

741 Manufactured for:



742 ViiV Healthcare
743 Research Triangle Park, NC 27709

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745
746 by:



747 GlaxoSmithKline
748 Research Triangle Park, NC 27709

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MEDICATION GUIDE

ZIAGEN® (ZY-uh-jen) (abacavir sulfate)

Tablets and Oral Solution

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762 Read this Medication Guide before you start taking ZIAGEN and each time you get a
763 refill. There may be new information. This information does not take the place of
764 talking to your healthcare provider about your medical condition or your treatment.
765 Be sure to carry your ZIAGEN Warning Card with you at all times.

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

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768 **1. Serious allergic reaction (hypersensitivity reaction).** ZIAGEN contains
769 abacavir (also contained in EPZICOM® and TRIZIVIR®). Patients taking ZIAGEN
770 may have a serious allergic reaction (hypersensitivity reaction) that can cause
771 death. Your risk of this allergic reaction is much higher if you have a gene
772 variation called HLA-B*5701. Your healthcare provider can determine with a
773 blood test if you have this gene variation.

774 **If you get a symptom from 2 or more of the following groups while**
775 **taking ZIAGEN, call your healthcare provider right away to find out if**
776 **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

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A list of these symptoms is on the Warning Card your pharmacist gives you.

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Carry this Warning Card with you at all times.

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If you stop ZIAGEN because of an allergic reaction, never take ZIAGEN (abacavir sulfate) or any other abacavir-containing medicine (EPZICOM and TRIZIVIR) again. If you take ZIAGEN or any other abacavir-containing

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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.

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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.

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

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

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- 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

807 **3. Serious liver problems. Some people who have taken medicines like**
808 **ZIAGEN have developed serious liver problems called hepatotoxicity,**
809 **with liver enlargement (hepatomegaly) and fat in the liver (steatosis).**
810 **Hepatomegaly with steatosis is a serious medical emergency that can**
811 **cause death.**

812 **Call your healthcare provider right away if you get any of the following**
813 **signs or symptoms of liver problems:**

- 814 • your skin or the white part of your eyes turns yellow (jaundice)
- 815 • your urine turns dark
- 816 • your bowel movements (stools) turn light in color
- 817 • you don't feel like eating food for several days or longer
- 818 • you feel sick to your stomach (nausea)
- 819 • you have lower stomach area (abdominal) pain

820 **You may be more likely to get lactic acidosis or serious liver problems if**
821 **you are female, very overweight, or have been taking nucleoside**
822 **analogue medicines for a long time.**

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824 **What is ZIAGEN?**

825 ZIAGEN is a prescription medicine used to treat HIV infection. ZIAGEN is a medicine
826 called a nucleoside analogue reverse transcriptase inhibitor (NRTI). ZIAGEN is
827 always used with other anti-HIV medicines. When used in combination with these
828 other medicines, ZIAGEN helps lower the amount of HIV in your blood.

- 829 • **ZIAGEN does not cure HIV infection or AIDS.**
- 830 • It is not known if ZIAGEN will help you live longer or have fewer of the medical
831 problems that people get with HIV or AIDS.
- 832 • It is very important that you see your doctor regularly while you are taking
833 ZIAGEN.

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835 **Who should not take ZIAGEN?**

836 **Do not take ZIAGEN if you:**

- 837 • **are allergic to abacavir or any of the ingredients in ZIAGEN. See the**
838 **end of this Medication Guide for a complete list of ingredients in**
839 **ZIAGEN.**
- 840 • **have certain liver problems.**

841 **What should I tell my healthcare provider before taking ZIAGEN?**

842 **Before you take ZIAGEN, tell your healthcare provider if you:**

- 843 • **have been tested and know whether or not you have a particular gene**
844 **variation called HLA-B*5701.**

- 845 • **have hepatitis B virus infection or have other liver problems.**
846 • **have heart problems, smoke, or have diseases that increase your risk**
847 **of heart disease such as high blood pressure, high cholesterol, or**
848 **diabetes.**
- 849 • **are pregnant or plan to become pregnant.** It is not known if ZIAGEN will
850 harm your unborn baby. Talk to your healthcare provider if you are pregnant or
851 plan to become pregnant.
- 852 **Pregnancy Registry.** If you take ZIAGEN while you are pregnant, talk to your
853 healthcare provider about how you can take part in the Pregnancy Registry for
854 ZIAGEN. The purpose of the pregnancy registry is to collect information about
855 the health of you and your baby.
- 856 • **are breastfeeding or plan to breastfeed. Do not breastfeed.** We do not
857 know if ZIAGEN can be passed to your baby in your breast milk and whether it
858 could harm your baby. Also, mothers with HIV-1 should not breastfeed because
859 HIV-1 can be passed to the baby in the breast milk.

860 **Tell your healthcare provider about all the medicines you take,** including
861 prescription and nonprescription medicines, vitamins, and herbal supplements.

