

**USF Health Sciences Center  
Health Administration  
Infectious Disease Center  
974-3163**

**Post-Exposure Prophylaxis (PEP) For Healthcare Workers  
Reporting an Occupational Exposure to HIV  
(Updated March 23, 2004)  
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**Post-Exposure Prophylaxis (PEP) For Healthcare Workers  
Reporting an Occupational Exposure to HIV**

**BACKGROUND INFORMATION**

**Occupational Exposure Risk**

The average risk of acquiring HIV infection from a percutaneous (needlestick, sharp) from an HIV-infected patient exposure is 0.3% (1 in 300). However, the risk is increased if the exposure involves a larger volume of blood (i.e. hollow-bore needle, a deep injury, a needle previously placed in the patient's artery or vein) and a source patient with newly acquired HIV or end-stage AIDS. The risk of acquiring HIV infection after a mucous membrane exposure is 0.1% (1 in a 1,000) and for skin exposures less than 0.1%. The risk for skin contact is increased if the blood contact is prolonged, if it involves an area that is extensive or the skin integrity is visibly compromised, and/or if the blood contains a higher HIV viral load.

**Benefits of Treatment**

Currently the CDC recommends post-exposure prophylaxis (PEP) for persons reporting high-risk occupational exposures to HIV. In a CDC case control study, the use of zidovudine PEP was associated with a 79% decrease in the risk of HIV seroconversion after exposure to HIV-infected blood. For HIV exposures with

lower risks, PEP should be offered but the risk must be balanced against the use of drugs having uncertain efficacy and toxicity.

An Infectious Disease physician and/or Health Administration will review the exposure and may recommend the two or three PEP drug protocol. It is advised that the PEP medications be started within 2 hours of exposure and no longer than 24 hours post-exposure. The interval in which PEP is no longer beneficial for humans is undefined, although animal studies suggest that PEP is not effective if started later than 24-36 hours postexposure.

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## **POST-EXPOSURE PROPHYLAXIS MEDICATION INFORMATION**

### **ZIDOVUDINE (Retrovir, AZT) and LAMIVUDINE (Epivir, 3TC)**

Retrovir and Epivir are antiretroviral agents classified as reverse transcriptase inhibitors. Reverse transcriptase inhibitors work by preventing HIV from infecting a cell. Studies have shown that, in HIV-infected patients, combination therapy with Retrovir and Epivir has greater anti-retroviral activity than Retrovir alone and is active against many zidovudine-resistant HIV strains without significantly increasing toxicity.

In a case control study among healthcare workers, use of zidovudine for post-exposure prophylaxis decreased by approximately 79% the risk of HIV seroconversion after percutaneous exposure. In a prospective trial in which zidovudine was administered to HIV-infected pregnant women and their infants, zidovudine prophylaxis may have contributed to a 67% reduction in perinatal HIV transmission. Epivir has been added to Retrovir for postexposure prophylaxis therapy to increase antiretroviral activity and for coverage against many zidovudine resistant strains of HIV.

### **COMBIVIR (300 mg zidovudine and 150 mg lamivudine)**

Combivir combines the two antiretroviral agents, zidovudine and lamivudine into a one tablet formulation for twice daily dosing. Combivir does not require refrigeration and can be taken with or without food.

### **INDINAVIR (Crixivan, IDV)**

Crixivan is a protease inhibitor. Protease inhibitors work by inhibiting the HIV protease enzyme in the cell. If the protease does not function, the HIV virus is assembled into a noninfectious virus which cannot infect other cells. Crixivan reduces the viral load in the body by preventing the reproduction of infectious HIV virus in infected cells.

### **LOPINAVIR/RITONAVIR (Kaletra)**

Lopinavir/Ritonavir (Kaletra) is a boosted protease inhibitor which helps reduce the viral load in the body by inhibiting the HIV protease enzyme within the HIV cell, thereby preventing the reproduction of HIV in infected cells.

Viral load refers to the amount of virus present in the blood. From the onset of infection, HIV reproduces continuously and rapidly. Each day, as many as 2 billion new viruses are produced in the body. At the same time, the immune system produces about 2 billion CD4 cells (T cells) to fight the HIV virus.

