

What is HIV Post-exposure Prophylaxis (HIV PEP)?

- ◆ **Post** = after
- ◆ **Exposure** = coming into contact with HIV
- ◆ **Prophylaxis** = a treatment to stop an infection from happening

HIV PEP is a 28-day treatment of anti-HIV drugs that could stop you from getting HIV. The HIV PEP drugs you will be taking are:

- Combivir® - 1 tablet 2 times a day, with or without food, and
- Kaletra® - 2 tablets 2 times a day, with or without food

These are the HIV PEP drugs used at all Ontario Sexual Assault/Domestic Violence Treatment Centre. However, these are not the only drugs used for HIV PEP. Some hospitals and some doctors use different drugs.

Can anyone go to a Sexual Assault/Domestic Violence Treatment Centre to get HIV PEP?

This program is only for victims/survivors of sexual assault. People that want to take HIV PEP after unsafe sex should talk with their family doctor about starting HIV PEP as soon as possible. If you do not have a family doctor or if they are unavailable, go to the nearest emergency department, or call the Ontario AIDS and Sexual Health Information Line (1-800-668-2437) to help you figure out your options. You should definitely start HIV PEP within 72 hours (3 days).

Why is there a 72-hour (3 day) cut-off for starting HIV PEP?

HIV divides and spreads very fast, as soon as it enters the body. Taking drugs that fight the virus need to be started quickly to stop HIV from infecting too many healthy cells. The earlier it is started the better - the longer you wait to start, the less likely it will work. Research studies have shown that after 72 hours of being exposed to HIV, the virus is strong enough to resist the drugs. This is why you need to start treatment within 72 hours of the assault.

What is available for sexual assault victims/survivors (presenting) after the 72-hour cut-off?

- ◆ If you know that the person who assaulted you is HIV-positive, you will be referred to an HIV doctor.
- ◆ If you are not sure if the assailant is HIV- positive, you will be offered an immediate HIV test. We suggest that you also have HIV tests at 4-6 weeks, 3 months and 6 months after the assault.
- ◆ You will be given a list of places you can contact that provide information about HIV and can offer you ongoing support

Why does HIV PEP last 28 days?

- ◆ HIV experts agree that 28 days is the best length of treatment to give patients the highest chance at avoiding infection after being exposed to HIV.¹
- ◆ Many of the serious side effects people may have when taking HIV PEP medications only happen after long-term use so 28 days is safe for most people.
- ◆ Animal studies show that 28 days of treatment is long enough to stop HIV infection from happening.²

Will I benefit from taking HIV PEP for longer than 28 days?

No, doctors do not think there is extra benefit. In rare cases of extremely high risk, if a person has missed doses of the medications, doctors may decide to prescribe another cycle of HIV PEP. This hardly ever happens.

Will I benefit from taking HIV PEP for less than 28 days?

We don't know if taking HIV PEP for less than 28 days helps prevent HIV.

- ◆ Animal studies show that taking HIV PEP for 3 days does not stop HIV infection.
- ◆ Animal studies also show that taking HIV PEP for 10 days only stops HIV infection sometimes.

Talk to your doctor about how you can deal with side effects. Your doctor can help you take HIV PEP for as long as possible.

Does HIV PEP work?

HIV PEP is not guaranteed to work all of the time. Studies show that if you take HIV PEP, it is a lot less likely that you will get HIV, however some people who take it may still end up with HIV after they are done the drugs.

- ◆ We do know that HIV PEP works when doctors and nurses take it after they are accidentally pricked with a needle. One study showed HIV infection was stopped in 81% of people taking HIV PEP.³
- ◆ We do know that HIV PEP works when you start it as soon as possible. Animal studies show that starting HIV PEP within 24 hours is best.^{2,4}
- ◆ We do know that HIV PEP works when HIV-positive pregnant women take it before and after their babies are born. One study showed HIV infection was stopped in 67% of babies born to HIV-positive mothers.⁵

Using this info, doctors feel that HIV PEP works at the same rates when used after sexual assault.

