

PEP

Post Exposure Preventive Treatment Starter Kits



GUIDELINES

(Name of UN organisation)

With acknowledgement and thanks to UNICEF

Post Exposure Preventive Treatment Starter Kits

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I. General

Background

1. Post Exposure Preventive (PEP) Treatment is an emergency medical response for individuals exposed to the HIV virus. PEP Treatment consists of medication, laboratory tests and counselling. PEP Treatment must be initiated within hours of possible HIV exposure and must continue for a period of approximately four weeks.
2. PEP Treatment was originally designed for medical workers who accidentally became exposed to HIV during the course of their work, for example, by needle stick injuries. However, the value of PEP Treatment is now recognized for other situations involving possible exposure to the HIV virus, such as sexual assault.
3. PEP Treatment has **not been proven** to prevent the transmission of the HIV virus. However, research studies suggest that if the medication is initiated quickly after possible HIV exposure - that is, **ideally within two hours and not later than 72 hours** following such exposure - it **may** be beneficial in preventing HIV infection.
4. For the past few years, an Inter-Agency Working Group has been working on how to provide timely access to PEP Treatment to those individuals serving in field locations who may be exposed to the HIV virus, in the event of sexual assault or occupational accident.
5. The Inter-Agency Working Group is composed of the:
 - a) International Organisation for Migration (IOM)¹;
 - b) United Nations (UN): (UN Medical Services Division (UNMSD), the UN Department of Peacekeeping Operations (DPKO), and the UN Staff Counsellor's Office);
 - c) Joint United Nations Programme on HIV/AIDS (UNAIDS);
 - d) United Nations Development Programme (UNDP);
 - e) United Nations Population Fund (UNFPA);
 - f) United Nations High Commissioner for Refugees (UNHCR);
 - g) United Nations Children's Fund (UNICEF);
 - h) United Nations Office for Project Services (UNOPS);
 - i) World Food Programme, WFP;
 - j) World Health Organization (WHO); and

¹ Member since 2000.

- k) International Bank for Reconstruction and Development (World Bank).²
- l) International Labour Office (ILO)

Purpose

6. The PEP Treatment starter kits are provided so that:
- a) the medication can be initiated as soon as feasible after possible HIV exposure – that is, **ideally within two hours and not later than 72 hours** following such exposure; **and**
 - b) the **(name of UN organisation)** Representative can make the necessary arrangements for the evacuation of the patient to a location with adequate medical facilities, in order to continue the PEP Treatment.

Contents

7. Each PEP Treatment starter kit contains:
- a) the medication required for the first five days of the PEP Treatment;
 - b) the guidelines for:
 - the attending physician (see Annexes F to G); and
 - the patient (see Annexes H to I); and
 - c) the required consent form (see Annexes J to K).

Eligibility

8. The PEP Treatment starter kits are available for individuals with a **(name of UN organisation)** contract³ (and their recognized spouses and dependent children) who are exposed to the HIV virus because of:

sexual assault; or
occupational accident.

9. The kits are **not** available for individuals who:
- a) are/may be already infected with the HIV virus, **or**

² Member since 2000.

³ This includes individual contractors/consultants.

- b) are/may be exposed to the HIV virus because of voluntary activities involving potential HIV transmission.
10. The kits may **only** be used if:
- a) the Attending Physician, following his/her evaluation of the patient, recommends to start PEP Treatment; and
 - b) the patient consents, in writing, to start PEP Treatment (see Annexes J to K and paragraphs 25 to 27).

Distribution

11. Three PEP Treatment starter kits have been sent to all UN Resident Coordinators.
12. In crisis situations, UN Resident Coordinators may request additional kits from:

Dr Pascale Gilbert-Miguet
Joint Medical Service (JMS)
World Health Organization (WHO)
20, Avenue Appia
CH-1211 Geneva 27
Switzerland

Fax.: 41-22-7914120
Tel.: 41-22-7913040
e-mail: gilbertmiguets@who.int

Cost

13. The cost of the PEP Treatment starter kits is financed jointly by IOM, UN, UNAIDS, UNDP, UNFPA, UNHCR, UNICEF, UNOPS, WFP, WHO and the World Bank.⁴
14. All other medical expenses for PEP Treatment are the patient's responsibility. The patient may claim reimbursement for these expenses to the relevant medical insurance plan according to the established procedures. In the event of incidents attributable to the performance of official duties, the provisions governing compensation Staff Rule 730 would apply.

