

Guide to taking HIV PEP



Follow-up Visits

You have decided to take HIV PEP. We will be working with you to help you take this medication. Here is a check list of what will happen at each visit.



Initial visit (today)	Date	
<input type="checkbox"/> You will be given one dose of each of the HIV PEP medications to take at the hospital as an early prevention measure (3 tablets in total).		
<input type="checkbox"/> You will be given a 5-day supply of medications to take with you.		
<input type="checkbox"/> You will have blood tests done.		
<input type="checkbox"/> You may have blood taken to be tested for HIV, or to be stored and tested at a later date.		

1st follow-up visit	Date	
within 2 to 4 days (in person)		
<input type="checkbox"/> We will review with you the risk of HIV transmission, how you are feeling about your risk and whether you want to continue the medications.		
<input type="checkbox"/> We will review how to take the drugs and the importance of taking every dose on schedule.		
<input type="checkbox"/> We will discuss any side effects you may be having and how to deal with them.		
<input type="checkbox"/> We will discuss any other drugs/medications you are taking that may interact with HIV PEP medications.		
<input type="checkbox"/> You will be given a 10 day supply of HIV PEP medications.		
<input type="checkbox"/> If not done at the initial visit, you may have blood taken to be tested for HIV, or to be stored and tested at a later date.		

2nd follow-up visit	Date	
1 week after initial visit (in person or by phone)		
<input type="checkbox"/> We will discuss any side effects you may be having and how to deal with them.		

- ☐ We will discuss any problems you may be having with the drug schedule.
- ☐ We will discuss any other drugs/medications you are taking that may interact with HIV PEP medications.

3rd follow-up visit	Date	
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2 weeks after initial visit (in person or by phone)

- ☐ You will be given a 7 day supply of HIV PEP medications.
- ☐ You will have blood tests to check for drug side effects.
- ☐ We will discuss any side effects you may be having and how to deal with them.
- ☐ We will discuss any problems you may be having with the drug schedule.
- ☐ We will discuss any other drugs/medications you are taking that may interact with HIV PEP medications.

4th follow-up visit	Date	
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3 weeks after initial visit (in person)

- ☐ You will be given a 6 day supply of HIV PEP medications.
- ☐ We will discuss any side effects you may be having and how to deal with them.
- ☐ We will discuss any problems you may be having with the drug schedule.
- ☐ We will discuss any other drugs/medications you are taking that may interact with HIV PEP medications.

5th follow-up visit	Date	
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4 weeks after initial visit (in person or by phone)

- ☐ We will review how you are doing and answer your questions.
- ☐ We recommend HIV testing within the next two weeks (4 – 6 weeks after initial visit).
- ☐ We will discuss any problems you may be having with the drug schedule.
- ☐ We will discuss any other drugs/medications you are taking that may interact with HIV PEP medications.

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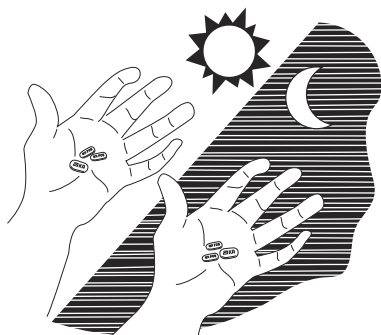
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Introduction

After talking with your Health Care Provider, you have decided to take the HIV Post-exposure prophylaxis (PEP) medications. These drugs reduce your risk of becoming infected by HIV. This booklet gives you more information about the medications you'll be taking. It describes your treatment schedule and gives advice on coping with side effects if they occur.

The three most important things about taking the HIV PEP treatment are:

- 1 Follow the treatment schedule carefully (take 1 Combivir® tablet and 2 Kaletra® tablets two times a day).
- 2 Keep every follow-up appointment with your Health Care Provider.
- 3 Try to answer questions about other drugs and medications.
Talk to us if you think you are pregnant or have other health concerns.



This guide book will help you take HIV PEP to prevent infection. It will help you manage the treatment with as few side effects as possible. Remember, we are here to help you manage the treatment over the next 28 days and answer your questions.

OK, I've decided to take HIV PEP. What happens now?

While you are in the emergency/treatment centre:

- 1 You will receive a 5-day supply of the HIV PEP medications.
- 2 You will look over this booklet with the nurse or doctor.
- 3 We will give you the first dose of each drug (3 tablets in total). The sooner you start, the more likely they will work.
- 4 We will give you more instructions about what to do after you leave the emergency/ treatment centre.
- 5 We will work out a date and time with you for your first follow-up appointment.