What is the risk of getting HIV from an assault?

Your risk of getting HIV depends on many factors. Your doctor will help you to weigh your HIV

risk.

The risk of HIV infection depends on:

- 1) If the person who assaulted you is HIV-positive or you know they are at high-risk of being HIV-positive (for example, they use drugs with needles, or have sex with men), and
- 2) What happened during the assault (penetration involving semen (cum), pre-ejaculatory fluid (pre-cum) or blood from the penis entering the vagina, anus and/or mouth)

The risk of getting HIV increases if:

- ◆ The assault caused injuries (especially injuries with blood)
- ◆ You or the person that assaulted you have a sexually transmitted infection (example: chlamydia, gonorrhea)
- ◆ You or the person that assaulted you have open sores on the vagina or penis
- ◆ More than 1 person assaulted you
- ◆ You were penetrated in more than one spot (anus, vagina and/or mouth)

The risk of getting HIV decreases if:

- ◆ There was oral penetration only (no vaginal and no anal penetration)
- ◆ The person that assaulted you did not ejaculate (cum)
- ◆ The person that assaulted you used a condom

It is hard to know if the assailant ejaculated (came) or used condoms. So, these factors only decrease the risk and do not make it zero.

What are the risks of taking HIV PEP (Combivir® and Kaletra®)?

There are two main risks:

1. The potential for side effects to occur; and
2. The potential for HIV in the body to become resistant to some drugs, especially if HIV PEP is not taken properly.

1. Potential for side effects when taking Combivir® and Kaletra®

Most people taking HIV PEP have some form of side effect, like headaches, upset stomach, vomiting, diarrhea and/or being tired. Because of the side effects many people need time off work or school and some have to stop taking HIV PEP. Side effects go away once you stop taking the drugs. In an Ontario study looking at HIV PEP use following sexual assault, 96% of 275 people taking HIV PEP reported some form of side effect. On average each person had 3 different side effects. Fatigue, nausea and vomiting were the most common. Most side effects were mild to moderate. 1.1% reported very severe side effects. You can manage most side effects with over-the-counter remedies, like TUMS®, Gravol®, Aspirin®, Tylenol®, and/or Advil® as well as making changes to your diet, getting extra rest and other temporary lifestyle changes.

More serious side effects are possible, but are not likely to happen in 28 days of treatment. Information that we have on serious side effects is from HIV-positive patients that have used

Combivir® and/or Kaletra® for a long time. While you take HIV PEP you will be followed closely by your doctor.

The more serious side effects of HIV PEP in:

- ◆ Patients who take Combivir®
 - A low red blood cell count (anemia) happens in about 2%
 - A decrease in the number of white blood cells occurs in 4-8%
- ◆ Patients who take Kaletra®
 - Inflammation (swelling) of the pancreas (pancreatitis) is a rare side effect
 - Inflammation (swelling) of the liver (hepatitis) is also a rare side effect, more likely to occur in individuals who already have liver disease

2. *Potential for HIV in the body to become resistant to some drugs*

If HIV PEP is not taken at regular times, following your doctor's orders, it is possible that you could develop a strain of HIV in your body that drugs cannot fight. This is rare and is not likely to happen if HIV PEP is taken as prescribed.

The drugs you are taking (Combivir® and Kaletra®) help to lessen the risk of drug resistance – 3 tablets in the morning + 3 tablets in the evening is easy to remember. Ongoing follow-up counselling also helps to make sure that the medications are taken at the right times.

Does HIV PEP interact with other drugs?

Yes, HIV PEP can interact with some drugs that you may be taking, such as other prescriptions, over-the-counter remedies, herbals, or recreational/street drugs (especially MDMA/ecstasy). It is very important that you talk to your doctor about all drugs you take.

Is it okay to take other routine medications following the assault, such as antibiotics or emergency contraceptives, at the same time as HIV PEP?

Yes, medications to prevent other sexually transmitted infections and pregnancy can be taken at the same time as HIV PEP.