Arrival of the Kits

15. Upon arrival of the kits, the office of the UN Resident Coordinators is required to acknowledge their receipt (see Annex D).

⁴ UNICEF's share is paid by UNICEF New York.

16. In many countries the “morning-after pill” is considered a legal emergency oral contraception medication while in others, it is illegal. To avoid any criminal action in those countries, the UN Resident Coordinators are required to check with the competent health authorities and comply with the directions in Annex E.

Custody

17. UN Resident Coordinators, following inter-agency consultation, may delegate the custody of the kits to a UN system staff member, for example, to the Designated Official (DO), the (name of UN organisation) Representative or the UN Dispensary Physician, or the Field Security Officer.
18. The custody of the PEP Treatment starter kits may only be given to an individual who is a UN staff member. Consequently, UN Designated Physicians may not be custodians of the kits.

Storage

19. The custodian must ensure that the PEP kits are stored in a **locked and cool space (not a refrigerator)**.

Country PEP Emergency Protocol

20. In order to ensure the efficient and effective response to any incident involving potential exposure to the HIV virus, UN Resident Coordinators are required to establish, following inter-agency consultation, a country PEP Emergency Protocol.
21. This Protocol should:
 - a) detail the responsibilities of specific individuals (Custodian of the PEP Starter Kits, UN DO, UN Resident Coordinator, Head of Office, UN Dispensary Physician or Designated Physician);
 - b) specify the actions to be carried out and the sequence to be followed to ensure the quickest possible access to PEP Treatment of individuals reporting sexual assault or occupational accident **in any location in the country with UN system presence;**
 - c) include the quickest evacuation route(s) and modality(ies); and
 - d) ensure the patient’s right to privacy (confidentiality).

Isolated Locations

22. During the inter-agency discussions to establish the country PEP Emergency Protocol, it may be that it is difficult to provide quick access to PEP Treatment to individuals assigned to isolated locations.

23. In such cases, UN Resident Coordinators may request up to three additional kits for each isolated location from:

Dr Pascale Gilbert-Miguet
Joint Medical Service (JMS)
World Health Organization (WHO)
20, Avenue Appia
CH-1211 Geneva 27
Switzerland

Fax.: 41-22-7914120
Tel.: 41-22-7913040
e-mail: gilbertmiguets@who.int

24. In the request, the following information is to be included:
- a) name of each isolated location;
 - b) details of each isolated location, for example, distance from the capital city, telecommunications, transportation, etc;
 - c) number of additional kits recommended for each isolated location;
 - d) number of individuals with a (name of UN organisation) contract assigned to each isolated location (per organisation); and
 - e) details on the Attending Physician who could provide support in the event of a sexual assault or occupational accident at each isolated location.

Patient's Consent

25. Please note that before the Attending Physician initiates PEP Treatment, he/she must first obtain the consent of the patient (provided such patient is physically or legally competent to do so, see Annexes H to I).
26. In the case of the administration of the medical treatment to:
- a) a staff member's dependent child who is under age 18, the staff member or other legally recognized parent or guardian should provide consent; or
 - b) a staff member's spouse or dependent child between age 18 and 21 who is otherwise unable to give informed consent, specifically because of mental incapacity, then the staff member or other legally recognized guardian should provide consent.
27. Moreover, in order for such consent to be effective, it must be an informed consent, that is, it must be given after the patient has received a fair and reasonable explanation by the Attending Physician of the contemplated medical treatment.

Medical Evacuation

28. In cases of suspected HIV infection because of sexual assault or occupational accident, the **(name of UN organisation)** Representative should arrange for the patient's medical evacuation, at the organization's expense, to a regional medical evacuation center (see Annex C) for PEP Treatment.