What happens after I leave the emergency/treatment centre?

- 1

You will visit your Health Care Provider every week for four weeks (28 days). During this time you will be taking the medicine two times a day, every day. Your visits let us monitor your progress, give you more HIV PEP medications and check for side effects.
- 2

Don't be afraid to ask any questions you may have. Write them down so you won't forget them when you visit your nurse, doctor or pharmacist.
- 3

Consider having your blood tested for HIV right away. We can do the test here or, if you want to have an anonymous test, we can tell you where you can go (if it's available in your area). You and your Health Care Provider will want to know whether or not you were HIV-positive before the assault. Many people who are HIV-positive don't know it. If you are already HIV-positive, you will need a different treatment strategy.
- 4

To check if you are HIV-positive, we recommend that you have a blood test 1 month after the assault. Some people react to the virus more slowly. You should have tests again at 3 and 6 months to be sure. Your Health Care Provider will do this testing or will refer you for anonymous testing.
- 5

There are detailed information pages about each of the drugs at the back of this book. Please read about Combivir® and Kaletra® and ask questions if something isn't clear. These drugs are going to affect your life for the next 28-days. You should know as much as possible about how they work and the side effects you might experience.



Follow Up

Why are there so many follow-up sessions? Can't you just give me all the tablets at once?

It may seem like a lot of visits but they are really important. They let us watch you for any signs of a bad reaction to the drugs. They give you a chance to ask questions you think of later. If you have side effects, we can suggest ways to cope. We can do blood tests to make sure everything is OK. Most people who have been through this say the follow-up visits helped them.

Giving the tablets out in small batches lets us see you regularly. It gives us a chance to check your dose and change your medications to something else if you need to. It also means the tablets won't be wasted if you decide to stop. They will be available for someone else who needs them.

Why is it so important to follow the drug schedule?

Taking the drugs on a regular schedule helps the medicine fight the virus. It keeps a high level of drug in your blood over the whole 28 days. If you take the drugs once in a while or skip doses, some of the virus might survive. You could get infected. During times when there was only a small amount of drug in your blood, some of the virus might get used to the drug. We call this drug resistance. Drug resistant virus has "learned" how to defend itself against the treatment. If the virus in your system became drug resistant, you would not be able to take these drugs later to treat HIV.

That's why it's so important to take the medications on schedule, and not to skip or reduce doses.

What if I miss a dose?

If you do miss a dose, take it as soon as you remember that day. Then continue on your regular schedule. Do not take two doses together. If it is less than 4 hours until the next scheduled dose, don't take the tablets you missed, just return to the regular schedule and try to take the next doses on time.

At your next visit please tell us if you have missed any doses.

If I decide to start, what if I change my mind? What happens if I don't finish the treatment?

That's OK. You can always decide to stop. Some people begin the treatment and stop after a few days, after they have had more time to think about their HIV risk. Other people find the drug schedule or side effects difficult. The nurse or doctor will help you stick with the program if you want to, but no one will force you to continue.

It is important to take these drugs at regular times, according to the schedule we have talked about. If you can't do that it is better to stop, rather than take the medicines less often. If you did become infected, taking the drugs off and on might let the virus become resistant. It is not likely that you will become infected, but if you did you would have fewer options for treatment.

If you are having trouble with the medications, please talk to us. We may have ideas to help you cope. If you decide to stop taking the drugs, it is also a good idea to come in and talk about it first.

Does HIV PEP have side effects?

Yes, side effects can happen. The most common ones are headache, nausea, stomach ache, and diarrhea. You may also feel tired. Some people have a hard time with these symptoms. About half of the people who take the drugs will need to take some time off work or school.

A very small number of people have to stop taking the drugs because of serious reactions or abnormal blood test results. Side effects should go away once you stop taking the drugs.

In Ontario, a study was done with people taking HIV PEP after a sexual assault. It found that, of 275 people taking the medications:

- 96% of people said they had at least one side effect
- On average each person had 3 different side effects. The most common ones were:
 - Nausea (90%),
 - Fatigue (86.5%),
 - Diarrhea (77%)
- About half of all HIV PEP users reported vomiting (53%), headaches (48%) and mood changes (53%).

