

(HIV) Post Exposure Prophylaxis (PEP) Register and Supporting Guidelines

**Directorate/Department: Raigmore Emergency
Department and Other HIV PEP Holding Centres
(excluding Argyll and Bute)**

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(HIV) Post Exposure Prophylaxis (PEP) Register and Supporting Guidelines

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Risk assessment for HIV Post Exposure Prophylaxis (PEP) following Sexual or Other exposure including Needlestick

Did exposure occur ≤ 72 hrs ago?

[PEP is an option up to 72hrs post exposure but treatment should be started ASAP, ideally within 2hrs]

No

PEP NOT recommended
(see overleaf)

Yes

The probability of HIV transmission depends on the exposure characteristics, the infectivity of the source and host susceptibility.

Assess risk of SOURCE having HIV viraemia

Overall the UK prevalence is 0.16% (1.6 per 1000) but there are distinct risk groups (e.g. prevalence 15-74yrs 0.21%)

(www.bashhguidelines.org/current-guidelines/hiv/post-exposure-prophylaxis-following-sexual-exposure)

Known to be HIV positive with a detectable viral load*	100%*
IVDU - Southern (Spain, Italy, Portugal) & Eastern Europe	>50%
MSM - London, Brighton	14%
MSM - rest of UK	4%
IVDU, UK as a whole	0.4%
Heterosexual male/female - Black African ethnicity	M 4%, F 7%
- Non Black African ethnicity	M and F both 0.06%
Known to be HIV positive with confirmed undetectable viral load*	0%

For country specific prevalence data go to www.unaids.org/en/regionscountries/countries NB high prevalence is considered to be >1%

For current UK prevalence go to www.gov.uk HIV in the UK [year] report

* If on treatment ascertain drugs and latest viral load (if known).

Assess risk of EXPOSURE

Based on figures from BASHH HIV PEP guidance

(www.bashhguidelines.org/current-guidelines/hiv/post-exposure-prophylaxis-following-sexual-exposure)

Exposure	Not quantified	
Rape (male or female)	Not quantified	
Receptive anal intercourse (overall)	1 in 90	(1.1%)
with ejaculation	1 in 65	(1.5%)
no ejaculation	1 in 170	(0.6%)
Insertive anal intercourse (overall)	1 in 666	(0.15%)
not circumcised	1 in 161	(0.62%)
circumcised	1 in 909	(0.11%)
Receptive vaginal intercourse	1 in 1000	(0.1%)
Insertive vaginal intercourse	1 in 1219	(0.08%)
Semen splash in eye	< 1 in 10,000	(<0.01%)
Receptive oral sex (giving fellatio)	< 1 in 10,000	(<0.01%)
Insertive oral sex (receiving fellatio)	< 1 in 10,000	(<0.01%)
Blood transfusion*	100 in 100	(100%)
Needlestick	1 in 333	(0.3%)
Sharing injecting equipment*	1 in 149	(0.67%)
Human bite	< 1 in 10,000	(<0.01%)

Prescribing guidelines

According to BASHH guidelines:

HIV PEP **RECOMMENDED** where **RISK OF TRANSMISSION** > 1/1000

HIV PEP should be **CONSIDERED** when **RISK OF TRANSMISSION** is between 1/100 and 1/10,000. Consider factors such as patient choice, presence of mucosal injury or ulceration

Quantification of risk of TRANSMISSION

HIV transmission risk (per exposure) is = **Risk that SOURCE is HIV positive** x **Risk of EXPOSURE**

Note:
[Where individuals have multiple exposures within 72hrs a cumulative risk should be considered]
[If source unknown BASHH recommend pro-active attempts to establish HIV status of source if possible]

