



GlaxoSmithKline
Research Triangle Park, NC 27709

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TRZ:XPI

MEDICATION GUIDE
TRIZIVIR® (TRY-zih-veer)
(abacavir, lamivudine, and zidovudine)
tablets

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

TRIZIVIR can cause serious side effects, including:

- **Serious allergic reactions (hypersensitivity reaction)** that can cause death have happened with TRIZIVIR 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 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, lamivudine

and zidovudine) or any other abacavir-containing medicine (EPZICOM[®], TRIUMEQ[®], or ZIAGEN[®]) 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.

- **Blood problems.** Zidovudine (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 people with advanced human immunodeficiency virus type 1 (HIV-1) disease or AIDS. Your healthcare provider should check your blood cell counts regularly during treatment with TRIZIVIR.
- **Muscle pain or weakness (myopathy)** can happen during treatment with TRIZIVIR. Zidovudine (RETROVIR[®]), one of the medicines in TRIZIVIR, can cause muscle pain or weakness when used for a long time.
- **Build-up of acid in your blood (lactic acidosis).** Lactic acidosis can happen in some people who take TRIZIVIR. Lactic acidosis is a serious medical emergency that can cause death. **Call your healthcare provider right away if you get any of the following symptoms that could be signs of lactic acidosis:**
 - 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
- **Serious liver problems** can happen in people who take TRIZIVIR. In some cases, these serious liver problems can lead to death. Your liver may become large (hepatomegaly) and you may develop fat in your liver (steatosis). **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)
 - dark or “tea-colored” urine
 - light colored stools (bowel movements)
 - loss of appetite for several days or longer
 - nausea
 - 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 female, very

overweight (obese), or have been taking nucleoside analogue medicines for a long time.

- **Worsening of hepatitis B virus in people who have HIV-1 infection.** If you have HIV-1 and hepatitis B virus (HBV) infection, your HBV may get worse (flare-up) if you stop taking TRIZIVIR. A “flare-up” is when your HBV infection suddenly returns in a worse way than before. Worsening liver disease is serious and may lead to death.
 - Do not run out of TRIZIVIR. Refill your prescription or talk to your healthcare provider before your TRIZIVIR is all gone.
 - Do not stop TRIZIVIR without first talking to your healthcare provider.
 - If you stop taking TRIZIVIR, your healthcare provider will need to check your health often and do blood tests regularly for several months to check your liver.
- **Resistant Hepatitis B Virus (HBV).** If you have HIV-1 and hepatitis B, the hepatitis B virus can change (mutate) during your treatment with TRIZIVIR and become harder to treat (resistant).
- **Use with interferon and ribavirin-based regimens.** Worsening of liver disease that has caused death has happened in people infected with both HIV-1 and hepatitis C virus who are taking antiretroviral medicines, and are also being treated for hepatitis C with interferon with or without ribavirin. If you are taking TRIZIVIR and interferon with or without ribavirin, tell your healthcare provider if you have any new symptoms.

What is TRIZIVIR?

TRIZIVIR is a prescription HIV-1 (Human Immunodeficiency Virus type 1) medicine used alone or with other antiretroviral medicines to treat HIV-1 infection. HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS). TRIZIVIR contains 3 prescription medicines, abacavir (ZIAGEN[®]), lamivudine (EPIVIR[®]) and zidovudine (RETROVIR[®]).

TRIZIVIR should not be used in children weighing less than 88 pounds (40 kg).

When used alone or with other antiretroviral medicines to treat HIV-1 infection, TRIZIVIR may help:

- reduce the amount of HIV-1 in your blood. This is called “viral load”.
- increase the number of CD4+ (T) cells in your blood, that help fight off other infections.

Reducing the amount of HIV-1 and increasing the CD4+ (T) cells in your blood may help improve your immune system. This may reduce your risk of death or getting infections that can happen when your immune system is weak (opportunistic infections).