Other reported side effects included:

- Muscle weakness (38.5%)
- Cough (30%)
- Neuropathy (pain, numbness or tingling in fingers, toes, hands and/or feet) (21%)
- Shortness of breath (19%)

- Fever (15%)
- Constipation (14%)
- Rash (12%)
- Allergic reaction (8%)

Most of these side effects were mild to moderate. Just 4 people (1%) had very serious reactions and had to be taken off HIV PEP.

Health Care Providers working at the SATCs have learned ways to help you manage these side effects. Drugs available in any drugstore like TUMS®, Gravol®, Aspirin®, Tylenol®, and/or Advil®, can help you deal with these symptoms. Changes to diet or temporary changes in your habits can also help.

More serious side effects are possible. People living with HIV who take these drugs take them for a long time. Eventually some of these people do develop serious side effects. These are unlikely in 28 days of treatment. However, while you are taking Combivir® and/or Kaletra® (HIV PEP), we will follow your health closely.

Being assaulted can also cause side effects. Some of these are the same as the side effects of HIV PEP. Headaches, fatigue, loss of appetite and nausea, as well as trouble sleeping are all symptoms reported by people after a sexual assault. Others say they feel confused, have difficulty making decisions or have dramatic changes in mood. None of this is related to HIV PEP, but if you do respond to the assault in these ways your drug side effects may feel worse.

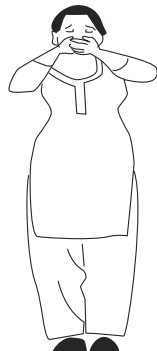
Managing HIV PEP Side Effects

Here are some ideas about managing some common HIV PEP side effects. If you do get any of these symptoms, or have any other problems, we can help you work out how best to deal with them.

Nausea (upset stomach, queasy feeling) and **Vomiting** (throwing up)

Take your drugs with meals to help reduce these problems. Eating slowly can help. Nausea is often worse on an empty stomach, so try to eat small meals every few hours. Sometimes it is the smell of food cooking that bothers you. Dry food (e.g., crackers, granola), cold food, or microwaved food may be easier.

Drink lots of fluids between meals. If you need to rest, try to keep your head propped up higher than your feet. Avoid physical activity immediately after eating. If necessary, take an anti-nausea tablet (e.g., Gravol®) 30-60 minutes before eating. Please talk to us before taking any medications.



Foods to avoid:

Try to avoid milk and dairy products for three days; fried, fatty, greasy and spicy foods; pork, veal, salmon and sardines; raw vegetables such as parsnips, beets, sauerkraut, corn on the cob, cabbage family, onions; citrus fruits: pineapples, oranges, grapefruits, tomatoes; cherries, grapes, figs, currants, raisins, rhubarb, seeded berries; extremely hot or cold beverages; alcohol; coffee and caffeinated sodas.



You may also want to try the BRAT diet (BRAT stands for bananas, rice, apples and toast) to manage nausea, vomiting and/or diarrhea.

What to do if you vomit

First six hours

For six hours after vomiting, don't eat anything. Give your stomach a rest. After one to two hours, suck on a hard candy or popsicle (no chewing). Try ice chips or sips of water if you still feel sick.

First 24 hours (Day 1)

Slowly start clear liquids if the vomiting has stopped, starting with a sip or two every ten minutes. Some options include water, apple juice, flat soda, weak tea, jello (in liquid or gelatin form), broth or bouillon (clear base from non-greasy soup). If nausea or vomiting return, begin the process again, taking nothing by mouth for an hour or so.

First 48 hours (Day 2)

Begin to add bland foods like bananas, rice, applesauce, crackers, cooked cereals (Farina, Cream of Wheat), toast and jelly.

First 72 hours (Day 3)

Move to a "regular" diet by adding things like soft cooked eggs, sherbet, stewed fruits, cooked vegetables, white meat of chicken or turkey.

If you vomit, drink lots of water or liquids to avoid dehydration. Rest and avoid exertion to give your body a chance to recover. Call us about taking any drug to prevent nausea.

Call your Health Care Provider within 48 hours if you can't eat solid foods at all, or if you have symptoms of fever, weight loss, lightheadedness (feeling of faintness), rectal bleeding or abdominal pain or if nausea lasts more than two to three days.

What if I vomit after taking the medications?