Reporting an Incident or Accident

29. In case of a sexual assault or occupational accident involving possible exposure to the virus:
- a) the Country PEP Emergency Protocol (see paragraphs 20 to 21) must be immediately followed; and
 - b) the **(name of UN organisation)** Representative must immediately notify **(Contact name, name of UN organisation)** Joint Medical Service (JMS), **(location)**

Confidentiality

30. All information and documentation regarding sexual assault or occupational accident is confidential and should be treated as such, whether within offices or in the transmission to the **(name of UN organisation)** Joint Medical Service, other offices or medical facilities.

24-Hour Availability of the **(name of UN organisation)** Joint Medical Service/**(name of UN organisation)** Security Coordinator

31. The **(name of UN organisation)** Joint Medical Service (JMS) and the **(name of UN organisation)** Security Coordinator are available for consultation and assistance, 24 hours a day, seven days a week. They may be reached by telephone, fax or e-mail (see Annexes A and B).

Replenishment

32. **Due to Use.** A number of kits are maintained ready in stock in Geneva for immediate distribution.
33. When a kit is used, the office of the UN Resident Coordinator is required to **immediately** request replenishment from:

Dr Pascale Gilbert-Miguet
Joint Medical Service (JMS)
World Health Organization (WHO)
20, Avenue Appia
CH-1211 Geneva 27
Switzerland

Fax.: 41-22-7914120
Tel.: 41-22-7913040
e-mail: gilbertmiguete@who.int

34. In the request for replenishment of the kit(s), the following information is to be provided:
- a) location of the incident;
 - b) location from where the kit(s) were used, if different than above;
 - c) number of kits used;
 - d) reason why the kit(s) were used (i.e. sexual assault or occupational accident); and
 - e) whether the patient is a staff member, consultant or an eligible family member.⁵
35. **Due to Expiration.** A record is maintained of the expiry dates of the PEP starter kits sent to each location. Kits are automatically replaced upon expiration. Upon receipt of the new kits, the custodian must immediately destroy the expired kits.

Orientation to Staff

36. **(Name of UN organisation)** Representatives are responsible for ensuring that all individuals with a **(name of UN organisation)** contract are fully informed about PEP treatment, the starter kits and the country PEP Emergency Protocol.

⁵ The patient's name is not to be provided.

ANNEX A
CONTACT INFORMATION FOR
(name of UN organisation) JOINT MEDICAL SERVICE (location)

(as of 20 April 2003)

Name/Title/email	Telephone Number ()	Fax ()	Telephone after office hours
Contact name: Position Email . :			
Contact name: Email . :			

(d) Direct line

(m) Mobile

ANNEX B
CONTACT INFORMATION FOR
(name of UN organisation) SECURITY COORDINATOR

(as of 20 April 2003)

Name/Title/email	Telephone Number ()	Fax ()	Telephone after office hours
Name Title Security Coordination Mail:	Office: Home: Mobile:	Office	
			(

(m) mobile

ANNEX C
RECOGNIZED REGIONAL MEDICAL
EVACUATION CENTRES

(as of 16 February 2001)

Below is the list of countries with inadequate medical facilities justifying medical evacuation to recognized Regional Medical Centres

Countries	Recognized Regional Medical Evacuation Centres
A – Central America	
Belize, El Salvador, Honduras, Nicaragua	Mexico
B – South America	
Bolivia Guyana	Chile Trinidad & Tobago, Venezuela
C – Caribbean	
Haiti	Dominican Republic
D - Arab States	
Iraq Libyan Arab Jamahiriya (the) Yemen	Jordan, Lebanon Egypt, Tunisia Egypt, Saudi Arabia
E – Africa	
Benin Burkina Faso Cape Verde Central African Republic (CAR) Chad Congo, Democratic Republic of Congo, Republic of Equatorial Guinea Gambia Ghana Guinea Guinea Bissau Liberia Mali Mauritania Nigeria Niger Sao Tome and Principe Sierra Leone Togo	Cameroon Côte d'Ivoire Gabon Senegal South Africa
Burundi	Egypt