TRIZIVIR does not cure HIV-1 infection or AIDS. You must keep taking HIV-1 medicines to control HIV-1 infection and decrease HIV-related illnesses.

Avoid doing things that can spread HIV-1 infection to others.

- Do not share or re-use 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 safer sex by using a latex or polyurethane condom to lower the chance of sexual contact with any body fluids such as semen, vaginal secretions, or blood.

Ask your healthcare provider if you have any questions about how to prevent passing HIV to other people.

Who should not take TRIZIVIR?

Do not take TRIZIVIR if you:

- 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 TRIZIVIR.
- 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 liver problems.

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 or have had liver problems, including hepatitis B or C virus infection.
- have kidney problems.
- have low blood cell counts (bone marrow problem). Ask your healthcare provider 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.
- drink alcohol or take medicines that contain alcohol.
- 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. There is a pregnancy registry for women who take antiretroviral medicines during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry.

- are breastfeeding or plan to breastfeed. **Do not breastfeed if you take TRIZIVIR.**
 - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.

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

Some medicines interact with TRIZIVIR. **Keep a list of your medicines to show your healthcare**

provider and pharmacist. You can ask your healthcare provider or pharmacist for a list of medicines that interact with TRIZIVIR. **Do not start taking a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take TRIZIVIR with other medicines.

You should not take TRIZIVIR if you also take:

- abacavir (EPZICOM, TRIUMEQ, or ZIAGEN)
- lamivudine (COMBIVIR[®], DUTREBIS[™], EPIVIR[®], EPIVIR-HBV[®], EPZICOM, or TRIUMEQ)
- zidovudine (COMBIVIR or RETROVIR)
- emtricitabine (EMTRIVA[®], ATRIPLA[®], COMPLERA[®], STRIBILD[®], or TRUVADA[®])

Tell your healthcare provider if you take:

- any other medicine to treat HIV-1
- ADRIAMYCIN[®] (doxorubicin)
- CYTOVENE[®] (ganciclovir), interferon alfa, ribavirin, or other bone marrow suppressive medicines or cytotoxic medicines
- methadone

How should I take TRIZIVIR?

- **Take TRIZIVIR exactly as your healthcare provider tells you.**
- Do not change your dose or stop taking TRIZIVIR without talking with your healthcare provider. If you miss a dose of TRIZIVIR, take it as soon as you remember. Do not take 2 doses at the same time. If you are not sure about your dosing, call your healthcare provider.
- Stay under the care of a healthcare provider while taking TRIZIVIR.
- TRIZIVIR may be taken with or without food.
- Tell your healthcare provider if you or your child has trouble swallowing TRIZIVIR tablets.
- Do not run out of TRIZIVIR. The virus in your blood may increase and the virus may become harder to treat. When your supply starts to run low, get more from your healthcare provider or pharmacy.
- If you take too much TRIZIVIR, call your healthcare provider 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:**
- **See “What is the most important information I should know about TRIZIVIR?”**
- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV-1 medicines. 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 right away if you start having

new symptoms after you start taking TRIZIVIR.

- **Changes in body fat** can happen in people who take HIV-1 medicines. These changes may include an increased amount of fat in the upper back and neck (“buffalo hump”), breast, and around the middle of your body (trunk). Loss of fat from the legs, arms, and face may also happen. The exact cause and long-term health effects of these conditions are not known.
- **Heart attack (myocardial infarction).** Some HIV-1 medicines including TRIZIVIR may increase your risk of heart attack.

The most common side effects of TRIZIVIR include:

- nausea
- headache
- weakness or tiredness
- vomiting

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.

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.

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 health professionals.

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

What are the ingredients in TRIZIVIR?

Active ingredients: abacavir, lamivudine, and zidovudine

Inactive ingredients: magnesium stearate, microcrystalline cellulose, sodium starch glycolate

Tablet film coating contains: OPADRY® green 03B11434 made of FD&C Blue No. 2, hypromellose, polyethylene glycol, titanium dioxide, and yellow iron oxide.

Manufactured for:

by:





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

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