

MEDICATION GUIDE

TRIZIVIR® (TRY-zih-veer) Tablets

Generic name: abacavir sulfate, lamivudine, and zidovudine

Read the Medication Guide that comes with Trizivir 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 Trizivir Warning Card with you at all times.

What is the most important information I should know about Trizivir?

- **Serious Allergic Reaction to Abacavir.** Trizivir contains abacavir (also contained in Ziagen® and Epzicom™). Patients taking Trizivir may have a serious allergic reaction (hypersensitivity reaction) that can cause death. **If you get a symptom from 2 or more of the following groups while taking Trizivir, stop taking Trizivir and call your doctor right away.**

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

- **Blood problems.** Retrovir®, one of the medicines in Trizivir, 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 patients with advanced HIV disease or AIDS. Your doctor should be checking your blood cell counts regularly while you are taking Trizivir. This is especially important if you have advanced HIV or AIDS. This is to make sure that any blood cell problems are found quickly.

- **Lactic Acidosis.** Some HIV medicines, including Trizivir, 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 Trizivir 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 Trizivir 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 Trizivir. You may need to take anti-HBV medicines.
- **Muscle weakness (myopathy).** Retrovir, one of the medicines in Trizivir, can cause muscle weakness. This can be a serious problem.
- **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 Trizivir as well as interferon with or without ribavirin and you experience side effects, be sure to tell your doctor.

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

What is Trizivir?

Trizivir is a prescription medicine used to treat HIV infection. Trizivir includes 3 medicines: Ziagen (abacavir), Epivir[®] (lamivudine or 3TC), and Retrovir[®] (zidovudine, AZT, or ZDV). See the end of this Medication Guide for a complete list of ingredients in Trizivir. All 3 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 it can 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.

- **Trizivir does not cure HIV infection or AIDS.** We do not know if Trizivir 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 Trizivir.
- **Trizivir 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 Trizivir?

Do not take Trizivir if you:

- **have ever had a serious allergic reaction (a hypersensitivity reaction) to Trizivir or any other medicine (Ziagen, Epzicom) that has abacavir as an ingredient.** See the end of this Medication Guide for a complete list of ingredients in Trizivir. If you have had such a reaction, return all of your unused Trizivir to your doctor or pharmacist.
- **have a liver that does not function properly**
- **are an adolescent who weighs less than 90 pounds.**

Before starting Trizivir, tell your doctor about all your medical problems, including if you:

- **are pregnant or planning to become pregnant.** We do not know if Trizivir will harm your unborn child. You and your doctor will need to decide if Trizivir is right for you. If you use Trizivir while you are pregnant, talk to your doctor about how you can be on the Antiviral Pregnancy Registry for Trizivir.
- **are breastfeeding.** Some of the ingredients in Trizivir 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 low blood cell counts (bone marrow problem).** Ask your doctor if you are not sure.

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:

- **methadone**
- **trimethoprim (TMP/sulfamethoxazole [SMX] [Bactrim[®], Septra[®]])**
- **ganciclovir (Cytovene[®], DHPG)**
- **interferon-alfa**
- **doxorubicin (Adriamycin[®])**
- **ribavirin (Copegus[®], Rebetol[®], Virazole[®])**
- **any bone marrow suppressive medicines or cytotoxic medicines.** Ask your doctor if you are not sure.
- **any of the following anti-HIV medicines: Combivir[®] (lamivudine and zidovudine), Emtriva[™] (emtricitabine), Epivir or Epivir-HBV[®] (lamivudine, 3TC), Epzicom (abacavir sulfate and lamivudine), Hivid[®] (zalcitabine, ddC), Retrovir (zidovudine, AZT, or ZDV), Truvada[®] (emtricitabine and tenofovir), Zerit[®] (stavudine, d4T), or Ziagen (abacavir sulfate).**

How should I take Trizivir?

Take Trizivir by mouth exactly as your doctor prescribes it. The usual dosage is 1 tablet twice a day. Do not skip doses.

