

- 692 • to not restart ZIAGEN or any other abacavir-containing product following a hypersensitivity
693 reaction because more severe symptoms can occur within hours and may include
694 life-threatening hypotension and death.
- 695 • that a hypersensitivity reaction is usually reversible if it is detected promptly and ZIAGEN is
696 stopped right away.
- 697 • that if they have interrupted ZIAGEN for reasons other than symptoms of hypersensitivity
698 (for example, those who have an interruption in drug supply), a serious or fatal
699 hypersensitivity reaction may occur with reintroduction of abacavir.
- 700 • to not restart ZIAGEN or any other abacavir-containing product without medical consultation
701 and that restarting abacavir needs to be undertaken only if medical care can be readily
702 accessed by the patient or others.
- 703 • ZIAGEN should not be coadministered with EPZICOM[®] or TRIZIVIR[®].

704 Lactic Acidosis/Hepatomegaly: Inform patients that some HIV medicines, including
705 ZIAGEN, can cause a rare, but serious condition called lactic acidosis with liver enlargement
706 (hepatomegaly).

707 Redistribution/Accumulation of Body Fat: Inform patients that redistribution or
708 accumulation of body fat may occur in patients receiving antiretroviral therapy and that the cause
709 and long-term health effects of these conditions are not known at this time.

710 Information About HIV-1 Infection: ZIAGEN is not a cure for HIV-1 infection and
711 patients may continue to experience illnesses associated with HIV-1 infection, including
712 opportunistic infections. Patients should remain under the care of a physician when using
713 ZIAGEN. Advise patients that the use of ZIAGEN has not been shown to reduce the risk of
714 transmission of HIV-1 to others through sexual contact or blood contamination. Patients should
715 be informed to take all HIV medications exactly as prescribed.

716

717 **17.2 FDA Approved Patient Labeling**

718

MEDICATION GUIDE

719

ZIAGEN[®] (ZY-uh-jen) Tablets

720

ZIAGEN[®] Oral Solution

721

722 **Generic name:** abacavir (uh-BACK-ah-veer) sulfate tablets and oral solution

723

724 Read the Medication Guide that comes with ZIAGEN before you start taking it and each time
725 you get a refill because there may be new information. This information does not take the place
726 of talking to your doctor about your medical condition or your treatment. Be sure to carry your
727 ZIAGEN Warning Card with you at all times.

728

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

- 730 • **Serious Allergic Reaction to Abacavir.** ZIAGEN contains abacavir (also contained in
 731 EPZICOM[®] and TRIZIVIR[®]). Patients taking ZIAGEN may have a serious allergic reaction
 732 (hypersensitivity reaction) that can cause death. **Your risk of this allergic reaction is much**
 733 **higher if you have a gene variation called HLA-B*5701 than if you do not. Your doctor**
 734 **can determine with a blood test if you have this gene variation. If you get a symptom**
 735 **from 2 or more of the following groups while taking ZIAGEN, call your doctor right**
 736 **away to determine if you should stop taking this medicine.**
 737

	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

738
 739 A list of these symptoms is on the Warning Card your pharmacist gives you. Carry this Warning
 740 Card with you.

741
 742 **If you stop ZIAGEN because of an allergic reaction, NEVER take ZIAGEN (abacavir**
 743 **sulfate) or any other abacavir-containing medicine (EPZICOM and TRIZIVIR) again.** If
 744 you take ZIAGEN or any other abacavir-containing medicine again after you have had an
 745 allergic reaction, **WITHIN HOURS** you may get **life-threatening symptoms** that may include
 746 **very low blood pressure or death.**

747
 748 **If you stop ZIAGEN for any other reason, even for a few days and you are not allergic to**
 749 **ZIAGEN, talk with your doctor before taking it again. Taking ZIAGEN again can cause a**
 750 **serious allergic or life-threatening reaction, even if you never had an allergic reaction to it**
 751 **before.** If your doctor tells you that you can take ZIAGEN again, **start taking it when you are**
 752 **around medical help or people who can call a doctor if you need one.**

- 753
 754 • **Lactic Acidosis.** Some human immunodeficiency virus (HIV-1) medicines, including
 755 **ZIAGEN, can cause a rare but serious condition called lactic acidosis with liver**
 756 **enlargement (hepatomegaly).** Nausea and tiredness that don't get better may be symptoms
 757 of lactic acidosis. In some cases this condition can cause death. Women, overweight people,
 758 and people who have taken HIV-1 medicines like ZIAGEN for a long time have a higher
 759 chance of getting lactic acidosis and liver enlargement. Lactic acidosis is a medical
 760 emergency and must be treated in the hospital.

761
 762 ZIAGEN can have other serious side effects. Be sure to read the section below entitled "What are
 763 the possible side effects of ZIAGEN?"

764
765
766
767
768
769
770
771
772
773
774
775
776
777
778
779
780
781
782
783
784
785
786
787
788
789
790
791
792
793
794
795
796
797
798
799
800
801
802
803

What is ZIAGEN?

ZIAGEN is a prescription medicine used to treat HIV-1 infection. ZIAGEN is taken by mouth as a tablet or a strawberry-banana-flavored liquid. ZIAGEN is a medicine called a nucleoside analogue reverse transcriptase inhibitor (NRTI). ZIAGEN is always used with other anti-HIV-1 medicines. When used in combination with these other medicines, ZIAGEN helps lower the amount of HIV-1 found in your blood. This helps to keep your immune system as healthy as possible so that it can help fight infection.

