

## MEDICATION GUIDE

### EPZICOM<sup>®</sup> (ep' zih com) Tablets

**Generic name:** abacavir (uH-BACK-ah-veer) sulfate and lamivudine (la-MIV-yoo-deen)

Read the Medication Guide that comes with EPZICOM before you start taking it and each time you get a refill because there may be new information. This information does not take the place of talking to your doctor about your medical condition or your treatment. Be sure to carry your EPZICOM Warning Card with you at all times.

#### **What is the most important information I should know about EPZICOM?**

- **Serious Allergic Reaction to Abacavir.** EPZICOM contains abacavir (also contained in ZIAGEN<sup>®</sup> and TRIZIVIR<sup>®</sup>). Patients taking EPZICOM may have a serious allergic reaction (hypersensitivity reaction) that can cause death. Your risk of this allergic reaction is much higher if you have a gene variation called HLA-B\*5701 than if you do not. Your doctor 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 EPZICOM, call your doctor right away to determine if you should stop taking this medicine.

	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.

**If you stop EPZICOM because of an allergic reaction, NEVER take EPZICOM (abacavir sulfate and lamivudine) or any other abacavir-containing medicine (ZIAGEN and TRIZIVIR) again.** If you take EPZICOM 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 EPZICOM for any other reason, even for a few days, and you are not allergic to EPZICOM, talk with your doctor before taking it again.** Taking EPZICOM again can cause a serious allergic or life-threatening reaction, even if you never had an allergic reaction to it before. If your doctor tells you that you can take EPZICOM again, **start taking it when you are around medical help or people who can call a doctor if you need one.**

- **Lactic Acidosis. Some human immunodeficiency virus (HIV) medicines, including EPZICOM, can cause a rare but serious condition called lactic acidosis with liver enlargement (hepatomegaly).** Nausea and tiredness that don't get better may be symptoms of lactic acidosis. In some cases this condition can cause death. Women, overweight people, and people who have taken HIV medicines like EPZICOM for a long time have a higher chance of getting lactic acidosis and liver enlargement. Lactic acidosis is a medical emergency and must be treated in the hospital.
- **Worsening of hepatitis B virus (HBV) infection.** Patients with HBV infection, who take EPZICOM and then stop it, may get “flare-ups” of their hepatitis. “Flare-up” is when the disease suddenly returns in a worse way than before. If you have HBV infection, your doctor should closely monitor your liver function for several months after stopping EPZICOM. You may need to take anti-HBV medicines.
- **Use with interferon- and ribavirin-based regimens.** Worsening of liver disease (sometimes resulting in death) has occurred in patients infected with both HIV and hepatitis C virus who are taking anti-HIV medicines and are also being treated for hepatitis C with interferon with or without ribavirin. If you are taking EPZICOM as well as interferon with or without ribavirin and you experience side effects, be sure to tell your doctor.

EPZICOM can have other serious side effects. Be sure to read the section below entitled “What are the possible side effects of EPZICOM?”

### **What is EPZICOM?**

EPZICOM is a prescription medicine used to treat HIV infection. EPZICOM includes 2 medicines: abacavir (ZIAGEN) and lamivudine or 3TC (EPIVIR<sup>®</sup>). See the end of this Medication Guide for a complete list of ingredients in EPZICOM. Both of these medicines are called nucleoside analogue reverse transcriptase inhibitors (NRTIs). When used together, they help lower the amount of HIV in your blood. This helps to keep your immune system as healthy as possible so that it can help fight infection.

Different combinations of medicines are used to treat HIV infection. You and your doctor should discuss which combination of medicines is best for you.

- **EPZICOM does not cure HIV infection or AIDS.** We do not know if EPZICOM will help you live longer or have fewer of the medical problems that people get with HIV or AIDS. It is very important that you see your doctor regularly while you are taking EPZICOM.
- **EPZICOM does not lower the risk of passing HIV to other people through sexual contact, sharing needles, or being exposed to your blood.** For your health

and the health of others, it is important to always practice safe sex by using a latex or polyurethane condom or other barrier method to lower the chance of sexual contact with semen, vaginal secretions, or blood. Never use or share dirty needles.

### **Who should not take EPZICOM?**

**Do not take EPZICOM if you:**

- **have ever had a serious allergic reaction (a hypersensitivity reaction) to EPZICOM or any other medicine that has abacavir as one of its ingredients (TRIZIVIR and ZIAGEN). See the end of this Medication Guide for a complete list of ingredients in EPZICOM.**
- **have a liver that does not function properly.**
- **are less than 18 years of age.**

**Before starting EPZICOM tell your doctor 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.**
- **are pregnant or planning to become pregnant.** We do not know if EPZICOM will harm your unborn child. You and your doctor will need to decide if EPZICOM is right for you. If you use EPZICOM while you are pregnant, talk to your doctor about how you can be on the Antiviral Pregnancy Registry for EPZICOM.
- **are breastfeeding.** Some of the ingredients in EPZICOM can be passed to your baby in your breast milk. It is not known if they could harm your baby. Also, mothers with HIV should not breastfeed because HIV can be passed to the baby in the breast milk.
- **have liver problems including hepatitis B virus infection.**
- **have kidney problems.**
- **have heart problems, smoke, or suffer from diseases that increase your risk of heart disease such as high blood pressure, high cholesterol, or diabetes.**

**Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Especially tell your doctor if you take any of the following medicines<sup>a</sup>:**

- **methadone**
- **HIVID<sup>®</sup> (zalcitabine, ddC)**

**EPIVIR or EPIVIR-HBV<sup>®</sup> (lamivudine, 3TC), ZIAGEN (abacavir sulfate), COMBIVIR<sup>®</sup> (lamivudine and zidovudine), or TRIZIVIR (abacavir sulfate, lamivudine, and zidovudine)**

### **How should I take EPZICOM?**

- **Take EPZICOM by mouth exactly as your doctor prescribes it.** The usual dose is 1 tablet once a day. Do not skip doses.
- **You can take EPZICOM with or without food.**

- **If you miss a dose of EPZICOM, take the missed dose right away. Then, take the next dose at the usual time.**
- **Do not let your EPZICOM run out.**
- **Starting EPZICOM again can cause a serious allergic or life-threatening reaction, even if you never had an allergic reaction to it before.** If you run out of EPZICOM even for a few days, you must ask your doctor if you can start EPZICOM again. If your doctor tells you that you can take EPZICOM again, start taking it when you are around medical help or people who can call a doctor if you need one.
- **If you stop your anti-HIV drugs, even for a short time, the amount of virus in your blood may increase and the virus may become harder to treat.**
- **If you take too much EPZICOM, call your doctor or poison control center right away.**

#### **What should I avoid while taking EPZICOM?**

- **Do not take EPIVIR (lamivudine, 3TC), COMBIVIR (lamivudine and zidovudine), ZIAGEN (abacavir sulfate), or TRIZIVIR (abacavir sulfate, lamivudine, and zidovudine) while taking EPZICOM. Some of these medicines are already in EPZICOM.**
- **Do not take zalcitabine (HIVID, ddC) while taking EPZICOM.**
- **Avoid doing things that can spread HIV infection, as EPZICOM does not stop you from passing the HIV infection to others.**
- **Do not share needles or other injection equipment.**
- **Do not share personal items that can have blood or body fluids on them, like toothbrushes and razor blades.**
- **Do not have any kind of sex without protection.** Always practice safe sex by using a latex or polyurethane condom or other barrier method to lower the chance of sexual contact with semen, vaginal secretions, or blood.
- **Do not breastfeed.** EPZICOM can be passed to babies in breast milk and could harm the baby. Also, mothers with HIV should not breastfeed because HIV can be passed to the baby in the breast milk.

#### **What are the possible side effects of EPZICOM?**

**EPZICOM can cause the following serious side effects:**

- **Serious allergic reaction that can cause death.** (See “What is the most important information I should know about EPZICOM?” at the beginning of this Medication Guide.)
- **Lactic acidosis with liver enlargement (hepatomegaly) that can cause death.** (See “What is the most important information I should know about EPZICOM?” at the beginning of this Medication Guide.)
- **Worsening of HBV infection.** (See “What is the most important information I should know about EPZICOM?” at the beginning of this Medication Guide.)

- **Changes in immune system.** When you start taking HIV medicines, your immune system may get stronger and could begin to fight infections that have been hidden in your body, such as pneumonia, herpes virus, or tuberculosis. If you have new symptoms after starting your HIV medicines, be sure to tell your doctor.
- **Changes in body fat.** These changes have happened in patients taking antiretroviral medicines like EPZICOM. The changes may include an increased amount of fat in the upper back and neck (“buffalo hump”), breast, and around the back, chest, and stomach area. Loss of fat from the legs, arms, and face may also happen. The cause and long-term health effects of these conditions are not known.

Some HIV medicines including EPZICOM may increase your risk of heart attack. If you have heart problems, smoke, or suffer from diseases that increase your risk of heart disease such as high blood pressure, high cholesterol, or diabetes, tell your doctor.

The most common side effects with EPZICOM are trouble sleeping, depression, headache, tiredness, dizziness, nausea, diarrhea, rash, fever, stomach pain, abnormal dreams, and anxiety. Most of these side effects did not cause people to stop taking EPZICOM.

This list of side effects is not complete. 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 EPZICOM?**

- Store EPZICOM at room temperature between 59° to 86°F (15° to 30°C).
- Keep EPZICOM and all medicines out of the reach of children.

#### **General information for safe and effective use of EPZICOM**

Medicines are sometimes prescribed for conditions that are not mentioned in Medication Guides. Do not use EPZICOM for a condition for which it was not prescribed. Do not give EPZICOM to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about EPZICOM. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for the information that is written for healthcare professionals or call 1-888-825-5249.

#### **What are the ingredients in EPZICOM?**

**Active ingredients:** abacavir sulfate and lamivudine

**Inactive ingredients:** Each film-coated EPZICOM Tablet contains the inactive ingredients magnesium stearate, microcrystalline cellulose, and sodium starch glycolate. The tablets are coated with a film (OPADRY® orange YS-1-13065-A) that is made of FD&C Yellow No. 6, hypromellose, polyethylene glycol 400, polysorbate 80, and titanium dioxide.

*This Medication Guide has been approved by the US Food and Drug Administration.*

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