Over time, the immune system cannot keep pace with the rapid reproduction of virus that takes place year after year. As a result, viral load levels of HIV increase, CD4 cell counts fall, and the symptoms of AIDS begin to develop. Studies have shown that reductions in viral load are linked to a slower rate of disease progression.

The addition of a protease inhibitor to antiretroviral drug therapy provides greater protection against retroviral activity, especially if zidovudine-resistant strains are present.

The risks of delayed or long-term toxicity, including cancer and adverse effects on pregnancy related to a 30 day combination course of Zidovudine and Efavirenz or Zidovudine, Efavirenz, Indinavir, or Lopinavir/Ritonavir are unknown.

Additional medication may be used upon the discretion of the Infectious Diseases physician as indicated by current CDC recommendations. Health Care Workers will be given information on any additional medication prescribed at the time of consent for treatment.

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## CONTRAINDICATIONS

1. Pregnancy and breast-feeding
2. Severe renal or hepatic insufficiency
3. Severe anemia or immunosuppression

### Adverse Reactions

1. Zidovudine (Retrovir, AZT): In currently recommended doses zidovudine PEP is usually well tolerated by healthcare workers. Possible side effects reported with short-term therapy (under 6 weeks) include fever, muscle aches, gastrointestinal symptoms, fatigue, trouble sleeping and headache.
2. Lamivudine (Epivir, 3TC): The toxicity of Epivir in persons who are not HIV infected is not well known. Possible side effects reported with Epivir taken with Retrovir include headache, malaise, fatigue, nausea, diarrhea, abdominal pain and decreased appetite.
3. Combivir: Combivir is generally well tolerated, with headache, nausea, malaise and fatigue, nasal congestion and rhinitis, diarrhea, low white blood cell counts, and anemia constituting the most common side effects.
4. Indinavir (Crixivan): The toxicity of Crixivan in persons who are not HIV infected is not well known. Possible side effects reported with persons taking Indinavir with Retrovir include nausea, vomiting, diarrhea, abdominal pain, headache and sleeplessness. Kidney stones have been reported during the first four weeks of Indinavir therapy in 0.8% of persons receiving therapy.
5. Lopinavir/Ritonavir (Kaletra) is generally well tolerated but its toxicity in non-HIV infected persons is not well known. Possible side effects include nausea, malaise, diarrhea, and abdominal pain.

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**CONSENT FORM**

I understand that treatment with the post-exposure prophylaxis (PEP) medications is voluntary. If I choose to refuse or discontinue PEP medication, neither my employment nor my treatment will be affected. Refusal to take PEP medications will not affect my Workers Compensation benefits.

(Circle One)

**REFUSAL** I understand that post-exposure prophylaxis medication has been recommended for my occupational exposure to HIV. I have been given the opportunity to ask questions and have read the information on the PEP medication. I refuse to start the PEP medication at this time.

**CONSENT** I have read the information on post-exposure prophylaxis treatment for occupational exposure to HIV. I have been given the opportunity to ask questions concerning PEP treatment and agree to take the prescribed PEP treatment for my exposure.

\*NOTE: Based on limited data, AZT use in the second and third trimesters of pregnancy and early infancy has not been associated with serious adverse effects in mothers or infants; data is limited regarding the safety of AZT during the first trimester of pregnancy or of other antiretroviral agents during pregnancy. Pregnant women are advised to discuss this information with their physician.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Name (Print): \_\_\_\_\_ Department: \_\_\_\_\_

Witness Signature: \_\_\_\_\_

Date of Exposure: \_\_\_\_\_

Date and Time of First Dose of Medication: \_\_\_\_\_

\*References: NEJM 1994; 331:1173-80  
Abstracts of the 35th ICAAC; ASM, 1995; 205  
Revised 12/16/96

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**USF Health Sciences Center  
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**Two-Drug Post-Exposure Prophylaxis (PEP) Protocol**

