- **Do not breastfeed. Lamivudine and zidovudine are excreted in human breast milk. It is not known if abacavir can be passed to your baby in your breast milk and whether it could harm your baby. Also, mothers with HIV-1 should not breastfeed because HIV-1 can be passed to the baby in the breast milk.**

Patients should be informed to take all HIV medications exactly as prescribed.

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

TRZ:PI

MEDICATION GUIDE

TRIZIVIR® (TRY-zih-veer)

(abacavir sulfate, lamivudine, and zidovudine)

Tablets

Read this Medication Guide before you start taking TRIZIVIR 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 TRIZIVIR Warning Card with you at all times.

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

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

	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 TRIZIVIR because of an allergic reaction, never take TRIZIVIR (abacavir sulfate, lamivudine, and zidovudine) or any other abacavir-containing medicine (ZIAGEN and 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 TRIZIVIR, talk with your healthcare provider before taking it again. Taking TRIZIVIR 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 TRIZIVIR again, start taking it when you are around medical help or people who can call a healthcare provider if you need one.

2. **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 human immunodeficiency virus (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.

3. **Lactic Acidosis (buildup of acid in the blood). Some human immunodeficiency virus (HIV) medicines, including TRIZIVIR, 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.**

   Call your healthcare provider right away if you get any of the following signs or symptoms of lactic acidosis:

   - you feel very weak or tired
   - you have unusual (not normal) muscle pain
   - you have trouble breathing
   - you have stomach pain with nausea and vomiting
   - you feel cold, especially in your arms and legs
   - you feel dizzy or light-headed
   - you have a fast or irregular heartbeat

4. **Serious liver problems. Some people who have taken medicines like TRIZIVIR 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.

5. **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 healthcare provider.

6. **If you have HIV and hepatitis B virus infection, your hepatitis B virus infection may get worse if you stop taking TRIZIVIR.**
   - Take TRIZIVIR exactly as prescribed.
   - Do not run out of TRIZIVIR.
   - Do not stop TRIZIVIR 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 TRIZIVIR.

7. **Muscle weakness (myopathy). RETROVIR, one of the medicines in TRIZIVIR, can cause muscle weakness. This can be a serious problem.**

What is TRIZIVIR?

TRIZIVIR is a prescription medicine used to treat HIV infection. TRIZIVIR contains 3 medicines: abacavir (ZIAGEN), lamivudine or 3TC (EPIVIR®), and zidovudine, AZT, or ZDV (RETROVIR). 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.

- **TRIZIVIR does not cure HIV infection or AIDS.**
- It is not known 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 healthcare provider regularly while you are taking TRIZIVIR.

Who should not take TRIZIVIR?

Do not take TRIZIVIR if you:

- **are allergic to abacavir or any of the ingredients in TRIZIVIR. See the end of this Medication Guide for a complete list of ingredients in TRIZIVIR.**
- **have certain liver problems.**
- **are an adolescent who weighs less than 90 pounds.**

What should I tell my healthcare provider before taking TRIZIVIR?

Before you take TRIZIVIR, 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 low blood cell counts (bone marrow problem).** Ask your doctor if you are not sure.
- **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 TRIZIVIR will harm your unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant.

  Pregnancy Registry. If you take TRIZIVIR while you are pregnant, talk to your healthcare provider about how you can take part in the Pregnancy Registry for TRIZIVIR. The purpose of the pregnancy registry is to collect information about the health of you and your baby.
- **are breastfeeding or plan to breastfeed. Do not breastfeed.** Lamivudine and zidovudine are excreted in human breast milk. We do not know if abacavir can be passed to your baby in your breast milk and whether it could harm your baby. Also, mothers with HIV-1 should not breastfeed because HIV-1 can be passed to the baby in the breast milk.

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
- BACTRIM®, SEPTRA® (trimethoprim [TMP/sulfamethoxazole SMX])
- CYTOVENE®, DHPG (ganciclovir)
- interferon-alfa
- ADRIAMYCIN® (doxorubicin)
- COPEGUS®, REBETOL®, VIRAZOLE® (ribavirin)
- any bone marrow suppressive medicines or cytotoxic medicines. Ask your doctor if you are not sure.
- ATRIPLA® (efavirenz/emtricitabine/tenofovir disoproxil fumarate)
- COMBIVIR® (lamivudine and zidovudine)
- COMPLERA™ (emtricitabine/rilpivirine/tenofovir disoproxil fumarate)
- EMTRIVA® (emtricitabine)

- EPIVIR or EPIVIR-HBV® (lamivudine)
- EPZICOM (abacavir sulfate and lamivudine)
- RETROVIR (zidovudine)
- TRUVADA® (emtricitabine/tenofovir disoproxil fumarate)
- ZERIT® (stavudine)
- ZIAGEN (abacavir sulfate)

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

TRIZIVIR may affect the way other medicines work, and other medicines may affect how TRIZIVIR 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 TRIZIVIR?

- **Take TRIZIVIR exactly as your healthcare provider tells you to take it.**
- TRIZIVIR may be taken with or without food.
- Do not skip doses.
- **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. If you take too much TRIZIVIR, 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 TRIZIVIR?

TRIZIVIR can cause serious side effects including allergic reactions, lactic acidosis, and liver problems. See "What is the most important information I should know about TRIZIVIR?"

- **Blood problems.**
- **Muscle weakness.**
- **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 TRIZIVIR.
- **Changes in body fat (fat redistribution).** Changes in body fat (lipoatrophy or lipodystrophy) can happen in some people taking antiretroviral medicines including TRIZIVIR.

  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 TRIZIVIR may increase your risk of heart attack.

The most common side effects of TRIZIVIR include:

- nausea
- headache
- weakness or tiredness
- vomiting
- diarrhea
- fever and/or chills
- depression
- muscle and joint pain
- skin rashes
- ear, nose, throat infections
- cold symptoms
- nervousness

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 TRIZIVIR. 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 TRIZIVIR?

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

General information for safe and effective use of TRIZIVIR.

Avoid doing things that can spread HIV-1 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 to lower the chance of sexual contact with semen, vaginal secretions, or blood.

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

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

What are the ingredients in TRIZIVIR?

Active ingredients: abacavir sulfate, lamivudine, and zidovudine

Inactive ingredients: magnesium stearate, microcrystalline cellulose, sodium starch glycolate, and OPADRY® green 03B11434, a film coating made of FD&C Blue No. 2, hypromellose, polyethylene glycol, titanium dioxide, and yellow iron oxide.

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

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by:

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