

MEDICATION GUIDE

Abacavir and Lamivudine (a-BAK-a-vir and la-MIV-ue-deen) Tablets USP

Rx Only

What is the most important information I should know about Abacavir and Lamivudine Tablets?

Abacavir and Lamivudine Tablets can cause serious side effects, including

- **Serious allergic reactions (hypersensitivity reaction)** that can cause death have happened with abacavir and lamivudine tablets and other abacavir-containing products. Your risk of this allergic reaction is much higher if you have a gene variation called HLA-B*5701. Your healthcare provider can determine with a blood test if you have this gene variation.

If you get a symptom from 2 or more of the following groups while taking abacavir and lamivudine tablets, call your healthcare provider right away to find out if you should stop taking abacavir and lamivudine tablets.

	Symptom(s)
Group 1	Fever
Group 2	Rash
Group 3	Nausea, vomiting, diarrhea, abdominal (stomach area) pain
Group 4	Generally ill feeling, extreme tiredness, or achiness
Group 5	Shortness of breath, cough, sore throat

A list of these symptoms is on the Warning Card your pharmacist gives you. **Carry this Warning Card with you at all times.**

If you stop abacavir and lamivudine tablets because of an allergic reaction, never take abacavir and lamivudine tablets or any other abacavir-containing medicine (TRIUMEQ®, TRIZIVIR® or ZIAGEN®) again.

- If you have an allergic reaction, dispose of any unused abacavir and lamivudine tablets. Ask your pharmacist how to properly dispose of medicines.
- If you take abacavir and lamivudine tablets or any other abacavir-containing medicine again after you have had an allergic reaction, **within hours** you may get **life-threatening symptoms** that may include **very low blood pressure or death**.
- If you stop abacavir and lamivudine tablets for any other reason, even for a few days, and you are not allergic to abacavir and lamivudine tablets, talk with your healthcare provider before taking it again. Taking abacavir and lamivudine tablets again can cause a serious allergic or life-threatening reaction, even if you never had an allergic reaction to it before.

If your healthcare provider tells you that you can take abacavir and lamivudine tablets again, start taking it when you are around medical help or people who can call a healthcare provider if you need one.

- **Build-up of acid in your blood (lactic acidosis).** Lactic acidosis can happen in some people who take abacavir and lamivudine tablets. Lactic acidosis is a serious medical emergency that can cause death. **Call your healthcare provider right away if you get any of the following symptoms that could be signs of lactic acidosis:**
 - feel very weak or tired
 - unusual (not normal) muscle pain
 - trouble breathing
 - stomach pain with nausea and vomiting
 - feel cold, especially in your arms and legs
 - feel dizzy or light-headed
 - have a fast or irregular heartbeat
- **Serious liver problems** can happen in people who take abacavir and lamivudine tablets. In some cases, these serious liver problems can lead to death. Your liver may become large (hepatomegaly) and you may develop fat in your liver (steatosis). **Call your healthcare provider right away if you get any of the following signs or symptoms of liver problems:**
 - your skin or the white part of your eyes turns yellow (jaundice)
 - dark or “tea-colored” urine
 - light colored stools (bowel movements)
 - loss of appetite for several days or longer
 - nausea
 - pain, aching, or tenderness on the right side of your stomach area

You may be more likely to get lactic acidosis or serious liver problems if you are female, very overweight (obese), or have been taking nucleoside analogue medicines for a long time.

- **Worsening of hepatitis B virus in people who have HIV-1 infection.** If you have HIV-1 and hepatitis B virus (HBV) infection, your HBV may get worse (flare-up) if you stop taking abacavir and lamivudine tablets. A “flare-up” is when your HBV infection suddenly returns in a worse way than before. Worsening liver disease can be serious and may lead to death
 - Do not run out of abacavir and lamivudine tablets. Refill your prescription or talk to your healthcare provider before your abacavir and lamivudine tablets is all gone.
 - Do not stop abacavir and lamivudine tablets without first talking to your healthcare provider.
 - If you stop taking abacavir and lamivudine tablets, your healthcare provider will need to check your health often and do blood tests regularly for several months to check your liver.
- **Resistant Hepatitis B Virus (HBV).** If you have HIV-1 and hepatitis B, the hepatitis B virus can change (mutate) during your treatment with abacavir and lamivudine tablets and become harder to treat (resistant).
- **Use with interferon and ribavirin-based regimens.** Worsening of liver disease that has caused death has happened in people infected with both HIV-1 and hepatitis C virus who

are taking antiretroviral medicines and are also being treated for hepatitis C with interferon with or without ribavirin. If you are taking abacavir and lamivudine tablets and interferon with or without ribavirin tell your healthcare provider if you have any new symptoms.

What is Abacavir and Lamivudine Tablet?

Abacavir and lamivudine tablet is a prescription HIV-1 (Human Immunodeficiency Virus-type 1) medicine used with other antiretroviral medicines to treat HIV-1 infection. HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS). Abacavir and lamivudine tablet contains 2 prescription medicines, abacavir (ZIAGEN) and lamivudine (EPIVIR®).

Abacavir and lamivudine tablets should not be used in children weighing less than 55 pounds (25 kg).