Countries	Recognized Regional Medical Evacuation Centres
Djibouti Eritrea Ethiopia Rwanda Somalia Sudan Uganda United Republic of Tanzania	Kenya South Africa
Angola Botswana Lesotho Malawi Mozambique Swaziland Zambia	South Africa
Comoros Madagascar	Ile de la Réunion
F - Asia	
Armenia Azerbaijan Georgia Kyrgyzstan	Turkey
Afghanistan Bangladesh Bhutan Kazakhstan Nepal Turkmenistan Uzbekistan	India, Pakistan
Maldives	India, Sri Lanka
Cambodia Lao People's Democratic Republic Myanmar Vietnam	Thailand
Democratic People's Republic of Korea (DPRK) Mongolia	China
G - Micronesia & Melanesia	
All countries	Australia, New Zealand

**ANNEX D
ACKNOWLEDGEMENT RECEIPT OF PEP KITS**

To Dr. Pascale Gilbert-Miguet
Coordinator, Joint Medical Service
World Health Organization
20, Avenue Appia
CH-1211 Geneva 27

I _____(name), _____(title) in _____(duty station), acknowledge receipt of _____ Post Exposure Preventive (PEP) Treatment starter kits sent on _____.

I have checked with the competent health authorities locally and the use of the “morning-after-pill” :

is not legally authorized in any event, therefore I have taken out from all three starter kits:

- > the “morning-after-pill”;
- > Leaflet PEP-01-01A containing the Guidelines for Attending Physicians;
- > Leaflet PEP-01-02A containing the Guidelines for the Patient; *and*
- > Consent Form PEP-01-03A; *or*

is legally authorized ___ in general or ___ for specific cases including rape, therefore I have taken out from all three starter kits:

- > Leaflet PEP-01-01B containing the Guidelines for Attending Physicians;
- > Leaflet PEP-01-02B containing the Guidelines for the Patient; *and*
- > Consent Form PEP-01-03B.

the custodian of the kits are:

Duty station	Name	Function	Agency	Telephone	E-mail	Alternate

Signature : _____

Date : _____

Dr Pascale Gilbert-Miguet, WHO, Joint Medical Service, 20, avenue Appia, 1211 Geneva 27, Switzerland
tel. (+41 22) 791 30 40; fax.(+41 22) 791 41 20; e.mail: gilbertmiguets@who.int

ANNEX E
INSTRUCTIONS ON THE MORNING-AFTER PILL

- ***If the use of the “morning-after pill” is not legally authorized under any circumstances, you should immediately remove from all three kits:***
 - the two Levonorgestrel tablets⁶;
 - Leaflet PEP-01-1A containing the Guidelines for Attending Physicians on how to proceed with the patient in case of rape;
 - Leaflet PEP-01-2A containing the Guidelines for the Patient of the therapeutic options and their implications in case of rape; and
 - Consent Form PEP-01-3A.

- ***If the use of the “morning-after pill” is legally authorized in general or is only legally authorized for specific cases including rape, you should immediately remove from all three kits:***
 - Leaflet PEP-01-1B containing the Guidelines for Attending Physicians on how to proceed with the patient in case of rape;
 - Leaflet PEP-01-2B containing the Guidelines for the Patient of the therapeutic options and their implications in case of rape; and
 - Consent Form PEP-01-3B.

⁶ The date on the stripe of two tablets is the manufacturing date. Tablets expire five years after the manufacturing date.