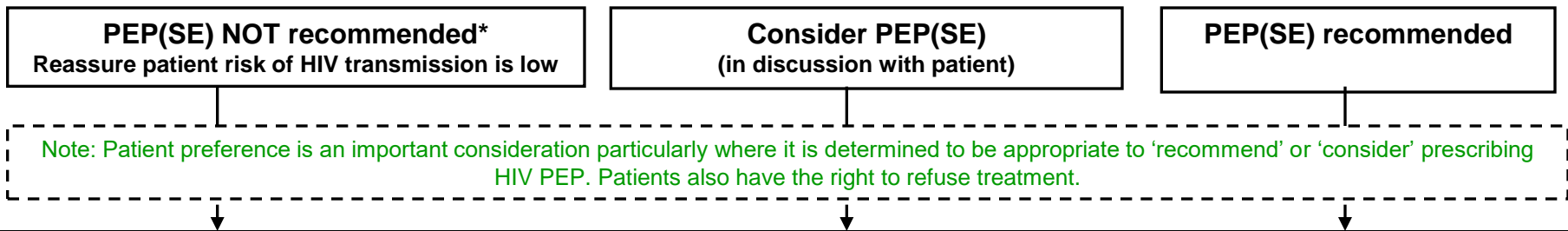
Examples which may help:

- 1) Patient has unprotected receptive anal intercourse with homosexual male from London:
 $14\% \times 1.1\% = 0.154\%$ (i.e. approx 1 in 650)
- 2) Patient has unprotected heterosexual sex with local Scottish male:
 $0.3\% \times 0.2\% = 0.0006\%$ (i.e. approx 1 in 166,667)
- 3) Patient has a needlestick from a known HIV +ve person with detectable viral load:
 $100\% \times 0.3\% = 0.3\%$ (i.e. approx 1 in 333)
- 4) Patient has needlestick from unknown source:
 $<1\% \times 0.3\% = <0.003\%$ (i.e. less than 1 in 33,333)

Summary table of prescribing recommendations:

Source HIV status	HIV + VL unknown or detectable (>200copies/ml)	HIV + VL known (<200copies/ml)	unknown from high prev country /risk group (MSM)	unknown from low prev country/group
Receptive anal sex	Recommend	NOT provided source confirmed <200c/ml for >6 months	recommend	NOT
Insertive anal sex	Recommend	NOT	Consider	NOT
Receptive vaginal sex	Recommend	NOT	Consider	NOT
Insertive vaginal sex	Consider	NOT	Consider	NOT
Fellatio + ejaculation*	NOT	NOT	NOT	NOT
Fellatio no ejaculation*	NOT	NOT	NOT	NOT
Splash semen into eye	NOT	NOT	NOT	NOT
Cunnilingus	NOT	NOT	NOT	NOT
Sharing needles	Recommend	NOT	Consider	NOT
Human bite	NOT	NOT	NOT	NOT
Needlestick (discarded in community)	-	-	NOT	NOT

*NB Not if receiving fellatio, but consider if giving fellatio and have oropharyngeal trauma / ulceration



For All Patients

- Discuss other issues (Hepatitis, contraception, sexual assault, etc if relevant)
- Record discussion / advice
- Enter data into [ED HIV PEP Register](#) (Held with 'Starter Pack of PEP) for **all** consultations relating to PEP/PEPSE - **whether given or not**

For all patients given PEP(SE) and all patients following sexual exposure

- Counsel safer sex (abstinence or barrier methods) until further advised by 'Highland Sexual Health' (HSH).
- Complete ['Urgent Referral Sheet to HSH for follow up of HIV PEP'](#) (Appendix 2)
- Email 'Urgent Referral Sheet' to HSH at nhshighland.healthadvisor@nhs.net and keep original with Raigmore ED notes (or equivalent if seen in another setting).
- Patients should be advised to expect a call from HSH **but to contact them themselves (Tel: 01463 70 4202) if nothing heard after one full working day**

Give PEP(SE)