When used with other antiretroviral medicines to treat HIV-1 infection, abacavir and lamivudine tablet may help:

- reduce the amount of HIV-1 in your blood. This is called “viral load”.
- increase the number of CD4+ (T) cells in your blood, that help fight off other infections.

Reducing the amount of HIV-1 and increasing the CD4+ (T) cells in your blood may help improve your immune system. This may reduce your risk of death or getting infections that can happen when your immune system is weak (opportunistic infections).

Abacavir and lamivudine tablet does not cure HIV-1 infection or AIDS. You must keep taking HIV-1 medicines to control HIV-1 infection and decrease HIV-related illnesses.

Who should not take Abacavir and Lamivudine Tablets?

Do not take abacavir and lamivudine tablets if you:

- have a certain type of gene variation called the HLA-B*5701 allele. Your healthcare provider will test you for this before prescribing treatment with abacavir and lamivudine tablet.
- are allergic to abacavir or any of the ingredients in abacavir and lamivudine tablets. See the end of this Medication Guide for a complete list of ingredients in abacavir and lamivudine tablets.
- have liver problems.

What should I tell my healthcare provider before taking Abacavir and Lamivudine Tablets?

Before you take abacavir and lamivudine tablets tell your healthcare provider if you:

- have been tested and know whether or not you have a particular gene variation called HLA-B*5701.
- have or have had liver problems, including hepatitis B or C virus infection.
- have kidney problems.
- have heart problems, smoke, or have diseases that increase your risk of heart disease such as high blood pressure, high cholesterol, or diabetes.
- drink alcohol or take medicines that contain alcohol.
- are pregnant or plan to become pregnant. Talk to your healthcare provider if you are pregnant or plan to become pregnant.

Pregnancy Registry. There is a pregnancy registry for women who take antiretroviral medicines during pregnancy. The purpose of this registry is to collect information about

the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry.

- are breastfeeding or plan to breastfeed. **Do not breastfeed if you take abacavir and lamivudine tablets.**
 - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Some medicines interact with abacavir and lamivudine tablets. **Keep a list of your medicines to show your healthcare provider and pharmacist.** You can ask your healthcare provider or pharmacist for a list of medicines that interact with abacavir and lamivudine tablets. **Do not start taking a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take abacavir and lamivudine tablets with other medicines.

Tell your healthcare provider if you take:

- any other medicine to treat HIV-1
- medicines to treat hepatitis viruses such as interferon or ribavirin
- methadone

How should I take Abacavir and Lamivudine Tablets?

- **Take abacavir and lamivudine tablets exactly as your healthcare provider tells you.**
- Do not change your dose or stop taking abacavir and lamivudine tablets without talking with your healthcare provider. If you miss a dose of abacavir and lamivudine tablets, take it as soon as you remember. Do not take 2 doses at the same time. If you are not sure about your dosing, call your healthcare provider.
- Stay under the care of a healthcare provider while taking abacavir and lamivudine tablets.
- Abacavir and lamivudine tablets may be taken with or without food.
- Tell your healthcare provider if your child has trouble swallowing abacavir and lamivudine tablets.
- Do not run out of abacavir and lamivudine tablets. The virus in your blood may increase and the virus may become harder to treat. When your supply starts to run low, get more from your healthcare provider or pharmacy
- If you take too much abacavir and lamivudine tablets, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of Abacavir and Lamivudine Tablets?

- **Abacavir and lamivudine tablets can cause serious side effects including:**
- **See “What is the most important information I should know about abacavir and lamivudine tablets?”**
- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider right away if you start having new symptoms after you start taking abacavir and lamivudine tablets.
- **Changes in body fat** can happen in people who take HIV-1 medicines. These changes may include an increased amount of fat in the upper back and neck (“buffalo hump”),

breast, and around the middle of your body (trunk). Loss of fat from the legs, arms, and face may also happen. The exact cause and long-term health effects of these conditions are not known.

- **Heart attack (myocardial infarction).** Some HIV-1 medicines including abacavir and lamivudine tablets may increase your risk of heart attack.

The most common side effects of abacavir and lamivudine tablets include:

- trouble sleeping
- depression
- headache
- tiredness
- dizziness
- nausea
- diarrhea
- rash
- fever

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of abacavir and lamivudine tablets. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effect to Lupin Pharmaceuticals, Inc. at 1-800-399-2561.

How should I store Abacavir and Lamivudine Tablets?

Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F).

Keep abacavir and lamivudine tablets and all medicines out of the reach of children.

General information for safe and effective use of abacavir and lamivudine tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use abacavir and lamivudine tablets for a condition for which it was not prescribed. Do not give abacavir and lamivudine tablets to other people, even if they have the same symptoms that you have. It may harm them.

If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for the information about abacavir and lamivudine tablets that is written for healthcare professionals.

For more information, go to www.lupinpharmaceuticals.com or call Lupin Pharmaceuticals, Inc. at 1-800-399-2561 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

What are the ingredients in Abacavir and Lamivudine Tablets?

Active ingredients: abacavir sulfate and lamivudine

Inactive ingredients: crospovidone, magnesium stearate, microcrystalline cellulose, and povidone. The tablets are coated with a film that is made of FD&C Yellow No. 6, hypromellose, polyethylene glycol, polysorbate and titanium dioxide.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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