ANNEX F
GUIDELINES FOR THE ATTENDING PHYSICIAN

GUIDELINES FOR THE ATTENDING PHYSICIAN - PEP-01-01A⁷

- Offer the patient the possibility of being accompanied during the medical examination by a staff member, friend or counsellor.
- Reassure the patient of privacy and confidentiality.
- Record precise time of the incident and of the circumstances.
- In the case of sexual assault, explain to the patient the risk of having been exposed to **STDs, HIV** and the possibility of pregnancy; *when the HIV status of the perpetrator is not known, decisions are to be made as if the perpetrator were HIV positive.*
- In the case of occupational accident, explain to the patient the potential risk in relation to the type of exposure.
- Explain the possibility of reducing the risk of HIV transmission by taking a *post-exposure preventive (PEP) treatment*; although the efficacy of taking **Combivir (AZT/3TC)** to prevent HIV transmission following sexual assault is not proven, research studies suggest this regime, taken within a few hours to a few days following a possible HIV exposure, may be beneficial in preventing HIV infection.
- Give the patient the *leaflet* containing the “*Guidelines for the Patient*,” describing the modalities of this PEP treatment and its implications, including the urgency for the patient to make a decision on this issue (*since the PEP regimen must start ideally within two (2) hours of exposure, and no later than seventy-two (72) hours after exposure*), as well as the necessity of medical evacuation for a period of four (4) weeks, in order to complete the medical/psychological evaluations and treatments.
- If the patient agrees to start treatment, and after the consent form is signed by the patient, the following is immediately given (from the “post-exposure kit”):
 - *(for female patient only) Pregnancy test*, to exclude an already existing pregnancy which would be a contra-indication to giving the “morning-after” pill and PEP treatment;
 - *(for female patient only) The first tablet* of the “morning-after” pill to be taken orally immediately, and one (1) additional tablet to be taken twelve (12) hours after the first;⁸ and
 - *(for female or male patient) The first doses of the PEP regimen: one tablet of Combivir⁹ twice a day. Combivir is a combined medication of AZT : Zidovudine 300mg and 3TC : Lamuvidine 150mg. The contra-indications for Combivir are the same as those for both AZT and 3TC.*

⁷ For countries where the use of the “morning-after pill” is legally authorized in general or is only legally authorized for specific cases, including rape.

⁸ The date on the stripe of two tablets of Levonorgestrel is the manufacturing date. Tablets expire five years after the manufacturing date.

⁹ The expiry date appears on the pack.

AZT is contra-indicated in patients with chronic renal insufficiency, hepatic insufficiency, bone marrow insufficiency, and in patients being treated with myelosuppressive, hemotoxic or nephrotoxic drugs within two weeks prior to starting AZT. AZT is approved for use during pregnancy *after* 14 weeks of gestation.

3TC is *not* recommended in patients with a history of pancreatitis or a history of peripheral neuropathy. 3TC is *not* indicated at any time during pregnancy.

- Breastfeeding should be discontinued when **Combivir** is taken.
- Explain to patient that the combination of the “morning-after” pill taken with Combivir will give *severe nausea*. The other possible side-effects of **Combivir** is described in the leaflet containing the “Guidelines for the Patient.”
- Write a medical report to the attention of the physician at the site of medical evacuation, indicating the circumstances, initial medical findings and treatments started. *Send a copy* of this report to the attention of the Medical Director of the UN Agency employing the patient.

PEP-01-01A

ANNEX G GUIDELINES FOR THE ATTENDING PHYSICIAN

GUIDELINES FOR THE ATTENDING PHYSICIAN - PEP-01-01B¹⁰

- Offer the patient the possibility of being accompanied during the medical examination by a staff member, friend or counsellor.
- Reassure the patient privacy and confidentiality.
- Record precise time of the incident and of the circumstances.
- In the case of sexual assault, explain to the patient the risk of having been exposed to **STDs, HIV** and the possibility of pregnancy; ***when the HIV status of the perpetrator is not known, decisions are to be made as if the perpetrator were HIV positive.***
- In the case of occupational accident, explain to the patient the potential risk in relation to the type of exposure.
- Explain the possibility of reducing the risk of HIV transmission by taking a ***post-exposure preventive (PEP) treatment***; although the efficacy of taking **AZT/3TC (Combivir)** to prevent HIV transmission following sexual assault is not proven, research studies suggest this regime, taken within a few hours to a few days following a possible HIV exposure, may be beneficial in preventing HIV infection.
- Give the patient the leaflet containing the “Guidelines for the Patient,” describing the modalities of this PEP treatment and its implications, including the urgency for the patient to make a decision on this issue (***since the PEP regimen must start ideally within two (2) hours of exposure, and no later than seventy-two (72) hours after exposure***), as well as the necessity of medical evacuation for a period of four (4) weeks, in order to complete the medical/psychological evaluations and treatments.
- If the patient agrees to start treatment, and after the consent form is signed by the patient, the following is immediately given (from the “post-exposure kit”):
 - ***(for female patient only) Pregnancy test***, to exclude an already existing pregnancy which would be a contra-indication to giving the “morning-after” pill and PEP treatment; and
 - ***(for male or female patient) The first doses of the PEP regimen: one tablet of Combivir twice a day. Combivir¹¹ is a combined medication of AZT : Zidovudine 300mg and 3TC : Lamuvidine 150mg. The contra-indications for Combivir are the same as those for both AZT and 3TC.***

