



Post Exposure Prophylaxis (PEP) Guidelines for children and adolescents potentially exposed to HIV

Our Lady's Children's Hospital, Crumlin

To the pharmacist or doctor dispensing these medicines:

- See **Guidelines for the Emergency Management of Injuries** available at <http://www.hpsc.ie/A-Z/EMIToolkit/EMIToolkit.pdf>
- **Before prescribing any medication it is essential to contact the OLCHC Infectious Diseases Consultant through the hospital switchboard.**
- If the consultant is not immediately available, the first dose of each antiretroviral should be given.
- Consult the Patient Information Leaflets provided with this pack before prescribing these medicines. Ensure that the parent/carer understands all the information in the leaflet before dispensing the medication.
- Prescribe antiemetic Ondansetron to take 30minutes before antiretroviral medicines if not contraindicated. See notes on antiemetics page 5 of this document

Table 1: Suggested PEP regimens (see dosing Table 2 below)

Age (years)	Preferred PEP	Alternative PEP	Notes
10+	Raltegravir (Isentress®) + Truvada® (emtricitabine 200mg / tenofovir disoproxil fumarate (TDF) 300mg NB if under 35KG, we would recommend age and weight appropriate dosing of raltegravir + TDF + Lamivudine	1. Raltegravir (Isentress®) + Lamivudine 150mg/ Zidovudine 300mg (Combivir®) combined tablet	As per adult guideline with an alternative for Tenofovir in those with renal insufficiency

Age (years)	Preferred PEP	Alternative PEP	Notes
6-9	Raltegravir (Isentress®) + Lamivudine (Epivir®) + Zidovudine (Retrovir®)	1. Kaletra® (lopinavir/Ritonavir) + Lamivudine (Epivir®) + Zidovudine (Retrovir®) 2. Raltegravir (Isentress®) or Kaletra® (Lopinavir/Ritonavir) + Tenofovir TDF (Viread®) + Lamivudine (Epivir®)	Adult dose of Raltegravir for children >25Kg. Note the chewable formulation of raltegravir is not bioequivalent to the tablets (See table of preparations available below)
2- <6	Raltegravir (Isentress®) + Lamivudine (Epivir®) + Zidovudine (Retrovir®)	1. Kaletra® (Lopinavir/Ritonavir) + Lamivudine (Epivir®) + Zidovudine (Retrovir®) 2. Raltegravir (Isentress®) or Kaletra® (Lopinavir/Ritonavir) + Tenofovir TDF + Lamivudine (Epivir®)	Use Raltegravir (Isentress® chewable tablets) when available
<2	Kaletra® (Lopinavir/Ritonavir) + Lamivudine (Epivir®) + Zidovudine (Retrovir®)		Liquid formulations

Notes:

1. Young people from 10 years of age and over 35Kg who are able to swallow tablets should receive PEP as for adults: Raltegravir 400mg (Isentress®) 1 tablet twice daily + Truvada® 1 tablet daily

2. Young people 10 years of age or older with renal insufficiency should not receive Tenofovir and should therefore be given : Raltegravir 400mg (Isentress®) 1 tablet twice daily + fixed dose combination of Lamivudine 150mg/Zidovudine 300mg (Combivir®) 1 tablet twice daily

3. Tenofovir TDF should be avoided in the context of renal impairment at any age if at all possible (seek expert advice)

4. Although Raltegravir is currently licensed in children younger than 6 years and weighing >11Kg, experience of use in children in this age group is limited. Kaletra® remains an alternative in children under 6 years of age with chewable Raltegravir as first line. (Seek expert advice).

Table 2: HIV PEP Drugs, Doses and Side Effects

Dosing is correct as per date of guideline publication but for updated dosing see CHIVA ART dosing table <http://www.chiva.org.uk/>

Generally, medicines are well tolerated with the exception of minor, initial gastrointestinal disturbance and possible headache.

Drug	Formulation	Dose	Potential Side Effects
Raltegravir (RAL) (Isentress®) Note: Formulations are not bioequivalent; use chewable tablets for children 11-25Kg and children >25Kg who cannot swallow tablets	Tablet: 400mg Chewable Tablet: 25mg, 100mg (can be chewed or swallowed)	Tablet: From 25Kg 400mg BD Chewable Tablet: 11-14Kg: 75mg BD 14-20Kg: 100mg BD 20-28Kg: 150mg BD 28-40Kg: 200mg BD >40Kg: 300mg BD Take with or without food.	Rash, nausea, hepatitis
Zidovudine (AZT, ZDV) (Retrovir®)	Capsule: 100mg Liquid: 10mg/mL	Capsule or liquid: 180mg/m ² /Dose BD to a maximum dose of 250mg BD (max. 300mg BD when used in combination products) Preferably on an empty stomach. If nausea occurs can be taken with food.	Granulocytopenia and/or anaemia, nausea, headache, myopathy, hepatitis, neuropathy
Lamivudine (3TC) (EpiVir®)	Tablet: 150mg Liquid: 10mg/mL	Tablet or Liquid: 4mg/Kg/dose BD to a maximum of 150mg BD Take with or without food.	Peripheral neuropathy, nausea, diarrhoea, headache
Truvada® Do not use if known renal impairment	Combined tablet: (Tenofovir TDF 300mg / Emtricitabine FTC 200mg)	Combined tablet: >35Kg: 1 tablet daily	Headache nausea, vomiting, diarrhoea, renal tubular, dysfunction bone demineralization
Tenofovir TDF (Viread®) Note: 300mg Tenofovir disoproxil fumarate (TDF) = 245mg Tenofovir disoproxil (TD) All doses expressed as TDF(TD)	Tablet TDF (TD) 300mg (245mg) For paediatric use: the tablet: TDF (TD) 300mg (245mg) disperses in 10mL water within 5 minutes	Tablet: >35Kg: 1 tablet daily 2-12 years: 8mg (6.5mg)/Kg once daily 10-12Kg: 80mg(66mg)= 2.7mL 12-14Kg: 100mg(83mg)= 3.4mL 14-17Kg:120mg(99mg)= 4mL	Do not use if known renal impairment