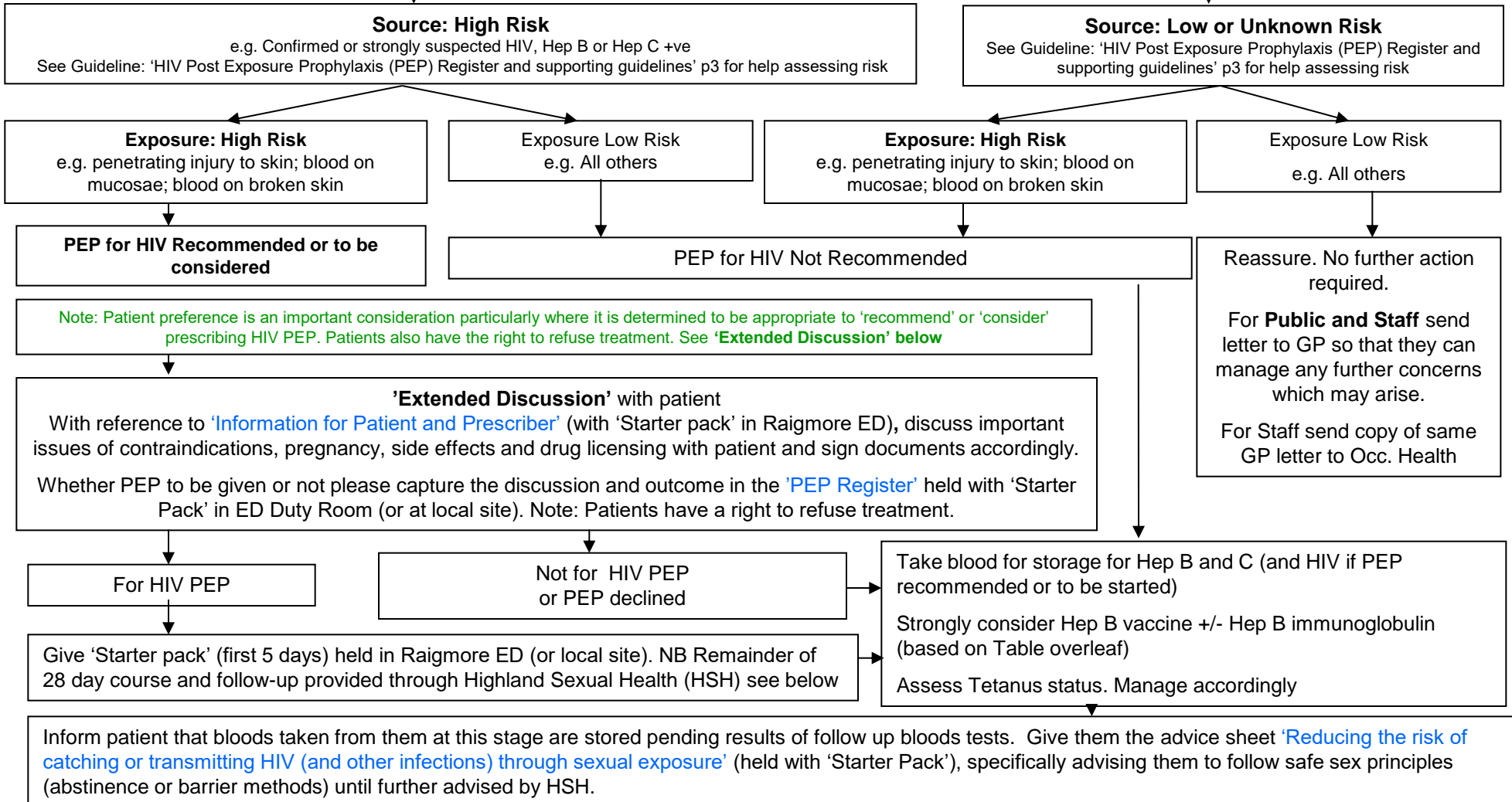
- Find PEP(SE) 'Starter pack' In local ED / HIV PEP(SE) Holding centre (in Raigmore this is ED Duty Room drug cupboard) with [Memorandum: HIV PEP 'Starter Pack'](#) attached. Open outer packaging to access drugs and paperwork. For consultation guidance specifically look for the envelope containing:
 - 3 x copies of ['HIV Post Exposure Prophylaxis: Information for patient and Provider'](#) for signing (1 for patient, 1 for notes, 1 for Occ Health if NHS Staff)
 - 1 x copy of ['Advice for reducing the risk of catching or transmitting HIV through sexual exposure'](#)
- Advise the patient that although these drugs are not specifically licensed for this use they are recommended for this use by the Chief Medical Officer.
- Counsel the patient regarding the importance of adhering to treatment and also side effects of treatment.
- Dispense Starter pack of drugs (5 day supply)
- Inform patient that rest of full course (28 days) is provided through HSH, as arranged above
- Consider suggesting that first dose is taken in the Department**
- Inform ED Co-ordinator that the package has been opened / used so that the pack (drugs and information sheets) can be resupplied