AZT is contra-indicated in patients with chronic renal insufficiency, hepatic insufficiency, bone marrow insufficiency, and in patients being treated with myelosuppressive, hemotoxic or nephrotoxic drugs within two weeks prior to starting AZT. AZT is approved for use during pregnancy **after** 14 weeks of gestation.

¹⁰ For countries where the use of the "morning-after pill" is not legally authorized under any circumstances.

¹¹ The expiry date appears on the pack.

3TC is **not** recommended in patients with a history of pancreatitis or a history of peripheral neuropathy. 3TC is **not** indicated at any time during pregnancy.

- Breastfeeding should be discontinued when **Combivir** is taken.
- The other possible side-effects of **Combivir** is described in the leaflet containing the “Guidelines for the Patient.”
- Write a medical report to the attention of the physician at the site of medical evacuation, indicating the circumstances, initial medical findings and treatments started. **Send a copy** of this report to the attention of the Medical Director of the UN Agency employing the patient.

PEP-01-01B

ANNEX H GUIDELINES FOR THE PATIENT

GUIDELINES FOR THE PATIENT - PEP-01-02A¹²

(In the case of sexual assault):

When you have been sexually assaulted, it is natural to experience feelings of fear, pain, anger, shame, and confusion. In addition, you may ask yourself questions such as:

- What are the chances that I was exposed to sexually transmitted diseases?
- What are the chances that I was exposed to the HIV virus?
- And if you are a woman, what are the chances that I become pregnant?

All these concerns are legitimate, and the UN Physician will assist you in addressing these issues. In order to recommend the best course of action, it is important that this medical doctor be made aware of any chronic/acute medical condition you may have, and of any treatment you might be taking at the time of this initial evaluation.

Pregnancy is always a risk in pre-menopausal women. Fortunately, this risk can be eliminated by taking the so-called “morning-after” pill¹³. This medication is given as follows: one (1) tablet within seventy-two (72) hours of exposure; and a second tablet, twelve (12) hours after the first. This medication is likely to cause severe nausea.

Becoming infected with a sexually transmitted disease is also a possibility. Fortunately again, these diseases are easy to diagnose and to treat. Your Attending Physician, whether at the site of your evacuation, or locally, will take care of these.

We do not know the exact risk of HIV infection following a sexual assault, but it is estimated to be low, probably in the range of less than 1%. However, the chances of being exposed to the HIV virus increase:

- If more than one man sexually assaulted you;
- If you have any torn or damaged skin;
- If the type of assault was an anal assault;
- If you know that the person who assaulted you is HIV positive;
- If you know that the person who assaulted you is an injection drug user; or
- If you do not know the HIV status of the assailant, HIV positivity must be assumed.

(In the case of sexual assault or occupational accident):

¹² For countries where the use of the "morning-after pill" is legally authorized in general or is only legally authorized for specific cases, including rape.

¹³ The date on the stripe of two tablets of Levonorgestrel is the manufacturing date. Tablets expire five years after the manufacturing date.

If you were exposed to the HIV virus, it may be possible to reduce the chances of getting the disease by taking four (4) weeks combination of anti-HIV medication. This medication is called **Combivir**¹⁴ (a combined drug containing both AZT and 3TC). There is no absolute medical proof that the Combivir (AZT/3TC) regimen works, but there is evidence that it *may* help.