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

- Repeat the dose

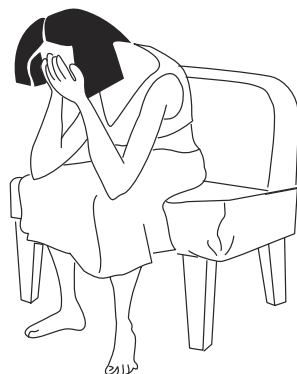
If you vomit more than 30 minutes after taking HIV PEP:

- Continue your regular dosing schedule

Fatigue (feeling tired or having no energy)

People on HIV PEP often feel tired. This can be a drug side effect, but there may also be other causes.

You may be eating less and not getting enough vitamins or minerals. Drug side effects like diarrhea, lack of sleep, pain or muscle weakness can make you tired. Anxiety and depression related to the assault can also cause fatigue.



Listen to what your body is telling you.

Try to adjust your lifestyle, to let you rest. Here are some tips:

Take it easy

Don't try to do everything, decide what's important to do each day and know your limits; schedule activities with "higher energy" times of day; ask others to help (chores, shopping); take frequent breaks; get a good night's sleep.

Try to eat well

Stick to a healthy diet as much as possible, make easy-to-prepare meals; prepare extra portions for freezing

Stay active

Some people find physical activity helps them relieve stress and actually gives them energy; be sure to scale down to lighter exercises (walk instead of jog); consider trying less physical exercises and therapies (such as yoga, tai chi, massage or acupuncture)

Adjust your environment

Change or reduce work hours if necessary; at home and or work, make sure things you need are within easy reach;

Take care of your emotional self

Give yourself the time and space to figure out what you need and how you are feeling; take advantage of your support systems - this can include informal circles like friends or family; we can also refer you to services like counselling and support groups.

Medication to increase physical energy levels or to address emotional health is available. Talk to your Health Care Provider before taking any medication for physical or mental fatigue.

Diarrhea (watery, loose bowel movements)

If you have more bowel movements than usual, or if your stools are loose and watery, you lose a lot of water. Try to eat breads and cereals, peeled fruit and vegetables. Drink 8-10 cups of fluid every day. This works best if you drink between meals. Try to avoid foods or liquids that contain caffeine, alcohol or lots of fat. (See list below.)



Try to Eat/Drink

- ✓ Lower-fibre foods or foods rich in pectin, such as: refined cereals; white bread; buns or bagels; plain white rice or pasta.
- ✓ Lower-fat foods such as: meat with the fat trimmed, skinless chicken breasts, any broiled, baked, roasted, BBQ'd, steamed or microwaved foods with little added fat; eggs; lower-fat cheeses; fish canned in water; foods and drinks that have lots of sodium or potassium (such as broth, sports drinks, bananas and melons).
- ✓ 8-10 cups of liquid per day – better between meals rather than with meals.

Try to Avoid

- ✗ Foods that stimulate the bowels, such as: coffee (including decaffeinated), strong tea, soft drinks; chocolate and cocoa; alcohol; prunes and prune juice; some herbal products; foods with large amounts of sugar (e.g., candies, juices and fruit drinks).
- ✗ High-fibre foods such as: bran and bran cereals; whole grain breads; beans, lentils; corn, peas, berries and grapes; popcorn,

nuts, seeds, dried fruits (like raisins and prunes); vegetables and fruits with seeds and skins.

- ✘ High-fat foods such as bacon, pepperoni, cold cuts, and fried/deep-fried foods.
- ✘ Dairy products can make diarrhea worse. Avoid milk products for a while. When diarrhea settles, try small amounts of Lactaid or Lacteeze milk.

If you have these symptoms your body is losing too much water:

- Very dry mouth.
- Feeling dizzy or weak.
- Urine (pee) is darker yellow than usual.
- Weight loss (more than 2 lbs (1kg) in one week).

Please call us if you notice any of these symptoms. If you notice blood in your stool, you should also let us know.

Headaches (pain, ache or throbbing in the head)

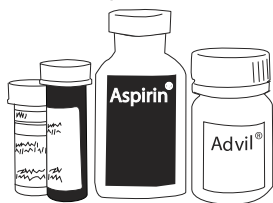
Try to rest. Avoid reading or exercise. Put a cold cloth to your forehead. Over-the-counter pain relievers such as ASA (e.g., Aspirin®) acetaminophen (Tylenol®) and ibuprofen (Motrin® or Advil®) can help.

