

Research Triangle Park, NC 27709

by:



GlaxoSmithKline

Research Triangle Park, NC 27709

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ZGN:XPI

MEDICATION GUIDE	
ZIAGEN® (ZY-uh-jen) (abacavir) tablets	ZIAGEN® (ZY-uh-jen) (abacavir) oral solution

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

ZIAGEN can cause serious side effects, including:

- **Serious allergic reactions (hypersensitivity reaction)** that can cause death have happened with ZIAGEN 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 ZIAGEN, call your healthcare provider right away to find out if you should stop taking ZIAGEN.

	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 ZIAGEN because of an allergic reaction, never take ZIAGEN (abacavir) or any other abacavir-containing medicine (EPZICOM®, TRIUMEQ®, or TRIZIVIR®) again.

- If you take ZIAGEN 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 ZIAGEN for any other reason, even for a few days, and you are not allergic to ZIAGEN, talk with your healthcare provider before taking it again. Taking ZIAGEN 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 ZIAGEN again, start taking it when you are around medical help or people who can call a healthcare provider if you need one.

- **Build-up of acid in your blood (lactic acidosis).** Lactic acidosis can happen in some people who take ZIAGEN. 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 ZIAGEN. 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) when you take ZIAGEN. **Call your healthcare provider right away if you have any of the following signs 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.

What is ZIAGEN?

ZIAGEN is a prescription HIV-1 (Human Immunodeficiency Virus type 1) medicine used with other antiretroviral medicines to treat HIV-1 infection. HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS).

The safety and effectiveness of ZIAGEN has not been established in children under 3 months of age.

When used with other antiretroviral medicines to treat HIV-1 infection, ZIAGEN 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).

ZIAGEN 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 ZIAGEN?

Do not take ZIAGEN 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 ZIAGEN.
- are allergic to abacavir or any of the ingredients in ZIAGEN. See the end of this Medication Guide for a complete list of ingredients in ZIAGEN.
- have liver problems.

What should I tell my healthcare provider before taking ZIAGEN?

Before you take ZIAGEN, 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 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. Taking ZIAGEN during pregnancy has not been associated with an increased risk of birth defects. 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 ZIAGEN.**

- 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 ZIAGEN. **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 ZIAGEN. **Do not start taking a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take ZIAGEN with other medicines.

You should not take ZIAGEN if you also take:

- abacavir (EPZICOM, TRIUMEQ, or TRIZIVIR)

Tell your healthcare provider if you take:

- any other medicine to treat HIV-1
- methadone

How should I take ZIAGEN?

- **Take ZIAGEN exactly as your healthcare provider tells you.**
- Do not change your dose or stop taking ZIAGEN without talking with your healthcare provider. If you miss a dose of ZIAGEN, 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 ZIAGEN.
- ZIAGEN may be taken with or without food.
- For children aged 3 months and older, your healthcare provider will prescribe a dose of ZIAGEN based on your child's body weight.
- Tell your healthcare provider if you or your child has trouble swallowing tablets. ZIAGEN comes as a tablet or as a liquid (oral solution).
- Do not run out of ZIAGEN. The virus in your blood may increase and the virus may become harder to treat. When your supply starts to run out, get more from your healthcare provider or pharmacy.
- If you take too much ZIAGEN, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of ZIAGEN?

- **ZIAGEN can cause serious side effects including:**
- **See “What is the most important information I should know about ZIAGEN?”**
- **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 ZIAGEN.

- **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 ZIAGEN may increase your risk of heart attack.

The most common side effects of ZIAGEN in adults include:

- nausea
- headache
- generally not feeling well
- tiredness
- vomiting
- bad dreams or sleep problems

The most common side effects of ZIAGEN in children include:

- fever and chills
- nausea
- vomiting
- rash
- ear, nose, or throat infections

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 ZIAGEN. 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 ZIAGEN?

- Store ZIAGEN at room temperature, between 68°F to 77°F (20°C to 25°C).
- Do not freeze ZIAGEN oral solution. You may store ZIAGEN oral solution in a refrigerator.

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

General information for safe and effective use of ZIAGEN

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ZIAGEN for a condition for which it was not prescribed. Do not give ZIAGEN 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 ZIAGEN that is written for health professionals.

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

What are the ingredients in ZIAGEN?

Active ingredient: abacavir

Inactive ingredients:

Tablets:

Colloidal silicon dioxide, magnesium stearate, microcrystalline cellulose, and sodium starch glycolate

Tablet film-coating contains: hypromellose, polysorbate 80, synthetic yellow iron oxide, titanium dioxide, and triacetin.

Oral Solution:

Artificial strawberry and banana flavors, citric acid (anhydrous), methylparaben and propylparaben (added as preservatives), propylene glycol, saccharin sodium, sodium citrate (dihydrate), sorbitol solution, and water.

Manufactured for:



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

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