Guideline for the early management of **Members of Public** or **NHS Staff*** (incl. students) exposed to blood or body fluids through **Needlestick** or other types of injuries

*** Only come to Raigmore ED if Raigmore Occupational Health closed at the time**

Basic First Aid – Immediate: promote bleeding if small wound then gently wash with soap and water (irrigate mucous membranes with water). Do NOT scrub or suck area)

Consider **type of exposure** and **infectivity of source**. If source is known (e.g. hospital patient) recommend **testing of 'Source'** with informed consent (see overleaf) [5-10ml clotted blood sent **urgently** to Virology for HIV, Hep B&C testing]. With consent of Source advise that results sent to a) the 'Source' AND b) Occupational Health (if exposed patient is NHS Staff) OR c) Exposed patient's GP (if exposed patient is not NHS Staff)



For ALL patients recommended for or given PEP, email completed 'Urgent referral sheet' held with Starter Pack to HSH nhshighland.healthadvisor@nhs.net). **Also advise them to contact HSH (Tel: 01463 704202) if they have not heard back from them within 1 working day.** (For staff send copy of the same emailed HSH referral to Occ Health). All staff (whether given PEP or not) should be advised to contact Occ Health ASAP to arrange review. For Non-Staff ensure appropriate information re attendance and outcome passed to GP (eg GP letter in EDIS)

Table¹: Guidance on giving Hep B vaccine and/or Immunoglobulin following significant exposure

Hep B status of person exposed	HbsAG positive source	Unknown source	HbsAG negative source
≤1 dose Hep B vaccine pre-exposure	Accelerated course of Hep B vaccine*, HB immunoglobulin x 1	Accelerated course of Hep B vaccine*	Initiate course of Hep B vaccine
≥2 doses Hep B vaccine pre-exposure (anti-HBs not known)	One dose of Hep B vaccine followed by second dose one month later	One dose of Hep B vaccine	Finish course of Hep B vaccine
Known responder to Hep B vaccine (anti-HBs>10mIU/ml)	Consider booster dose of Hep B vaccine	Consider booster dose of Hep B vaccine	Consider booster dose of Hep B vaccine
Known non-responder to Hep B vaccine (anti-Hep Bs<10mIU/ml 2-4 months post immunisation)	Hep B immunoglobulin x1. Consider booster dose of Hep B vaccine. A second dose should be given at one month	Hep B immunoglobulin x1. Consider booster dose of Hep B vaccine. A second dose should be given at one month	No Hep B immunoglobulin. Consider booster dose of Hep B vaccine.

*A 'normal' accelerated course of vaccine consists of doses spaced at zero, one and two months with a booster given at 12 months.

NB An extension to the product licence for Engerix B® allows an alternative 'very rapid' immunisation schedule of three doses given at zero, 7 and 21 days with a booster at 12 months. This schedule is licensed for use where adults over 18 years of age are at immediate risk and where a more rapid induction of protection is required.

Advice re Informed Consent for testing 'Source' patient:

Where the 'Source' is a hospital patient the responsibility for testing them lies with the team they are under. Informed consent will be required. This conversation should be held **between the Source patient and a (third party)** i.e. NOT the person who sustained the needlestick injury). Suggested elements of the conversation with any Source patient include:

"An incident has occurred where another person may well have been contaminated with some of your blood (or body fluid). To help decide what, if any, treatment we need to offer that person it would be extremely helpful if we can test your blood – specifically for HIV, Hep B and Hep C. Are you happy enough to allow us to do that?"

"You can expect to get a copy of the result but in order to act on it for the sake of the other affected person we will need to inform the Occupational Health Service and / or their GP. Are you happy to allow us to do that?"

"If the result is negative it will not affect you. If however, we find you are positive for one or more of the above infections you have the advantage of knowing that appropriate treatment and advice can be provided much sooner than it otherwise would have been if this result had remained unknown"

Note 1: It should be made clear that routine testing such as this will be seen as non-discriminatory and that the decision to have the sample taken rests entirely with the 'Source' patient¹

Note 2: Where a Source patient is under a General Anaesthetic ('GA') testing will have to wait until the patient is fully conscious and can give informed consent. If in the meantime the exposure risk and likely infectivity of the Source is deemed sufficiently high the decision to give HIV PEP or not will need to be made without the benefit of a result.