**TREATMENT INSTRUCTIONS**

**BASIC REGIMEN**

1. Dosage for Two-Drug PEP Protocol is:

Zidovudine (Retrovir) 300 mg (two capsules) two times a day for 30 days  
and  
Lamivudine (Epivir) 150 mg (one tablet) two times a day for 30 days  
**or**  
Combivir (zidovudine 300 mg and lamivudine 150 mg) one tablet two times a day for  
30 days
2. Store the medication in a cool, dry location. Do not refrigerate.
3. Consult Health Administration if you must take any other medication while on the PEP protocol.
4. You may take the medication with food or on an empty stomach. You may take your medication at the same time. A preferred dosing schedule is every 12 hours, (7 a.m. and 7 p.m.).
5. For headaches, muscle aches, low-grade fever, take ibuprofen (Advil) 400 mg every six hours. Call Health Administration if relief is not obtained within two days.
6. For nausea, take a phosphated carbohydrate solution such as Emetrol or Emecheck as directed. Call Health Administration if nausea persists over 48 hours and/or is accompanied by vomiting.
7. If you miss a dose of Epivir, Retrovir, or Combivir take the missed dose as soon as possible. If it is within two hours of your next dose, skip the dose and continue your regular dosing schedule. Do not take two doses at once.
8. Call Dede Craig, Health Administration, 974-3163 or beeper 216-0153 if you have any questions or problems with your treatment.

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**Health Administration  
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**Three-Drug Post-Exposure Prophylaxis (PEP) Protocol**

**TREATMENT INSTRUCTIONS**

**EXPANDED REGIMEN**

1. Dosage for the Three Drug PEP Protocol is as follows:

Zidovudine (Retrovir) 300 mg, two capsules, two times a day for 30 days  
and  
Lamivudine (Epivir) 150 mg, one tablet, two times a day  
and  
Indinavir (Crixivan, IDV) 800 mg, two capsules, three times a day  
**OR**  
Combivir (zidovudine 300 mg and lamivudine 150 mg), one tablet, two times a day  
for 30 days and  
Indinavir (Crixivan, IDV) 800 mg, two capsules, three times a day  
**OR**  
Combivir (zidovudine 300 mg and lamivudine 150 mg), one tablet, two times a day  
for 30 days  
and  
Lopinavir/Ritonavir (Kaletra) 400 mg (Lopinavir 133.3 mg and Ritonavir 33 mg),  
three capsules, two times a day for 30 days
2. Store the medication in a cool, dry location.
3. For best absorption, Crixivan should be taken without food but with water one hour before or two hours after a meal. Alternatively, Crixivan may be taken with other liquids such as skim milk, juice, coffee, tea or with a light meal (i.e. toast with jelly, cereal).
4. While taking Crixivan, you **must drink at least 48 ounces of liquid every day** (i.e. six eight-ounce glasses of water, juice, or other fluid). Notify Health Administration or the Infectious Disease physician on call (after hours) if you develop any flank pain or blood in your urine.
5. If you are taking Crixivan or Kaletra, do not take Seldane, Propulsid, Hismanal, Halcion, Versed or Rifampin. Inform Health Administration or Infectious Disease physician if you are taking ketoconazole (Nizoral) or rifabutin (Mycobutin) while on Crixivan or Kaletra as dose reduction or modification may be necessary.
6. You may take your medications at the same time each day. A suggested dosing schedule for Crixivan is 7 a.m., 3 p.m., and 11 p.m.
7. If you are taking Kaletra instead of Crixivan, it is best absorbed with food and can be taken at the same time as Combivir. The optimal dosing schedule is every 12 hours.

8. If you miss a dose of PEP, take the missed dose(s) as soon as possible. If it is within two hours of your next dose, skip the dose and continue your regular dosing schedule. Do not take two doses at once.
9. For headaches, muscle aches, low-grade fever, take ibuprofen (Advil) 400 mg every six hours. Call Health Administration if relief is not obtained within two days.
10. For nausea, take a phosphated carbohydrate solution such as Emetrol or Emecheck as directed. Call Health Administration if nausea persists over 48 hours and/or is accompanied by vomiting.
11. Call Dede Craig, Health Administration, at 974-3163 or beeper 216-0153 if you have any questions or problems with your treatment.