Talk to your Health Care Provider about which (if

any) pain reliever is best for you. Follow the schedule

on the label and take these pain relievers regularly. Don't wait for the headache to be painful. Alternative therapies such as

acupuncture, acupressure, yoga, meditation, biofeedback, or relaxation tapes can also sometimes help manage headaches.



On your visits, let us know if you are experiencing headaches. Tell us if they change pattern or location.

Rash (skin irritation)

If you get a rash be sure to tell your Health Care Provider. They will want to know the following information: Where is the rash? What does it look like? Is it itchy? Do you have a history of allergies? What have you been doing to manage the rash? When did it start? They may want to see a list of the medications you are taking.

Here are some tips to control a rash and lessen the discomfort:

Try to

- ✓ Drink lots of water;
- ✓ Follow a healthy diet;
- ✓ Take showers or baths less often and use warm (not hot) water;
- ✓ Use lanolin-based (not detergent-based or anti-bacterial) soap (e.g. Jergens naturals), and apply moisturizing cream afterwards; and,
- ✓ Use a humidifier in the bedroom at night to soothe dry skin.



Try to avoid

- ✗ Rubbing and scratching;
- ✗ Over-dressing (it causes sweating); and,
- ✗ Dry, air-conditioned environments.

Antihistamines or Tylenol® (acetaminophen) can sometimes help. Talk to your Health Care Provider before taking any medication. In cases of severe rash, a change in HIV PEP medications may be needed.

A rash combined with a fever, blistering or sores can be very serious. See a doctor right away.

Fever (abnormally high body temperature)

Usually a fever is only treated when it is above 100.4 degrees F (38 degrees C). Fight a fever by drinking slightly warm liquids. Avoid anything that causes shivering (e.g., drafts, sponge baths, ice packs). If you take Tylenol® (acetaminophen), follow the recommended limits on the packaging of 4g per 24 hours (equal to 2 regular Tylenol® every 4 hours). Call your Health Care Provider before taking any medication and if your fever lasts more than 2 days.

WHEN TO CALL THE DOCTOR

At your follow-up appointments, your Health Care Provider will ask you about any problems. These appointments are a chance to tell us about symptoms and check before you start any medication.

If you experience any of the symptoms below, don't wait until your next appointment - contact your Health Care Provider right away. If they cannot be reached, contact your family physician or closest hospital emergency department. If you have any other symptoms that you are worried about, call your Health Care Provider. You can also call Telehealth (1-866-797-0000; TTY: 1-866-797-0007) for immediate, confidential medical advice.

Nausea & vomiting: If you haven't been able to eat solid foods at all for 48 hours (2 days) or if nausea lasts more than two to three days or you have persistent vomiting for over 24 hours or vomiting accompanied by severe headache, dizziness/light-headedness, abdominal pain, or blood.

Fatigue: You are feeling confused or dizzy, have blurred vision or think you might be dehydrated.

Diarrhea with blood in it, or accompanied by sudden weight loss (more than 2 lbs (1 kg) in one week) or symptoms of dehydration, including:

- feeling dizzy or weak;
- urine (pee) is darker yellow than usual; and/or,
- you have lost (more than 2 lbs (1kg) in one week).

Headache:

- that has changed pattern or location;
- accompanied by shortness of breath, fever, and/or unexpected symptoms that affect your eyes, ears, nose, or throat;
- accompanied by dizziness and you are unsteady, or have slurred speech, weakness, or changes in sensation (numbness and/or tingling);
- that makes you feel confused or drowsy; and/or,
- accompanied by persistent or severe vomiting.

A rash combined with a fever, blistering or sores.

A fever that lasts more than 2 days or is higher than 104 degrees F (40 degrees C).

When a person becomes infected with HIV, they usually have flu-like symptoms. This is called a seroconversion reaction. Symptoms included fever, muscle aches, lymph node swelling and possibly a rash. ***If you are experiencing any of these symptoms, contact your Health Care Provider.***

Follow-up HIV testing

Testing for HIV is voluntary. You don't have to take the test. Like all medical care, it is also confidential. However if you want to make sure no one knows, you can chose anonymous testing, where a number or code is used on your lab report. Testing done at your doctor's office or at a clinic requires your name and OHIP info. If you test positive for HIV, the doctor is required by law to report your name, address, date of birth and other personal information to public health authorities. If you want your tests to be anonymous, ask your follow-up nurse if anonymous HIV testing is available in your area and where you can go to get tested.