Note 3: Other than when under GA, where a Source patient lacks capacity to give informed consent their next of kin may be approached to help with the decision to test their blood.

Reference - 1. The Green Book on immunisations

HIV PEP Register

For use when patients (staff or public) attend ED (or local holding site) following possible HIV exposure:
either non-sexual exposure (PEP) e.g. needlestick injury OR sexual exposure (PEPSE)
[Log to be kept with PEP Starter Pack in Raigmore ED Duty Room Drug Cupboard (or in suitable place at local site)]

Date	Time	Patient Details (CHI or R number)	Patient Group S = Staff P = Public	Exposure S = Sexual N = Needlestick O = Other	Outcome of Risk Assessment N = No PEP C = Consider P = Give PEP	Referral Made to HSH Y = Yes N = No	PEP Given or not? [NB Patients can opt to take it even if risk low] Y = Yes N = No

URGENT REFERRAL SHEET

To Highland Sexual health for Follow Up of HIV Post Exposure Prophylaxis after Sexual Exposure (PEPSE) or Needlestick (or Similar) Exposure (PEP)

For a printable version of this form please copy the link below and paste it into the address line:

[http://intranet.nhsh.scot.nhs.uk/FormsLibrary/Documents/Urgent%20Referral%20Sheet%20for%20follow%20up%20of%20HIV%20PEPSE%20or%20Needlestick%20\(or%20Similar\)%20Exposure.pdf](http://intranet.nhsh.scot.nhs.uk/FormsLibrary/Documents/Urgent%20Referral%20Sheet%20for%20follow%20up%20of%20HIV%20PEPSE%20or%20Needlestick%20(or%20Similar)%20Exposure.pdf)

or alternatively go to the Forms Library on the Intranet to access it.

Memorandum: HIV Post Exposure Prophylaxis ‘Starter Pack’

Please note this pack should contain:

- 2x Drugs (see below)

The full course is 28 days. This ‘Starter Pack’ covers the first 5 days of treatment with the remainder being provided through Highland Sexual Health as necessary.

- 3 x copies of Drug Information Sheet re Emticitabine/ Tenofovir disoproxil and Raltegravir used as HIV PEP – to be signed. (One for patient, one for ED notes (or local equivalent)), one for Occupational Health (where relevant)

These are designed to be used to inform the consultation between Prescriber and Patient and ultimately require signatures as part of the prescribing and recording process.

- 1 x copy Advice sheet ‘Reducing the risk of catching or transmitting HIV (and other infections) through sexual exposure’

NB – In Raigmore, master copies of these advice sheets and further information to support the consultation following sexual exposure, needlestick injury or other similarly risky exposure event are in the ED Duty Room in folder marked:

**‘(HIV) Post Exposure Prophylaxis (PEP) Register
and Supporting Guidelines’**

Please use the Register to record the elements and outcomes of the consultation even if HIV PEP not eventually prescribed.

In addition to the Drug Information Sheet mentioned above standard drug information leaflets are contained within the corresponding drug packaging

- Raltegravir + Emtricitabine/ tenofovir disoproxil– anti-retroviral drugs for treating HIV

PLEASE FILL IN THE DETAILS ON THE LABEL ON THE FRONT OF EACH OF THE DRUG PACKS BEFORE HANDING TO THE PATIENT!

HIV Post-exposure Prophylaxis
Information for Patient and Prescriber
Drug Information – Emtricitabine/ Tenofovir disoproxil & Raltegravir

Introduction

You have either been prescribed, or are being considered for a prescription of what is known as, post-exposure prophylaxis* or 'PEP' because of the possibility that you have been exposed to the HIV virus either through sexual exposure; a needlestick type injury; or other similar high risk type event. (*NB Prophylaxis means a preventative treatment)

The aim of this treatment is to reduce the likelihood of you actually developing HIV infection itself following such an exposure. It can only be offered within 72hours of exposure event as it is likely to be more effective the sooner it is given (ideally within a couple of hours). So once given the medication should be taken as soon as possible after exposure. Nevertheless there are some important features of this treatment about which you need to be aware as part of the decision making process:

The Treatment

Some of the drugs prescribed will be specifically anti-viral (anti-HIV) but others are offered to help minimise the side effects of the anti-viral treatment itself.