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## **How to take CRIXIVAN**

**There are six important things you must do to help you benefit from CRIXIVAN**

**Take CRIXIVAN capsules EVERY DAY as prescribed by your doctor.**

Continue taking CRIXIVAN unless your doctor tells you to stop. Take the exact amount of CRIXIVAN that your doctor tells you to take, right from the very start. To help make sure you will benefit from CRIXIVAN, you must not skip doses or take "drug holidays". If you don't take CRIXIVAN as prescribed, the activity of CRIXIVAN may be reduced (due to resistance).

**Take CRIXIVAN capsules every 8 hours around the clock, EVERY DAY.**

It may be easier to remember to take CRIXIVAN if you take it at the same time every day. If you have questions about when to take CRIXIVAN, your doctor or healthcare provider can help you decide what schedule works for you.

**If you miss a dose by more than 2 hours, wait and then take the next dose at the regularly scheduled time.**

However, if you miss a dose by less than 2 hours, take your missed dose immediately. Then take your next dose at the regularly scheduled time. Do not take more or less than your prescribed dose of CRIXIVAN at any one time.

**Take CRIXIVAN with water.**

You can also take CRIXIVAN with other beverages such as skim milk, juice, coffee, or tea.

**Ideally, take each dose of CRIXIVAN without food but with water at least one hour before or two hours after a meal.**

Or you can take CRIXIVAN with a light meal. Examples of light meals include: dry toast with jelly, juice, and coffee (with skim milk and sugar if you want); corn flakes with skim milk and sugar.

Do not take CRIXIVAN at the same time as any meals that are high in calories, fat, and protein (for example, a bacon and egg breakfast). When taken at the same time as CRIXIVAN, these foods can interfere with CRIXIVAN being absorbed into your bloodstream and may lessen its effect.

**Drink at least six 8-ounce glasses of liquids (preferably water)**

**throughout the day, EVERY DAY.**

**CRIXIVAN has caused kidney stones in some patients.**

By having enough fluids in your body, you may help reduce the chances of forming a kidney stone. Call your doctor or other healthcare provider if you develop kidney pains (middle to lower stomach or back pain) or blood in the urine.

**CRIXIVAN®**  
(indinavir sulfate)  
Capsules

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**How should I store CRIXIVAN® (indinavir sulfate) capsules?**

Keep CRIXIVAN capsules in the bottle they came in and at room temperature (59°F-86°F).

Keep CRIXIVAN capsules dry by leaving the small desiccant "pillow" in the bottle. Keep the bottle closed.

This medication was prescribed for your particular condition. DO NOT use it for any other condition or give it to anybody else. Keep CRIXIVAN and all medicines out of the reach of children. If you suspect that more than the prescribed dose of this medicine has been taken, contact your local poison control center or emergency room immediately.

This leaflet provides a summary of information about CRIXIVAN. If you have any questions or concerns about either CRIXIVAN or HIV, talk to your doctor.

**MERCK**

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**USF Health Sciences Center  
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**Regular Business Hours Procedure for Occupational Exposures to HIV  
and  
Post-Exposure Prophylaxis (PEP)**

**HEALTHCARE WORKER RESPONSIBILITIES:**

1. Notify supervisor immediately when incident occurs.
2. Contact Health Administration (Dede Craig) or Infectious Disease physician (John Greene, Office phone: 972-8408; Beeper 216-0153 (Dede) 222-2763 (Dr. Greene).
3. Document incident. Include source patient's name, location, HIV status, if known.