We recommend that you have follow-up HIV testing 3 times in the next year:

<input type="checkbox"/>	4 - 6 weeks after your first visit	Due Date:
<input type="checkbox"/>	3 months after first visit	Due Date:
<input type="checkbox"/>	6 months after first visit	Due Date:

This may seem like a lot of follow-up tests but HIV can't always be detected right away. If you have been exposed to HIV and the HIV PEP treatment doesn't work to prevent infection, it may have reduced the amount of virus in your blood. In that case, the test might not be positive right away, even if you have been infected. A negative test doesn't necessarily mean that you don't have HIV. It's better to be absolutely sure that you are not infected - the 6-month test is to guarantee that you are free from HIV.

Drug Information - Combivir®

What is Combivir®?

Combivir® is a tablet made up of two different medications - 300 milligrams (mg) of zidovudine and 150 mg of lamivudine (3TC®). They belong to a group of anti-HIV medications called Nucleoside Reverse Transcriptase Inhibitors (NRTIs). NRTIs fight the virus by blocking a protein called 'reverse transcriptase' that HIV needs to make copies of itself.

How is Combivir® taken?

The usual adult dose is one tablet, taken 2 times a day with water or another non-alcoholic drink. If you have trouble swallowing the tablet, you can break it up into pieces; liquid versions of Zidovudine and 3TC® are also available. If you are 12 years old or less and weigh less than 50 kg (110 lbs), your Health Care Provider will give you instructions on a different dosage.

The medications should be stored in a cool, dry place out of reach of children. Do not store them in your bathroom or kitchen because heat and moisture may make them less effective.

Side effects of Combivir®

The two medications that make up Combivir® rarely cause major side effects when used for only 28 days. Possible reactions can be divided into two categories: "up-front" side effects that happen soon after you start the medications and can usually be managed with over the counter medications if necessary; and rare but more severe side effects, that you will be closely monitored for and may require you to change or stop the medications.

Common side effects

The most common side effects of Combivir® are headaches, nausea (upset stomach) and vomiting, and fatigue (feeling tired, weak, no energy). Other less common “up-front” side effects include dizziness, flu-like symptoms such as fever or muscle and joint aches and skin rash.

See page 8 for ways to manage these side effects and when to contact the doctor.

More Severe Side Effects

These side effects rarely occur, especially in short-term (28-day) treatment but they could happen so you should know about them. You will be watched closely for each of these reactions during your follow-up visits while taking Combivir®. If any of these symptoms occur, contact your Health Care Provider.

Anemia (a decrease in red blood cells carrying oxygen): Symptoms include extreme tiredness and a lack of energy (fatigue), shortness of breath, and a pale appearance. Anemia goes away once Combivir® is stopped. Anemia affects about 2% of long-term patients.

Loss of white blood cells: A small drop is not dangerous, but a larger decrease can make you more likely to get infections. Tell your nurse or doctor about any fever, chills, sore throat, mouth sores or burning and discomfort when you urinate (pee). Between 4-8% of long-term patients may experience a significant drop in their white blood cell count.

Muscle-wasting (loss of muscle tissue): Usually happens only after long-term treatment (more than 1 year) but let your nurse or doctor know if you feel a big decrease in your physical strength. About 10% of long-term patients experience muscle-wasting while taking Combivir®.

Peripheral neuropathy (numbness or tingling in hands and feet): Unlikely to occur with short-term treatment but tell your Health Care Provider if you experience this sensation. About 12% of long-term patients experience numbness and/or tingling in hands or feet.

Does Combivir® react with other drugs?

Other medications that you take may be affected by taking zidovudine and may also make it less effective. Zidovudine's side effects may also be worse if you are taking several other drugs.

Tell your Health Care Provider about all medications you are already taking and before you start any other medication (including anything you take to manage side effects). This includes the use of prescriptions, over-the counter medications, street drugs, and herbal or natural products.

What if I have other health issues?

Before taking Combivir®, tell your nurse or doctor about any health conditions or diseases you have been diagnosed with or think you might have, especially involving your kidneys or liver, blood problems or hepatitis. You may need a change to the dosage or you may need to be carefully monitored during treatment.

What if I am pregnant or breastfeeding?

The safety of Combivir® in pregnancy or breastfeeding is not known. If you are or may be pregnant, tell your nurse or doctor. They may refer you to see an expert who specializes in HIV in pregnancy. It is recommended that breastfeeding be stopped while on anti-HIV medication.

