without permission of RQHR.

Bite wounds are another percutaneous body fluid exposure that may occur in children, but the risk of HIV transmission after exposure to saliva is very low. In the absence of blood in saliva and blood in the bite wound, PEP is not indicated. However, if there is blood exchange from a bite, both the person bitten and the person biting should be considered at risk of transmission of HIV and considered for PEP. Use in this setting would be extremely unusual and is potentially indicated only when there is significant exposure to deep, bloody wounds in persons with HIV infection.

Adolescents may be percutaneously exposed to potentially infectious fluids by needle sharing for injection drug use (including anabolic steroids) or for body piercing. The per-contact probabilities of HIV transmission in Table 3 apply in this setting, and for a single percutaneous exposure to blood of a person at risk for or known to have HIV infection, PEP can be considered. For adolescents with ongoing needle sharing and potential exposure to HIV, PEP is not routinely recommended, and behavioral interventions to decrease repeated exposures are more appropriate than is postexposure drug therapy after a single episode.<sup>110,111</sup>

#### **Choice of Antiretroviral Medications for PEP**

No clinical studies are available to determine the best antiretroviral regimen for PEP. The most extensive data in terms of potential efficacy and safety are for ZDV monotherapy.<sup>4,81</sup> A clinician with experience in treatment of persons with HIV infection should be consulted before starting PEP.

Many clinicians would use the 3-drug combination of ZDV, lamivudine, and nelfinavir for PEP in children and adolescents (doses in Table 10).<sup>116</sup> If the efficacy of PEP is in aborting early mucosal, submucosal, subcutaneous, or lymphatic HIV infection, then potent suppressive therapies, such as 2 NRTIs plus a PI, should be chosen, because such regimens have been shown to be more likely to suppress HIV replication than have monotherapy or dual therapy.

Taking the multiple medications required for PEP is a daunting task, and problems with drug toxicity (Table 11), patient adherence, and other factors severely limit the proportion of patients who finish PEP once they have started it.<sup>107,117-119</sup> Completing 28 days of a 2-drug regimen is easier than completing a 3-drug regimen and may be associated with fewer medication adverse effects. Although the burden and toxicity of a 3-drug regimen may be warranted for treatment of persons with established HIV infection, the risk-benefit ratio for PEP may favor a 2-drug regimen for some patients. Therefore, some clinicians recommend 2-drug combinations of ZDV and lamivudine for PEP, hoping that the improved ease of use and potential decrease in toxicity will balance out the theoretic decrease in efficacy. It may be reasonable to consider a 2-drug regimen for treatment of some patients. The effectiveness of a drug regimen in practice will be related to the efficacy of the drugs and the probability of completion of the course of therapy. ZDV and lamivudine are each available as syrups and are available together in a single tablet (Combivir [GlaxoSmithKline, London, United Kingdom]), enhancing ease of use for adolescents (doses in Table 10). If current and/or previous therapy used by the source patient is known and drug resistance is a concern, alternatives to the standard regimen might be considered in consultation with a specialist in HIV care in children and adolescents. Stavudine or didanosine are reasonable alternative NRTIs for use if resistance to ZDV or lamivudine is suspected. ZDV and stavudine should never be used in combination with one another because of intracellular antagonism. Because of the potential for a severe hypersensitivity reaction, the NRTI abacavir sulfate should be avoided in PEP regimens.

Any PRINTED version of this document is only accurate up to the date this document was developed. RQHR can not guarantee the currency or accuracy of any printed policy. RQHR accepts no responsibility for use of this material by any person or organization not associated with RQHR. No part of this document may be reproduced in any form for publication without permission of RQHR.