Does HIV PEP decrease the effectiveness of the birth control pill?

Yes, Kaletra® does decrease the effectiveness of the birth control pill. You can take birth control pills while taking HIV PEP but they won't work as well. If you are on the birth control pill, use extra forms of protection (example: condoms) to prevent pregnancy. You will need to do this for the 28 days you are taking HIV PEP and for 2 months afterwards.

Is it okay to take HIV PEP if I am pregnant?

HIV PEP can cause birth defects in the 1st trimester of pregnancy and is often avoided during this period.

- ◆ BUT – if you are at high risk of getting HIV, during the time that HIV divides and spreads throughout your body (this is called seroconversion), your baby is at very high risk of getting HIV too.
- ◆ Giving HIV PEP in this case may be more important than the risk of birth defects.
- ◆ Your doctor can help you decide if you want to take HIV PEP.

What can I do to help swallow the medications?

Thicker liquids and foods (like some juices or pudding) can help to make swallowing the tablets easier. Frozen food (like ice cream or popsicles) may also help to numb your taste buds and make taking the medications easier. You can also break the tablets into pieces and swallow them that way – it often helps if you take them between bites of food. If you keep having trouble swallowing the tablets, talk to your doctor about the possibility of taking your Combivir® and Kaletra® in liquid form instead.

How do I store these drugs at my home?

Combivir® and Kaletra® should be stored at room temperature (20°- 25°C) – nowhere too hot and nowhere too cold. They must be stored in a dry place – do not keep them in your bathroom because of the moisture in the air and changes in room temperature. If you are going to travel, be sure to bring your medications onboard with you as carry-on. Don't travel with your medications in your suitcase because the temperature can change during travel.

What if I miss a dose of HIV PEP?

If it is less than 4 hours until your next dose:

- ◆ Skip the dose you missed, then take your next dose ASAP
- ◆ Restart your regular dosing schedule

If it is more than 4 hours until your next dose:

- ◆ Take the missed dose ASAP
- ◆ Continue the regular dosing schedule

What if I vomit after taking HIV PEP?

If you vomit within 30 minutes of taking HIV PEP, OR if you can see the tablets in your vomit:

- ◆ Repeat the dose

If you vomit more than 30 minutes after taking HIV PEP:

- ◆ Continue your regular dosing schedule

¹ CDC. 2005. Antiretroviral Postexposure Prophylaxis After Sexual, Injection-Drug Use, or Other Non-occupational Exposure to HIV in the United States: Recommendations from the U.S. Department of Health and Human Services. *MMWR*. 54(RR-2): 1-20.

² Tsai CC, Emau P, Follis KE, Beck TW, Benveniste RE, Bischofeberger N, Lifson JD, Morton WR. 1998. Effectiveness of postinoculation (R)-9-(2-phosphonylmethoxypropyl) adenine treatment for prevention of persistent simian immunodeficiency virus SIV_{mac} infection depends critically on timing of initiation and duration of treatment. *Journal of Virology*. 72: 4265–73.

³ Cardo DM, Culver DH, Ciesielski CA, Srivastava PU, Marcus R, Abiteboul D, Heptonstall J, Ippolito G, Lot F, McKibben PS, Bell DM. 1997. A case-control study of HIV seroconversion in health care workers after percutaneous exposure. *New England Journal of Medicine*. 337(21): 1485-90.

⁴ Otten RA, Smith DK, Adams DR, Pullium JK, Jackson E, Kim CN, Jaffe H, Janssen R, Butera S, Folks TM. 2000. Efficacy of postexposure prophylaxis after intravaginal exposure of pig-tailed macaques to a human-derived retrovirus (human immunodeficiency virus type 2). *Journal of Virology*. 74: 9771–5.

⁵ Connor EM, Sperling RS, Gelber R. 1994. Reduction of maternal-infant transmission of human immunodeficiency virus type 1 with zidovudine treatment. Pediatric AIDS Clinical Trials Group Protocol 076 Study Group. *New England Journal of Medicine*. 331(18):1173-1180.