- **You can take Trizivir with or without food.**
- **If you miss a dose of Trizivir, take the missed dose right away.** Then, take the next dose at the usual scheduled time.
- **Do not let your Trizivir run out.** If you stop your anti-HIV medicines, even for a short time, the amount of virus in your blood may increase and the virus may become harder to treat.

- **Starting Trizivir again can cause a serious allergic reaction or life-threatening reaction, even if you have never had an allergic reaction to it before.** If you run out of Trizivir even for a few days, you must ask your doctor if you can start Trizivir again. If your doctor tells you that you can take Trizivir again, start taking it when you are around medical help or people who can call a doctor if you need one.
- **If you take too much Trizivir, call your doctor or poison control center right away.**

What should I avoid while taking Trizivir?

Do not take **Combivir** (lamivudine and zidovudine), **Epivir** (lamivudine, 3TC), **Epzicom** (abacavir sulfate and lamivudine), **Retrovir** (zidovudine, AZT, or ZDV), or **Ziagen** (abacavir sulfate) while taking Trizivir. These medicines are already in Trizivir.

Avoid doing things that can spread HIV infection, as Trizivir 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.** Some of the medicines in Trizivir 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 Trizivir?

Trizivir can cause the following serious side effects. See "What is the most important information I should know about Trizivir?" at the beginning of this Medication Guide.

- **Serious allergic reaction that can cause death.**
- **Lactic acidosis with liver enlargement (hepatomegaly) that can cause death.**
- **Blood problems.**
- **Muscle weakness.**
- **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 Trizivir. 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.

The most common adverse events ($\geq 5\%$) of at least moderate intensity associated with the use of Trizivir include nausea, headache, weakness or tiredness, vomiting, hypersensitivity reaction, diarrhea, fever and/or chills, depression, muscle and joint pain, skin rashes, ear/nose/throat infections, cold symptoms, and nervousness.

This list of side effects is not complete. Ask your doctor or pharmacist for more information.

How should I store Trizivir?

- Store Trizivir between 59° to 86°F (15° to 30°C).
- **Keep Trizivir and all medicines out of the reach of children.**

General information for safe and effective use of Trizivir

Medicines are sometimes prescribed for conditions that are not mentioned in Medication Guides. Do not use Trizivir for a condition for which it was not prescribed. Do not give Trizivir 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 Trizivir. 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 Trizivir?

Active ingredients: abacavir sulfate, lamivudine, and zidovudine

Inactive ingredients: Each film-coated Trizivir Tablet contains the inactive ingredients magnesium stearate, microcrystalline cellulose, and sodium starch glycolate. The tablets are coated with a film (Opadry® green 03B11434) that is made of FD&C Blue No. 2, hypromellose, polyethylene glycol, titanium dioxide, and yellow iron oxide.



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

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WARNING CARD

TRIZIVIR® (abacavir sulfate, lamivudine, and zidovudine) Tablets

Patients taking Trizivir may have a serious allergic reaction (hypersensitivity reaction) that can cause death. If you get a symptom from 2 or more of the following groups while taking Trizivir, stop taking Trizivir and call your doctor right away.

	Symptom(s)
Group 1	Fever
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Group 4	Generally ill feeling, extreme tiredness, or achiness

Group 5	Shortness of breath, cough, or sore throat
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Always carry this Warning Card with you to help recognize symptoms of this allergic reaction.

(Back of Card)

WARNING CARD

TRIZIVIR® (abacavir sulfate, lamivudine, and zidovudine) Tablets

If you must stop treatment with Trizivir because you have had an allergic reaction to abacavir, **NEVER** take Trizivir or any other abacavir-containing medicine (Ziagen®, Ezicom) again. . If you take Trizivir or another 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. You should return all of your unused Trizivir to your doctor or pharmacist for proper disposal.

Please read the Medication Guide for additional information on Trizivir.

Date of Issue

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