For more information on Combivir®: www.combivir.com

What is Kaletra®?

Kaletra® is a tablet containing 200 mg of lopinavir and 50 mg of ritonavir. Lopinavir/ritonavir belongs to a group of drugs called protease inhibitors (PIs). Lopinavir is the active anti-HIV ingredient that slows HIV's ability to copy itself. Ritonavir is added to boost the amount of lopinavir in the blood stream.

How is Kaletra® taken?

The usual adult dose is two tablets 2 times a day (a total of 4 tablets each day), swallowed with water or a non-alcoholic drink. If you are 12 years old or less and weigh less than 50 kg (110 lbs), your Health Care Provider will give you instructions on a different dosage.

Kaletra® can be taken either with or without food. Some people have found taking Kaletra® with food reduces the likelihood of an upset stomach.

If you have trouble swallowing the tablet, ask your Health Care Provider about the possibility of liquid Kaletra®.

The drug should be stored in a cool, dry place out of reach of children. Do not store it in your bathroom or kitchen because heat and moisture may make it less effective.

Side effects of Kaletra®

Common side effects

The most common side effects associated with Kaletra® are ***diarrhea*** and ***nausea*** (upset stomach with or without ***vomiting***). Less common side effects include ***skin rash***, ***intestinal gas*** and ***bloating***, and ***headache***.

See page 8 for ways to manage these side effects.

Another side effect that is rare in short-term therapy but is possible is called lipodystrophy (abnormal changes in fat distribution on your

body). It can involve either a build-up of fat, (usually in the stomach and breasts), or a loss of fat (most often in the face, arms and legs or buttocks). It will go away when you stop taking Kaletra®.

More severe side effects

These side effects are rare but they could happen. You will be watched closely for each of these during your follow-up visits while taking Kaletra®. ***If symptoms relating to any of these side effects occur, contact your Health Care Provider.***

Pancreatitis (inflammation/swelling of the pancreas): Pancreatitis may be linked with large increases in the amount of fat (triglycerides) in your blood. The pancreas is the organ in your body that makes insulin and the enzymes which help you to digest food. If untreated, pancreatitis can cause death. So even though you will be monitored during your follow-up visits, call your doctor immediately if you have any of these symptoms between visits: severe nausea, pain that may spread to your back, or vomiting.

Hepatitis (liver inflammation): More likely to occur in people who already have liver disease (such as Hepatitis C), but possible for others as well. Symptoms include loss of appetite, nausea and vomiting, darkening of the urine, jaundice and pale stools (bowel movements).

Does Kaletra® react with other drugs?

Kaletra® is broken down by the liver and can interact with other drugs that also use the liver. Drugs to be particularly careful about include some anti-allergy drugs (anti-histamines), sedatives, drugs that lower blood cholesterol, and some antibiotic and anti-fungal drugs.

Tell your Health Care Provider about all medications you are currently taking and before you start any new medication. This includes herbal and naturopathic remedies, prescriptions, over-the-counter medications and street drugs.

Some drugs should not be taken at all with Kaletra® and others should be taken cautiously so your Health Care Provider will review a list with you to make sure there won't be any problems. Some medications can be stopped for the duration of the treatment but others are necessary for your health and should be continued. If there is a risk of a bad interaction, your Health Care Provider may recommend that you take Combivir® only.

What if I am taking birth control pills?

Kaletra® makes the birth control pill less effective. If you are on the birth control pill, keep taking your pills as usual but also use another form of protection, such as condoms and contraceptive foam, or diaphragm and contraceptive gel, to prevent becoming pregnant while taking Kaletra®. Continue to use the other forms of protection for up to two months after you finish taking Kaletra®.

Kaletra® does not interfere with emergency contraceptives such as Plan B® or Ovral®.

What if I am pregnant or breastfeeding?

The safety of Kaletra® in pregnancy or breastfeeding is unknown. If you are or may be pregnant, tell your Health Care Provider. They may consult with or refer you to see an expert in the field of HIV in pregnancy. It is recommended that you not breastfeed when taking Kaletra®.

What if I have other health issues?

Before taking Kaletra®, tell your Health Care Provider if you have diabetes, liver problems, or hemophilia. You may not be able to take Kaletra® if you have these conditions; or, you may need a change to the dosage or careful monitoring during treatment.

For more information on Kaletra®: www.kaletra.com

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Notes

