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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.

- **Worsening of hepatitis B virus (HBV) infection.** If you have HBV infection and take abacavir and lamivudine tablets, 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.
 - Do not run out of abacavir and lamivudine tablets. Refill your prescription or talk to your healthcare provider before your abacavir and lamivudine tablets are 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 function and monitor your HBV infection. It may be necessary to give you a medicine to treat HBV. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking abacavir and lamivudine tablets.
- **Resistant HBV.** If you have human immunodeficiency virus-1 (HIV-1) and HBV, the HBV can change (mutate) during your treatment with abacavir and lamivudine tablets and become harder to treat (resistant).
- **For more information about side effects, see “What are the possible side effects of abacavir and lamivudine tablets?”**

What is Abacavir and Lamivudine Tablet?

Abacavir and lamivudine tablet is a prescription medicine used with other HIV-1 medicines to treat HIV-1 infection.

HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS).

Abacavir and lamivudine tablet contains the prescription medicines, abacavir and lamivudine.

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

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, lamivudine, 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 certain liver problems.

Before you take Abacavir and Lamivudine Tablets tell your healthcare provider about all of your medical conditions, including 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.
- are pregnant or plan to become pregnant.

Pregnancy Registry. There is a pregnancy registry for women who take HIV-1 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 when you get a new medicine.**

- 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.

How should I take Abacavir and Lamivudine Tablets?

- **Take abacavir and lamivudine tablets exactly as your healthcare provider tells you to take it.**
- 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 or take more than your healthcare provider tells you to take.
- Stay under the care of a healthcare provider during treatment with 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?”**
 - **Too much lactic acid in your blood (lactic acidosis).** 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
- **Severe liver problems.** In some cases, severe 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 overweight (obese)

- **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.
- **Heart attack.** 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:

- | | |
|------------------------|-------------------------|
| • allergic reactions | • tiredness or weakness |
| • trouble sleeping | • dizziness |
| • depression | • nausea |
| • headache or migraine | • diarrhea |

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. 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 abacavir and lamivudine tablets at room temperature.

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.

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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