This **Combivir** regimen, also referred to as *post exposure prevention (PEP)* regimen, is to be started within two (2) to seventy-two (72) hours after exposure, and *must* continue for four (4) weeks. Because of the potential side-effects of these medications, a medical evacuation to a place with better medical facilities may be necessary, since the follow-up involves laboratory testing and good medical experience in administering these medications.

The contra-indications for **Combivir** are the same as those for both AZT and 3TC.

AZT can give the following symptoms:

diarrhoea	dizziness	fatigue
fever	headaches	insomnia
inflammation of the liver	loss of appetite	vomiting
muscle pains	nausea	

It is believed that such side-effects are less likely in healthy people taking the drug for only four (4) weeks.

3TC can give the following symptoms:

diarrhoea	fatigue	headache
insomnia	mild muscle pains	
stomach pains	nausea	

Very rarely, more serious side-effects can occur with this medication: severe stomach pain with nausea and vomiting; aching, numbness; tingling; burning sensation in legs, hands, feet; skin rash; fever; and/or mouth sores. (These symptoms require immediate medical attention.)

If you decide to take the PEP regimen:

- You will be medically evacuated;
- The UN physician will ask you to sign the consent form indicating your acceptance of the PEP regimen; and
- You will be given enough medications to cover treatment for five (5) days.

This medication is taken as follows:

Combivir : one tablet twice a day.

Take this medication with food but never with alcohol. If you miss a dose, take it as soon as you remember AND take the next dose at its regular scheduled time. A doctor must be consulted before taking any other medications, including over-the counter medications and herbal medicines.

¹⁴ The expiry date appears on the pack.

Combivir can be taken with the “morning-after” pill. You must be aware that the combination of these three medications is likely to cause severe nausea.

Once you have arrived at the site of your evacuation, your Attending Physician will continue your evaluation and treatment, will monitor your progress until completion of the PEP regimen and order laboratory tests as necessary. There will be a need to perform an HIV test at six (6) weeks, twelve (12) weeks, twenty-four (24) weeks, and one year after the exposure.

Unless you indicate otherwise, you will be referred to a psychologist/psychiatrist to address the psychological trauma you have suffered.

PEP-01-02A

ANNEX I GUIDELINES FOR THE PATIENT

GUIDELINES FOR THE PATIENT - PEP-01-02B¹⁵

((In the case of sexual assault):

When you have been sexually assaulted, it is natural to experience feelings of fear, pain, anger, shame, and confusion. In addition, you may ask yourself questions such as:

- What are the chances that I was exposed to sexually transmitted diseases?
- What are the chances that I was exposed to the HIV virus?
- And if you are a woman, what are the chances that I become pregnant?

All these concerns are legitimate, and the UN Physician will assist you in addressing these issues. In order to recommend the best course of action, it is important that this medical doctor be made aware of any chronic/acute medical condition you may have, and of any treatment you might be taking at the time of this initial evaluation.

Pregnancy is a risk in pre-menopausal women. The "morning-after pill" is prohibited by law in the country of your duty station. You may address this issue with your Attending Physician.

Becoming infected with a sexually transmitted disease is also a possibility. Fortunately again, these diseases are easy to diagnose and to treat. Your Attending Physician, whether at the site of your evacuation, or locally, will take care of these.

We do not know the exact risk of HIV infection following a sexual assault, but it is estimated to be low, probably in the range of less than 1%. However, the chances of being exposed to the HIV virus increase:

- If more than one man sexually assaulted you;
- If you have any torn or damaged skin;
- If the type of assault was an anal assault;
- If you know that the person who assaulted you is HIV positive;
- If you know that the person who assaulted you is an injection drug user; or
- If you do not know the HIV status of the assailant, HIV positivity must be assumed.

((In the case of sexual assault or occupational accident):

If you were exposed to the HIV virus, it may be possible to reduce the chances of getting the disease by taking four (4) weeks combination of anti-HIV medication. This medication is called **Combivir**¹⁶ (a combined drug containing both AZT and 3TC). There is no absolute medical proof that the Combivir (AZT/3TC) regimen works, but there is evidence that it may help.

