

MEDICATION GUIDE
Abacavir, Lamivudine and Zidovudine Tablets
(a-BAK-a-vir, la-MIV-ue-deen, zye-DOE-vue-deen)

What is the most important information I should know about abacavir, lamivudine and zidovudine tablets?

Abacavir, lamivudine and zidovudine tablets can cause serious side effects, including:

- **Serious allergic reactions (hypersensitivity reaction)** that can cause death have happened with abacavir, lamivudine and zidovudine 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, lamivudine and zidovudine tablets, call your healthcare provider right away to find out if you should stop taking abacavir, lamivudine and zidovudine 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, lamivudine and zidovudine tablets because of an allergic reaction, never take abacavir, lamivudine and zidovudine tablets or any other abacavir-containing medicine (EPZICOM[®], TRIUMEQ[®], or ZIAGEN[®]) again.

- If you have an allergic reaction, dispose of any unused abacavir, lamivudine and zidovudine tablets. Ask your pharmacist how to properly dispose of medicines.
- If you take abacavir, lamivudine and zidovudine 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, lamivudine and zidovudine tablets for any other reason, even for a few days, and you are not allergic to abacavir, lamivudine and zidovudine tablets, talk with your healthcare provider before taking it again. Taking abacavir, lamivudine and zidovudine 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, lamivudine and zidovudine tablets again, start taking it when you are around medical help or people who can call a healthcare provider if you need one.

- **Blood problems.** Zidovudine (RETROVIR[®]), one of the medicines in abacavir, lamivudine

and zidovudine tablets, can cause serious blood cell problems. These include reduced numbers of white blood cells (neutropenia) and extremely reduced numbers of red blood cells (anemia). These blood cell problems are especially likely to happen in people with advanced human immunodeficiency virus type 1 (HIV-1) disease or AIDS. Your healthcare provider should check your blood cell counts regularly during treatment with abacavir, lamivudine and zidovudine tablets.

- **Muscle pain or weakness (myopathy)** can happen during treatment with abacavir, lamivudine and zidovudine tablets. Zidovudine (RETROVIR®), one of the medicines in abacavir, lamivudine and zidovudine tablets, can cause muscle pain or weakness when used for a long time.
- **Build-up of acid in your blood (lactic acidosis).** Lactic acidosis can happen in some people who take abacavir, lamivudine and zidovudine 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, lamivudine and zidovudine 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 or very overweight (obese).

- **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, lamivudine and zidovudine tablets. A “flare-up” is when your HBV infection suddenly returns in a worse way than before. Worsening liver disease is serious and may lead to death.
 - Do not run out of abacavir, lamivudine and zidovudine tablets. Refill your prescription or talk to your healthcare provider before your abacavir, lamivudine and zidovudine tablets are all gone.
 - Do not stop abacavir, lamivudine and zidovudine tablets without first talking to your healthcare provider.
 - If you stop taking abacavir, lamivudine and zidovudine 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, lamivudine and zidovudine 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, lamivudine and zidovudine tablets and interferon with or without ribavirin, tell your healthcare provider if you have any new symptoms.

What are abacavir, lamivudine and zidovudine tablets?

Abacavir, lamivudine and zidovudine tablet is a prescription HIV-1 (Human Immunodeficiency Virus type 1) medicine used alone or with other antiretroviral medicines to treat HIV-1 infection. HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS). Abacavir, lamivudine and zidovudine tablet contains 3 prescription medicines, abacavir (ZIAGEN[®]), lamivudine (EPIVIR[®]) and zidovudine (RETROVIR[®]).

Abacavir, lamivudine and zidovudine tablets should not be used in children weighing less than 88 pounds (40 kg).

Do not take abacavir, lamivudine and zidovudine 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, lamivudine and zidovudine tablets.
- are allergic to abacavir or any of the ingredients in abacavir, lamivudine and zidovudine tablets. See the end of this Medication Guide for a complete list of ingredients in abacavir, lamivudine and zidovudine tablets.
- have liver problems.

What should I tell my healthcare provider before taking abacavir, lamivudine and zidovudine tablets?

Before you take abacavir, lamivudine and zidovudine 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 low blood cell counts (bone marrow problem). Ask your healthcare provider if you are not sure.
- 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, lamivudine and zidovudine 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, lamivudine and zidovudine tablets. Keep a list of your medicines to show your healthcare provider and pharmacist when you get a new medicine. You can ask your healthcare provider or pharmacist for a list of medicines that interact with abacavir, lamivudine and zidovudine 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, lamivudine and zidovudine tablets with other medicines.

How should I take abacavir, lamivudine and zidovudine tablets?

- **Take abacavir, lamivudine and zidovudine tablets exactly as your healthcare provider tells you to take it.**
- If you miss a dose of abacavir, lamivudine and zidovudine tablets, take it as soon as you remember. Do not take 2 doses at the same time or take more than your healthcare provider tells you to take.
- Stay under the care of a healthcare provider during treatment with abacavir, lamivudine and zidovudine tablets.
- Abacavir, lamivudine and zidovudine tablets may be taken with or without food.
- Tell your healthcare provider if you or your child has trouble swallowing abacavir, lamivudine and zidovudine tablets.
- Do not run out of abacavir, lamivudine and zidovudine 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, lamivudine and zidovudine tablets, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of abacavir, lamivudine and zidovudine tablets?

- **Abacavir, lamivudine and zidovudine tablets can cause serious side effects including:**
- **See “What is the most important information I should know about abacavir, lamivudine and zidovudine 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, lamivudine and

zidovudine tablets.

- **Loss of body fat** can happen in people who take HIV-1 medicines that contain zidovudine. This loss of fat may occur in the legs, arms, buttocks, and face. The loss of fat may be permanent and long-term health effects are not known.
- **Heart attack (myocardial infarction).** Some HIV-1 medicines including abacavir, lamivudine and zidovudine tablets may increase your risk of heart attack.

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

- nausea
- headache
- weakness or tiredness
- vomiting

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, lamivudine and zidovudine 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.

How should I store abacavir, lamivudine and zidovudine tablets?

- Store abacavir, lamivudine and zidovudine tablets at 59°F to 86°F (15°C to 30°C).

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

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

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

You can ask your healthcare provider or pharmacist for the information about abacavir, lamivudine and zidovudine tablets that is written for health professionals.

For more information go to www.lupinpharmaceuticals.com or call 1-800-399-2561.

What are the ingredients in abacavir, lamivudine and zidovudine tablets?

Active ingredients: abacavir, lamivudine and zidovudine

Inactive ingredients: crospovidone, magnesium stearate, microcrystalline cellulose, povidone, and yellow ferric oxide.

Tablet film coating contains: opadry green made of FD&C blue no. 2, polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide and yellow ferric oxide.

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

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Revised: September 2018

ID#: 256360