The anti-viral drugs are not specifically licensed for this use (prophylaxis) however they can be prescribed on what is known as an 'Off-licence' basis. Signing at the bottom of this form indicates that you understand and accepted this.

The anti-viral treatment itself consists of a course of two tablets (see below) although there are three drugs in total:

Emtricitabine/ tenofovir disoproxil tablets –containing emtricitabine 200mg and tenofovir disoproxil 245mg

Raltegravir tablets – containing raltegravir 400mg

Typically you will be supplied with a 5 day 'starter' pack, but the full course is 28 days. Accordingly, arrangements will be made for you to attend **Highland Sexual Health Clinic (HSH) at Raigmore Hospital (tel 01463 704202 – office hours)** for follow-up and to obtain the remainder of the course of treatment, as necessary. If you do not hear from HSH after 1 working day please contact them directly on the number above.

You need to complete the course to get maximum benefit so please do not stop taking the pills without speaking to a doctor.

If you take other medicines and / or have another medical problem

With this treatment there is a risk of problems developing if you are taking other medication (including herbal medicines) or if you have other medical problems (eg kidney or liver problems). Emtricitabine/tenofovir disoproxil specifically should not be taken by people with kidney disease. Raltegravir specifically should not be taken by people who have had muscle disease. You must tell your doctor about any medical problems you have, and about any medication you are taking, whether these are prescribed for you or bought over the counter.

Do not start any new medication without discussing it with your doctor first.

Just some of the drugs that are known to interact with the medicines include:

- Phenytoin or Carbamazepine (used for treating epilepsy)
- Rifabutin , Rifampicin or Erythromycin or Clarithromycin (used for treating bacterial infections)
- Aluminium or magnesium containing antacids

Pregnancy

You must tell your doctor if you could be pregnant. Experience of these drugs in early pregnancy has not shown any adverse outcomes.

You should take precautions to avoid becoming pregnant or fathering a child while taking the medicines.

Certain combinations of anti-retroviral medication can reduce the effectiveness of hormonal contraception; meaning these methods should not be relied on while you are taking the medication, and you should use a barrier method (condoms) in addition. **HOWEVER the combination Emtricitabine/tenofovir disoproxil tablets and Raltegravir do not alter effectiveness of hormonal contraception**

Breast feeding

You should not breast feed while taking these medicines.

Taking your medicines

For this treatment to be effective, it is important that you take your medicines properly. Treatment should start as soon as possible after potential exposure to HIV.

Read the label on your medicines. They should be taken as follows:

<u>Medicine</u>	<u>Morning</u>	<u>Evening</u>
Emtricitabine/Tenofovir disoproxil	Take one tablet with your breakfast	Nil
<u>Raltegravir</u>	Take one tablet with your breakfast	Take one tablet, ideally 12 hours after breakfast dose.

Swallow the **Raltegravir** tablets whole. It is important that they are not chewed or crushed. The **Emtricitabine/ Tenofovir disoproxil** tablets can be swallowed whole or can be disintegrated in approximately 100ml of water, orange juice or grape juice and taken immediately.

Take the medicines at the approximate times indicated even if you have not actually had a meal.

If you forget to take a dose, take it as soon as possible and then continue as before. If you have difficulty remembering to take them, use an alarm, eg on your mobile phone.

You may drink moderate amounts of alcohol while taking these medicines (within normal recommended safe limits).

Side effects

Common side effects of the medicines are dizziness, nausea (feeling sick), diarrhoea, headache, vomiting (being sick), tiredness, weakness and muscle aches.

These usually settle if you keep taking the medicines as directed, but simple painkillers or tablets to prevent sickness or diarrhoea may help. You may also be offered medicines to minimise these side effects with the starter pack. Tell your doctor if the symptoms persist.

Serious side effects are rare; they include allergic reactions, liver toxicity, pancreatic problems and reduced production of red bloods cells, causing anaemia, or white bloods cells, which can make you prone to infections.

Tell your doctor if you are concerned about any new symptoms.

General advice

Do not take more than the recommended dose. Do not give your medicines to others. Keep your medicines in a cool, dark, dry place, out of the reach of children.