¹⁵ For countries where the use of the "morning-after pill" is not legally authorized under any circumstances.

¹⁶ The expiry date appears on the pack.

This **Combivir** regimen, also referred to as *post exposure prevention (PEP)* regimen, is to be started within two (2) to seventy-two (72) hours after exposure, and **must** continue for four (4) weeks. Because of the potential side-effects of these medications, a medical evacuation to a place with better medical facilities may be necessary, since the follow-up involves laboratory testing and good medical experience in administering these medications.

The contra-indications for **Combivir** are the same as those for both AZT and 3TC.

AZT can give the following symptoms:

diarrhoea	dizziness	fatigue
fever	headaches	insomnia
inflammation of the liver	loss of appetite	vomiting
muscle pains	nausea	

It is believed that such side-effects are less likely in healthy people taking the drug for only four (4) weeks.

3TC can give the following symptoms:

diarrhoea	fatigue	headache
insomnia	mild muscle pains	
stomach pains	nausea	

Very rarely, more serious side-effects can occur with this medication: severe stomach pain with nausea and vomiting; aching, numbness; tingling; burning sensation in legs, hands, feet; skin rash; fever; and/or mouth sores. (These symptoms require immediate medical attention.)

If you decide to take the PEP regimen:

- You will be medically evacuated;
- The UN physician will ask you to sign the consent form indicating your acceptance of the PEP regimen; and
- You will be given enough medications to cover treatment for five (5) days.

This medication is taken as follows: **Combivir** : one tablet twice a day.

Take this medication with food but never with alcohol. If you miss a dose, take it as soon as you remember AND take the next dose at its regular scheduled time. A doctor must be consulted before taking any other medications, including over-the counter medications and herbal medicines.

Once you have arrived at the site of your evacuation, your Attending Physician will continue your evaluation and treatment, will monitor your progress until completion of the PEP regimen, and order laboratory tests as necessary. There will be a need to perform an HIV test at six (6) weeks, twelve (12) weeks, twenty-four (24) weeks, and one year after the exposure.

Unless you indicate otherwise, you will be referred to a psychologist/psychiatrist to address the psychological trauma you have suffered.

ANNEX J
CONSENT TO MEDICAL TREATMENT¹⁷

I, _____ , acknowledge that I have received and read the leaflet
(name of patient)

entitled "Post Exposure Preventive Treatment - Guidelines for the Patient". I also acknowledge
that Dr. _____ has explained the potential benefits, the
(name of attending physician)

limitations, the possible side effects, and the contra-indications of the medications that are being
offered to me. I further acknowledge that Dr. _____ has
(name of attending physician)

explained to me the modalities of the treatments.

Having understood all of the above, I accept to take:
(check mark to be made next to whichever treatment patient is accepting)

the so-called "morning-after pill";

the so-called "post-exposure preventive therapy".

Signature of Patient

Place, date and time

Signature and name of person giving consent on behalf of the Patient
(if patient under age 18 or if patient otherwise unable to give consent)

Place, date and time

Witness (Signature and name)

Place, date and time

PEP-01-03A

¹⁷ For countries where the use of the "morning-after pill" is legally authorized in general or is only legally authorized for specific cases including rape.

**ANNEX K
CONSENT TO MEDICAL TREATMENT¹⁸**

I, _____, acknowledge that I have received and read the
(name of patient)

leaflet entitled “Post Exposure Preventive Treatment - Guidelines for the Patient”. I also
acknowledge that Dr. _____ has explained the potential benefits,
(name of attending physician)

the limitations, the possible side effects, and the contra-indications of the medications that are
being offered to me. I further acknowledge that Dr. _____
(name of attending
physician)

has explained to me the modalities of the treatments.

Having understood all of the above, I accept to take:

the so-called “post-exposure preventive therapy”.

Signature of Patient	Place, date and time
Signature and name of person giving consent on behalf of the Patient (if patient under age 18 or if patient otherwise unable to give consent)	Place, date and time
Witness (Signature and name)	Place, date and time

PEP-01-03B

¹⁸ For countries where the use of the "morning-after pill" is not legally authorized under any circumstances.