

MEDICATION GUIDE

EPZICOM® (ep' zih com)

(abacavir sulfate and lamivudine)

Tablets

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

is the most important information I should know about EPZICOM?

- 1. Serious allergic reaction (hypersensitivity reaction).** EPZICOM contains abacavir (also contained in ZIAGEN® and TRIZIVIR®). 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. 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 EPZICOM, call your healthcare provider right away to find out if you should stop taking EPZICOM.

	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 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 healthcare provider 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 healthcare provider tells you that you can take EPZICOM again, start taking it when you are around medical help or people who can call a healthcare provider if you need one.

- 2. Lactic Acidosis (buildup of acid in the blood).** Some human immunodeficiency virus (HIV) medicines, including EPZICOM, can cause a rare but serious condition called lactic acidosis. Lactic acidosis is a serious medical emergency that can cause death and must be treated in the hospital.
- 3. Serious liver problems.** Some people who have taken medicines like EPZICOM have developed serious liver problems called hepatotoxicity, with liver enlargement (hepatomegaly) and fat in the liver (steatosis). Hepatomegaly with steatosis is a serious medical emergency that can cause death.

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)
- your urine turns dark
- your bowel movements (stools) turn light in color
- you don't feel like eating food for several days or longer
- you feel sick to your stomach (nausea)
- you have lower stomach area (abdominal) pain

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

4. 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 healthcare provider.

5. If you have HIV and hepatitis B virus infection, your hepatitis B virus infection may get worse if you stop taking EPZICOM.

- Take EPZICOM exactly as prescribed.
- Do not run out of EPZICOM.
- Do not stop EPZICOM without talking to your healthcare provider.

Your healthcare provider should monitor your health and do regular blood tests to check your liver if you stop taking EPZICOM.

What is EPZICOM?

EPZICOM is a prescription medicine used to treat HIV infection. EPZICOM contains 2 medicines: abacavir (ZIAGEN) and lamivudine or 3TC (EPIVIR®). 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.

- **EPZICOM does not cure HIV infection or AIDS.**
- It is not known 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 healthcare provider regularly while you are taking EPZICOM.
- It is not known if EPZICOM is safe or effective in children under the age of 18.

Who should not take EPZICOM?

Do not take EPZICOM if you:

- **are allergic to abacavir or any of the ingredients in EPZICOM. See the end of this Medication Guide for a complete list of ingredients in EPZICOM.**
- **have certain liver problems**

What should I tell my healthcare provider before taking EPZICOM?

Before you take EPZICOM 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 hepatitis B virus infection or have other liver problems**
- **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.** It is not known if EPZICOM will harm your unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant.

Pregnancy Registry. If you take EPZICOM while you are pregnant, talk to your healthcare provider about how you can take part in the Pregnancy Registry for EPZICOM. The purpose of the pregnancy registry is to collect information about the health of you and your baby.

- **are breastfeeding or plan to breastfeed.** EPZICOM can pass into your breast milk. You should not breastfeed if you are taking EPZICOM. If you are a woman who has or will have a baby while taking EPZICOM, talk to your healthcare provider about the best way to feed your baby. The Center for Disease Control and Prevention (CDC) recommend that HIV-infected mothers **not** breastfeed to avoid the risk of passing HIV infection to your baby.

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

Especially tell your healthcare provider if you take:

- alcohol
- medicines used to treat hepatitis viruses such as interferon or ribavirin.
- methadone
- ATRIPLA[®] (efavirenz, emtricitabine, and tenofovir)
- COMBIVIR[®] (lamivudine and zidovudine)
- EMTRIVA[®] (emtricitabine)

- EPIVIR or EPIVIR-HBV® (lamivudine, 3TC)
- TRIZIVIR (abacavir sulfate, lamivudine, and zidovudine)
- TRUVADA® (emtricitabine and tenofovir)
- ZIAGEN (abacavir sulfate)

Ask your healthcare provider if you are not sure if you take one of the medicines listed above.

EPZICOM may affect the way other medicines work, and other medicines may affect how EPZICOM works.

Know the medicines you take. Keep a list of your medicines with you to show to your healthcare provider and pharmacist when you get a new medicine.

How should I take EPZICOM?

- **Take EPZICOM exactly as your healthcare provider tells you to take it.**
- EPZICOM may be taken with or without food.
- Do not skip doses.
- **Do not let your EPZICOM run out.**

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 healthcare provider or poison control center or go to the nearest hospital emergency room right away

What are the possible side effects of EPZICOM?

- **EPZICOM can cause serious side effects including allergic reactions, lactic acidosis, and liver problems. See “What is the most important information I should know about EPZICOM?”**
- **Changes in immune system (Immune Reconstitution Syndrome).** 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 if you start having new or worse symptoms of infection after you start taking EPZICOM.
- **Changes in body fat (fat redistribution).** Changes in body fat (lipoatrophy or lipodystrophy) can happen in some people taking antiretroviral medicines including EPZICOM.

These changes may include:

- more fat in or around your trunk, upper back and neck (buffalo hump), breast, or chest

- loss of fat in your legs, arms, or face
- **Heart attack (myocardial infarction).** Some HIV medicines including EPZICOM may increase your risk of heart attack.

The most common side effects of EPZICOM 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 EPZICOM. 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 EPZICOM?

Store EPZICOM at 59°F to 86°F (15°C to 30°C).

Keep EPZICOM and all medicines out of the reach of children.

General information for safe and effective use of EPZICOM.

EPZICOM does not stop you from spreading HIV to other people by sex, sharing needles, or being exposed to your blood. Talk with your healthcare provider about safe sexual practices that protect your partner. Never share needles. Do not share personal items that can have blood or body fluids on them, like toothbrushes or razor blades.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. 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 healthcare provider. You can ask your healthcare provider or pharmacist for the information about EPZICOM that is written for healthcare professionals.

For more information go to www.EPZICOM.com or call 1-877-844-8872.

What are the ingredients in EPZICOM?

Active ingredients: abacavir sulfate and lamivudine

Inactive ingredients: magnesium stearate, microcrystalline cellulose, sodium starch glycolate, and OPADRY® orange YS-1-13065-A, a film coating made of FD&C Yellow No. 6, hypromellose, polyethylene glycol 400, polysorbate 80, and titanium dioxide.

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Manufactured for:



ViiV Healthcare

Research Triangle Park, NC 27709

by:



GlaxoSmithKline

Research Triangle Park, NC 27709

Lamivudine is manufactured under agreement from

Shire Pharmaceuticals Group plc

Basingstoke, UK

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

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