Common side effects

Feeling sick, stomach pains, wind, diarrhoea,
digestive problems

Headache, muscle aches

Difficulty in sleeping, abnormal dreams,
tiredness, dizziness

Skin rash, itching

Rare side effects

Tiredness associated with shortness of breath

Fever associated with feeling unwell and other
symptoms

Jaundice (yellowing of the skin and eyes)

Useful Numbers

Highland Sexual health (HSH), Raigmore Hospital:	01463 704202
NHS 24:	111
Emergency Department (A&E), Raigmore Hospital:	01463 70 4357
Emergency Department (A&E), Caithness General Hospital:	01955 880229
Emergency Department (A&E), Belford Hospital:	01397 702088
Emergency Department (A&E), Mackinnon Memorial Hospital:	01471 822491

What you should do

Keep on taking the tablets with food – it often settles. Tell your doctor if it persists or becomes distressing.

Take a simple painkiller such as paracetamol or ibuprofen . Tell your doctor if it persists.

Take care driving or operating machinery. It may go away. Tell your doctor if it persists.

Tell your doctor if it persists.

What you should do

Tell your doctor – this could be due to anaemia.

Tell your doctor – this could be due to a low white cell count.

Tell your doctor – this could be due to liver toxicity.

PATIENT

I intend to commence post-exposure chemoprophylaxis against HIV. I understand and accept the risks involved. I will seek expert advice and counselling from Highland Sexual Health at the earliest opportunity. I understand that the drugs are not licensed for this purpose.

SIGNED: _____

DATE: _____

ALSO

PATIENT (If member of NHS Staff)

I understand that I have a responsibility (for clinical staff this is a professional duty of care to patients) to seek appropriate advice and treatment following such an exposure. Accordingly, I shall make arrangements to be seen at Occupational Health at the earliest opportunity.

SIGNED: _____

DATE: _____

DOCTOR (Prescriber)

I understand that this prescription is not licensed for chemoprophylaxis following needlestick injury and is supplied for use in the above patient on my own responsibility exercising my rights under section 9 of the Medicines Act.

SIGNED: _____

DATE: _____

I confirm that, where they have access to one through their employer, I have advised the patient to inform their Occupational Health Service at the earliest opportunity.

SIGNED: _____

DATE: _____

- One copy of this form is needed for the Raigmore ED record (or local equivalent) or patient's hospital notes
- One copy is to be retained by the patient
- One copy should be sent to Occupational Health (NHS Staff only)

Advice for reducing the risk of catching or transmitting HIV (and other infections) through sexual exposure

This advice sheet is specifically for patients who have been commenced on 'HIV Post Exposure Prophylaxis (PEP)' following potential exposure to HIV infection either through sexual activity, needlestick injury or other high risk event. It does however, offer good general advice about reducing the risk of transmitting any such infections through further sexual contact.

You have been commenced on this treatment to reduce the chance of actually developing HIV following potential exposure. However, because there is a risk of you having been infected (no matter how small) it is only sensible that you take appropriate precautions to reduce the chance of transmitting HIV onto anyone else. Importantly it is worth being reminded that **No sexual activity is completely safe**. A person who is HIV negative can be exposed to HIV by having unprotected sex (oral, anal or vaginal) with an HIV positive sexual partner.

The following activities pose a significant risk of HIV transmission if a condom isn't used or if it breaks:

Anal sex giving and receiving
Vaginal sex giving and receiving

Note re Oral Sex - The risk of HIV transmission from oral sex is less than 1/10,000. Even with ejaculation, oral sex does not pose a significant risk of transmission of HIV.

It is important to have regular sexual health check-ups to exclude sexual infections and good dental care and oral hygiene to reduce the risk of catching and transmitting HIV.

You should certainly continue to use these precautions while on the PEP treatment and AT LEAST UNTIL further advised as part of your follow up – which may be several months.

IMPORTANT: Condoms are unlikely to break if they are used correctly

- Use the right size. Highland Sexual Health can offer you regular, large or extra large ones – try them!
- Check they are in date, are CE approved or have a “Kite mark”
- Use water based lubricant, especially if having anal sex or if there is a problem with vaginal dryness
- Remove air from the tip
- Change the condom if having sex for more than half an hour