Epzicom

WHAT IS EPZICOM?

Epzicom is a drug used as part of antiretroviral therapy (ART). Epzicom contains two antiretroviral drugs (ARVs) combined in one tablet:

- abacavir (ABC, Ziagen)
- lamivudine (3TC, Epivir)

The FDA approved Epzicom in 2004 as an ARV for people with HIV infection. Generic versions have been approved for sale under the President's Emergency Plan for AIDS Relief (PEPFAR). Epzicom is manufactured by ViiV Healthcare.

The drugs in Epzicom, abacavir and lamivudine, are both nucleoside reverse transcriptase inhibitors (NRTIs). NRTIs bind to and block reverse transcriptase (an HIV enzyme). HIV uses reverse transcriptase to convert its RNA into DNA (reverse transcription). Blocking reverse transcriptase and reverse transcription prevents HIV from replicating.

When used in combination with other ARVs to treat HIV infection, Epzicom may help:

- Reduce the amount of HIV in your blood. This is called viral load.
- Increase the number of CD4 cells in your blood that help fight off other infections.

Reducing the amount of HIV and increasing the CD4 cells in your blood may help improve your immune system. This may reduce your risk of death or getting opportunistic infections (OIs) that can happen when your immune system is weak. Read more about viral suppression.

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

WHO SHOULD TAKE EPZICOM?

Epzicom is a two-drug fixed-dose combination medication that is used in combination with other ARVs to treat HIV infection in adults and children who weigh at least 55 pounds (25 kg).

The safety and effectiveness of Epzicom has not been established in children who weigh less than 55 pounds (25 kg). Epzicom has not been carefully studied in the elderly (65 years of age and older).

All people living HIV should be on ART to keep healthy AND not transmit the virus to others. You and your healthcare provider should consider your CD4 cell count, your viral load, any symptoms you are having, and your preferences when deciding which HIV medications are right for you. Read more about U.S. ART guidelines.

Epzicom provides two drugs in one pill. It can be more convenient to use Epzicom than some other combinations of drugs that must be taken separately or at different times of the day. This could mean fewer missed doses and better control of HIV. **Epzicom is used in combination with other ARVs for the treatment of HIV infection.**

WHO SHOULD NOT TAKE EPZICOM?

Do not take Epzicom if you are allergic to abacavir, lamivudine, or any of the ingredients in this drug.

Do not take Epzicom if 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 Epzicom.

Epzicom is not recommended in people with severe kidney disease or moderate to severe liver disease.

WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING EPZICOM?

Before you take Epzicom, tell your healthcare provider about all of your medical conditions, and in particular 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 virus (HBV) or hepatitis C virus (HCV) 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

Talk to your healthcare provider if you are pregnant, you plan to become pregnant, you become pregnant, or think you may be pregnant during treatment with Epzicom. There is a pregnancy registry for people who take ARVs during pregnancy. The purpose of this registry is to collect information about the health of you and your baby and monitor outcomes in people exposed to ARVs during pregnancy. Talk to your healthcare provider about how you can take part in this registry. Read more about pregnancy and HIV.

Talk to your healthcare provider if you are breastfeeding or plan to breastfeed during treatment with Epzicom. Do not breastfeed if you have HIV because of the risk of passing HIV to your baby. Talk with your healthcare provider about the best way to feed your baby.

WHAT ABOUT DRUG RESISTANCE?

Many new copies of HIV are mutations. These new copies are slightly different from the original virus. Some mutations can keep multiplying even when you are taking an ARV. When this happens, the drug will stop working. This is called developing resistance to the drug. Sometimes, if your virus develops resistance to one ARV, it will also have resistance to other ARVs. This is called cross-resistance. Read more about HIV drug resistance.

Resistance can develop quickly. It is very important to take ARVs according to instructions, on schedule, and not to skip or reduce doses.

HOW IS EPZICOM TAKEN?

Epzicom is taken by mouth as a tablet. Each Epzicom tablet contains 600 mg of abacavir and 300 mg of lamivudine. The recommended dosage of Epzicom for adults and children who weigh at least 55 pounds (25 kg) is one tablet once daily.

Take Epzicom at the same time each day with or without food.

You need to take Epzicom in combination with other ARVs. Your healthcare provider will tell you what medicines to take and how to take them.

WHAT ARE THE SIDE EFFECTS?

When you start any ARV, you may have temporary side effects such as headaches, nausea, indigestion, or a general sense of feeling ill. These side effects usually get better or disappear over time.

The most common side effects of Epzicom are allergic reactions, trouble sleeping, depression, headache or migraine, tiredness or weakness, dizziness, nausea, and diarrhea.

Epzicom can cause serious side effects, including:

Serious allergic reactions (hypersensitivity reaction). Serious allergic reactions (hypersensitivity reactions) that can cause death have happened with Epzicom 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 this test comes back positive, you should add Epzicom to the list of medications you are allergic to.

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:

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 or any other abacavir-containing medicine (Ziagen, Triumeq, Trizivir) again. If you have an allergic reaction, dispose of any unused Epzicom. Ask your pharmacist how to properly dispose of medicines. 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.

Worsening of HBV infection. If you have HBV infection and take Epzicom, your HBV may get worse (flare-up) if you stop taking Epzicom. A flare-up is when your HBV infection suddenly returns in a worse way than before. Do not run out of Epzicom. Refill your prescription or talk to your healthcare provider before your Epzicom is all gone. Do not stop Epzicom without first talking to your healthcare provider. If you stop taking Epzicom, 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 Epzicom.

Resistant HBV. If you have HIV and HBV, the HBV can change (mutate) during your treatment with Epzicom and become harder to treat (resistant).

Too much lactic acid in your blood (lactic acidosis). Lactic acidosis is a serious but rare medical emergency that can cause death. Tell your healthcare provider right away if you develop any of these symptoms:

- 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 rare cases, severe liver problems can happen that can lead to death. Your liver may become large (hepatomegaly) and you may develop fat in your liver (steatosis) when you take abacavir. Tell your healthcare provider right away if you get these symptoms:

- 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 or vomiting
- 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 assigned female at birth (AFAB) or are very overweight (obese).

Immune Reconstitution Inflammatory Syndrome (IRIS). IRIS is a side effect that can happen when you start taking HIV medications. Your immune system might get stronger and begin to fight infections that have been hidden in your body for a long time. This may result in an inflammatory response which may require further evaluation and treatment. Tell your healthcare provider right away if you experience any new symptoms after starting Epzicom.

Heart attack (myocardial infarction). Some HIV medicines including Epzicom may increase your risk of heart attack.

These are not all the possible side effects of Epzicom. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

HOW DOES EPZICOM REACT WITH OTHER DRUGS?

All ARVs can interact with other drugs or supplements you are taking. These interactions can change the amount of each drug in your bloodstream and cause an under- or overdose. New interactions are constantly being identified. **Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Your healthcare provider can tell you if it is safe to take Epzicom with other medicines.

Research studies have identified drug interactions between abacavir and the following drugs: methadone and riociguat (Adempas). For some people taking abacavir-containing medicines such as Epzicom, an increased methadone dose may be required. For some people taking abacavir, the riociguat dose may need to be reduced.

MORE INFORMATION

Download the full Prescribing Information, including the Patient Information leaflet.

Check out the ViiV Healthcare Patient Assistance Program.

Get a ViiV Healthcare Savings Card.

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