**HEALTH ADMINISTRATION/INFECTIOUS DISEASE PHYSICIAN RESPONSIBILITIES:**

1. Review exposure with healthcare worker to determine exposure risk category.
2. Review information, consent form, and contraindications with exposed healthcare worker.
3. Determine if post-exposure prophylaxis is indicated. If so, discuss Two Drug or Three Drug Protocol with healthcare worker.
4. Instruct healthcare worker to sign consent form. Healthcare worker must sign refusal section of consent form if refusing recommended PEP.
5. Recommend that women of childbearing potential perform a urine HCG test prior to receiving medications.
6. Instruct healthcare worker to report within 72 hours to laboratory (Quest Laboratory at USF Medical Clinic) for baseline labs (HIV, HCV, and HBSAB). A code name will be used for labs. Tests will be charged to Dede Craig's OSHA account.
7. Provide one-week supply of Two Drug or Three Drug Protocol, based on exposure risk.
8. Investigate and request HIV and hepatitis testing of source patient, if possible.
9. Assure completion of Workers Compensation/exposure form.
10. Document health status of exposed healthcare worker.
  - a. Initial Visit
    - 1) Urine pregnancy (if necessary)
    - 2) Baseline HIV Antibody
    - 3) Anti-HCV
    - 4) HbsAb, quantitative
    - 5) CMP, CBC with differential, if PEP given
  - b. One Week Follow-up
    - 1) CMP, CBC with differential, if PEP given

- 2) Three-week supply of two or three drug PEP, if indicated
- c. Four Week Follow-up
  - 1) HCV RNA by PCR, if indicated by Hepatitis C exposure
  - 2) CMP, CBC with differential if PEP given
- d. Three Month (12 weeks) Follow-up
  - 1) HIV antibody
  - 2) Anti-HCV
- e. Six Month Follow-up
  - 1) HIV antibody
  - 2) Anti-HCV
- f. Twelve Month Follow-up
  - 1) HIV antibody
  - 2) Anti-HCV
  - 3) HbsAb, quantitative

Reference: Centers for Disease Control MMWR, May 15, 1998

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**USF Health Sciences Center  
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**Afterhour Procedure for Occupational Exposures to HIV  
and  
Post-Exposure Prophylaxis (PEP)**

**HEALTHCARE WORKER RESPONSIBILITIES:**

1. Notify supervisor immediately when incident occurs. If no supervisor available, page Infectious Disease Fellow on call at 974-2201 (USFPG answering service).
2. Document incident. Include source patient's name, location, HIV status, if known.

**SUPERVISOR/INFECTIOUS DLSEASE FELLOW ON CALL RESPONSIBILITIES**

1. Review exposure with healthcare worker to determine exposure risk category.
2. Review information, consent form, and contraindications with exposed healthcare worker.
3. Determine if post-exposure prophylaxis is indicated. If so, discuss Two Drug or Three Drug Protocol with healthcare worker.
4. Instruct healthcare worker to sign consent form. Healthcare worker must sign refusal section of consent form if refusing recommended PEP.
5. Recommend that women of childbearing potential perform a urine HCG test prior to receiving medications.
6. Instruct healthcare worker to report within 72 hours to laboratory (Quest Laboratory at USF Medical Clinic) for baseline labs (HIV, HCV, HBSAB, CMP, and CBC). A code name will be used for labs. Notify lab that tests

are to be charged to Dede Craig's OSHA account.

7. Provide 72 hour supply of Two Drug or Three Drug Protocol, based on exposure risk.
8. Notify Health Administration (Dede Craig) at work 974-3163, home 286-1608, beeper 216-0153, of exposure at next business day or within 72 hours of exposure.

### **USF HEALTH ADMINISTRATION RESPONSIBILITIES**

1. Investigate and request HIV and hepatitis testing of source patient, if possible.
2. Assure completion of Workers Compensation form.
3. Facilitate follow-up medical care.

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## **BLOODBORNE PATHOGEN EXPOSURE**

### **EXPOSURE CONTACT PERSONS**

|  | <b><u>Hospital Based</u></b>   | <b><u>Non Hospital Setting</u></b>  |
|--|--|---|
| <b><u>Regular Business Hours</u></b>       | <b>Contact Hospital's Employee Health Department</b>   | <b>Contact Dede Craig, ARNP<br/>B. 216-0153<br/>or<br/>John N. Greene, MD<br/>B. 222-2763</b> |
| <b><u>After Regular Business Hours</u></b> | <b>Contact hospital's evening or night nursing supervisor<br/><br/>If no nursing supervisor available, contact Infectious Disease Fellow on call at 974-2201 (USFPG answering service)</b> | <b>Contact Infectious Disease Fellow on call at 974-2201 (USFPG answering service)</b>        |

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