862 **Especially tell your healthcare provider if you take:**

- 863 • alcohol
864 • methadone
865 • TRIZIVIR (abacavir sulfate, lamivudine, and zidovudine)
866 • EPZICOM (abacavir sulfate and lamivudine)

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

869 ZIAGEN may affect the way other medicines work, and other medicines may affect
870 how ZIAGEN works.

871 Know the medicines you take. Keep a list of your medicines with you to show to
872 your healthcare provider and pharmacist when you get a new medicine.

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874 **How should I take ZIAGEN?**

- 875 • **Take ZIAGEN exactly as your healthcare provider tells you to take it.**
876 • **ZIAGEN is taken by mouth as a tablet or a strawberry- and banana-**
877 **flavored liquid.**
- 878 • ZIAGEN may be taken with or without food.
879 • Do not skip doses.
- 880 • Children aged 3 months and older can also take ZIAGEN. The child's healthcare
881 provider will decide the right dose and whether the child should take the tablet

882 or liquid, based on the child's weight. The dose should not be more than the
883 recommended adult dose.

884 • **Do not let your ZIAGEN run out.**

885 If you stop your anti-HIV medicines, even for a short time, the amount of virus
886 in your blood may increase and the virus may become harder to treat. If you
887 take too much ZIAGEN, call your healthcare provider or poison control center or
888 go to the nearest hospital emergency room right away.

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890 **What are the possible side effects of ZIAGEN?**

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

894 • **Changes in immune system (Immune Reconstitution Syndrome).** Your
895 immune system may get stronger and begin to fight infections that have been
896 hidden in your body for a long time. Tell your healthcare provider if you start
897 having new or worse symptoms of infection after you start taking ZIAGEN.

898 • **Changes in body fat (fat redistribution).** Changes in body fat (lipoatrophy or
899 lipodystrophy) can happen in some people taking antiretroviral medicines
900 including ZIAGEN.

901 These changes may include:

902 • more fat in or around your trunk, upper back and neck (buffalo hump),
903 breast, or chest

904 • loss of fat in your legs, arms, or face

905 • **Heart attack (myocardial infarction).** Some HIV medicines including ZIAGEN
906 may increase your risk of heart attack.

907 **The most common side effects of ZIAGEN in adults include:**

908 • bad dreams or sleep problems

909 • nausea

910 • headache

911 • tiredness

912 • vomiting

913 **The most common side effects of ZIAGEN in children include:**

914 • fever and chills

915 • nausea

916 • vomiting

917 • rash

- 918 • ear, nose, or throat infections
- 919 Tell your healthcare provider if you have any side effect that bothers you or that
920 does not go away.
- 921 These are not all the possible side effects of ZIAGEN. For more information, ask
922 your healthcare provider or pharmacist.
- 923 Call your doctor for medical advice about side effects. You may report side effects
924 to FDA at 1-800-FDA-1088.

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926 **How should I store ZIAGEN?**

- 927 • Store ZIAGEN at room temperature, between 68°F to 77°F (20°C to 25°C).
- 928 • Do not freeze ZIAGEN.
- 929 • **Keep ZIAGEN and all medicines out of the reach of children.**

930

931 **General information for safe and effective use of ZIAGEN**

932 Avoid doing things that can spread HIV infection to others.

- 933 • **Do not share needles or other injection equipment.**
- 934 • **Do not share personal items that can have blood or body fluids on
935 them, like toothbrushes and razor blades.**
- 936 • **Do not have any kind of sex without protection.** Always practice safe sex
937 by using a latex or polyurethane condom to lower the chance of sexual contact
938 with semen, vaginal secretions, or blood.

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940 Medicines are sometimes prescribed for purposes other than those listed in a
941 Medication Guide. Do not use ZIAGEN for a condition for which it was not
942 prescribed. Do not give ZIAGEN to other people, even if they have the same
943 symptoms that you have. It may harm them.

944

945 This Medication Guide summarizes the most important information about ZIAGEN.
946 If you would like more information, talk with your healthcare provider. You can ask
947 your healthcare provider or pharmacist for the information that is written for
948 healthcare professionals.

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

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952 **What are the ingredients in ZIAGEN?**

953 **Tablets**

954 Active ingredient: abacavir sulfate

955 Inactive ingredients: colloidal silicon dioxide, magnesium stearate, microcrystalline
956 cellulose, and sodium starch glycolate, and a film-coating made of hypromellose,
957 polysorbate 80, synthetic yellow iron oxide, titanium dioxide, and triacetin.

958 **Oral Solution**

959 Active ingredient: abacavir sulfate

960 Inactive ingredients: artificial strawberry and banana flavors, citric acid
961 (anhydrous), methylparaben and propylparaben (added as preservatives),
962 propylene glycol, saccharin sodium, sodium citrate (dihydrate), sorbitol solution,
963 and water.

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

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