Drug	Formulation	Dose	Potential Side Effects
Continued: Tenofovir TDF (Viread®) Note: 300mg Tenofovir disoproxil fumarate = 245mg Tenofovir disoproxil (TD) All does expressed as TDF(TD)	Tablet: TDF (TD) 300mg (245mg) For paediatric use: the tablet: TDF (TD) 300mg (245mg) disperses in 10mL water within 5 minutes	Continued: 17-19Kg:140mg(116mg)= 4.7mL 19-22Kg:160mg(132mg)= 5.4mL 22-24Kg: 180mg(149mg)= 6.1mL 24-27Kg: 200mg(165mg)= 6.7mL 27-29Kg: 220mg(182mg)= 7.4mL 29-32Kg: 240mg(198mg)=8.1mL 32-34Kg: 260mg(215mg)= 8.8mL 34-35Kg: 280mg(231mg)= 9.4mL ≥35Kg: 300mg(245mg)= 10mL The dose can be diluted in orange juice to improve taste	Do not use if known renal impairment
Combivir®	Combined tablet: Lamivudine 150mg (3TC) / Zidovudine (ZDV) 300mg	Combined tablet: >30Kg: 1 tablet twice daily	As for ZDV and 3TC
Kaletra® 2 adult tablets = 4 paediatric tablets = 5mL of liquid All doses are based on Lopinavir (LPV)	Liquid: Lopinavir (LPV) 80mg/ Ritonavir (RTV) 20mg per mL Paediatric tablet: (pale yellow) Lopinavir (LPV)100mg/ Ritonavir (RTV) 25mg Adult tablet: (yellow) Lopinavir (LPV)200mg/ Ritonavir (RTV) 50mg	Liquid: 300mg/m ² /dose BD Dose in mls = (300 x BSA) / 80 Paediatric tablet: 15-25Kg: 2 tablets BD 25-35Kg: 3 Tablets BD >35Kg: 4 Tablets BD Adult tablet: >35Kg: 2 Tablets BD	Diarrhoea, abdominal pain, nausea, vomiting, headache

Body surface area (BSA) can be calculated with the following equation:

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

Notes:

1. The list of side effects is not exhaustive – refer to Summary of Product Characteristics (SPC) for detailed information on side-effects, interactions with other medicines and other cautions for use. See <http://www.medicines.ie>

2. Drug interactions that may reduce effectiveness of Raltegravir:

- Rifampicin within the preceding two weeks
- Aluminium/Magnesium containing antacids

3. Avoid co-administration of Ritonavir with steroids including nasal/inhaled preparations of Fluticasone and budesonide, due to interaction with Ritonavir producing extremely high steroid levels impacting on bone metabolism. Further information on drug interactions with antiretrovirals can be obtained at <http://www.hiv-druginteractions.org> or discuss with a Pharmacist.

4. **Antiemetics:** Gastrointestinal side effects are more likely to occur with regimens that contain Kaletra® when compared with Raltegravir. For those with nausea and vomiting on Kaletra® based PEP a switch to paediatric Raltegravir should be considered. Alternatively the addition of an antiemetic to a Kaletra® based regimen requires a risk benefit discussion with the family (including a discussion regarding the unknown risk of prolonged QT interval in the paediatric population inferred from adult data) and specialist advice.

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References:

1. Summary of Product Characteristics (SPCs): <http://www.medicines.ie/> and <https://www.medicines.org.uk/emc/>
2. Post-Exposure Prophylaxis (PEP) Guidelines for Children and Adolescents C Foster, G Tudor-Williams, A Bamfors June 2015 http://www.chiva.org.uk/files/2814/3575/6995/CHIVA_PEP_2015_final.pdf
3. Guidelines for the Emergency Management of Injuries available at <http://www.hpsc.ie/A-Z/EMIToolkit/EMIToolkit.pdf>
4. Handbook of Drug Administration via Enteral Feeding Tubes Second Edition
By Rebecca White and Vicky Bradnam