Different combinations of medicines are used to treat HIV-1 infection. You and your doctor should discuss which combination of medicines is best for you.

- **ZIAGEN does not cure HIV-1 infection or AIDS.** We do not know if ZIAGEN will help you live longer or have fewer of the medical problems that people get with HIV-1 or AIDS. It is very important that you see your doctor regularly while you are taking ZIAGEN.
- **ZIAGEN does not lower the risk of passing HIV-1 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.

ZIAGEN has not been studied in children under 3 months of age or in adults over 65 years of age.

Who should not take ZIAGEN?

Do not take ZIAGEN if you:

- **have ever had a serious allergic reaction (a hypersensitivity reaction) to ZIAGEN or any other medicine that has abacavir as one of its ingredients (EPZICOM and TRIZIVIR).** See the end of this Medication Guide for a complete list of ingredients in ZIAGEN.
- **have a liver that does not function properly.**

Before starting ZIAGEN, tell your doctor about all of your medical conditions, including if you:

- **have been tested and know whether or not you have a particular gene variation called HLA-B*5701.**
- **are pregnant or planning to become pregnant.** We do not know if ZIAGEN will harm your unborn child. You and your doctor will need to decide if ZIAGEN is right for you. If you use ZIAGEN while you are pregnant, talk to your doctor about how you can be on the Antiviral Pregnancy Registry for ZIAGEN.

- 804 • **are breastfeeding.** We do not know if ZIAGEN can be passed to your baby in your breast
805 milk and whether it could harm your baby. Also, mothers with HIV-1 should not breastfeed
806 because HIV-1 can be passed to the baby in the breast milk.
- 807 • **have liver problems.**
- 808 • **have heart problems, smoke, or suffer from diseases that increase your risk of heart**
809 **disease such as high blood pressure, high cholesterol, or diabetes.**

810

811 **Tell your doctor about all the medicines you take, including prescription and**
812 **nonprescription medicines, vitamins, and herbal supplements. Especially tell your doctor if**
813 **you take:**

- 814 • **methadone**
- 815 • **EPZICOM (abacavir sulfate and lamivudine) and TRIZIVIR (abacavir sulfate,**
816 **lamivudine, and zidovudine).**

817

818 **How should I take ZIAGEN?**

- 819 • **Take ZIAGEN by mouth exactly as your doctor prescribes it.** Your doctor will tell you
820 the right dose to take. The usual doses are 1 tablet twice a day or 2 tablets once a day. Do not
821 skip doses.
- 822 • **Children aged 3 months and older can also take ZIAGEN.** The child's healthcare professional
823 will decide the right dose and formulation based on the child's weight. The dose should not
824 exceed the recommended adult dose.
- 825 • **You can take ZIAGEN with or without food.**
- 826 • **If you miss a dose of ZIAGEN, take the missed dose right away. Then, take the next**
827 **dose at the usual time.**
- 828 • **Do not let your ZIAGEN run out.**
- 829 • **Starting ZIAGEN again can cause a serious allergic or life-threatening reaction, even if**
830 **you never had an allergic reaction to it before.** If you run out of ZIAGEN even for a few
831 days, you must ask your doctor if you can start ZIAGEN again. If your doctor tells you that
832 you can take ZIAGEN again, start taking it when you are around medical help or people who
833 can call a doctor if you need one.
- 834 • **If you stop your anti-HIV drugs, even for a short time, the amount of virus in your**
835 **blood may increase and the virus may become harder to treat.**
- 836 • **If you take too much ZIAGEN, call your doctor or poison control center right away.**

837

838 **What should I avoid while taking ZIAGEN?**

- 839 • **Do not take EPZICOM (abacavir sulfate and lamivudine) or TRIZIVIR (abacavir sulfate,**
840 **lamivudine, and zidovudine) while taking ZIAGEN.** Some of these medicines are already in
841 ZIAGEN.

842

843 **Avoid doing things that can spread HIV-1 infection**, as ZIAGEN does not stop you from
844 passing the HIV-1 infection to others.

- 845 • **Do not share needles or other injection equipment.**
- 846 • **Do not share personal items that can have blood or body fluids on them, like**
847 **toothbrushes and razor blades.**
- 848 • **Do not have any kind of sex without protection.** Always practice safe sex by using a latex
849 or polyurethane condom or other barrier method to lower the chance of sexual contact with
850 semen, vaginal secretions, or blood.
- 851 • **Do not breastfeed.** We do not know if ZIAGEN can be passed to your baby in your breast
852 milk and whether it could harm your baby. Also, mothers with HIV-1 should not breastfeed
853 because HIV-1 can be passed to the baby in the breast milk.

854

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

856 **ZIAGEN can cause the following serious side effects:**

- 857 • **Serious allergic reaction that can cause death.** (See "What is the most important
858 information I should know about ZIAGEN?" at the beginning of this Medication Guide.)
- 859 • **Lactic acidosis with liver enlargement (hepatomegaly) that can cause death.** (See "What
860 is the most important information I should know about ZIAGEN?" at the beginning of this
861 Medication Guide.)
- 862 • **Changes in immune system.** When you start taking HIV medicines, your immune system
863 may get stronger and could begin to fight infections that have been hidden in your body, such
864 as pneumonia, herpes virus, or tuberculosis. If you have new symptoms after starting your
865 HIV medicines, be sure to tell your doctor.
- 866 • **Changes in body fat.** These changes have happened in patients taking antiretroviral
867 medicines like ZIAGEN. The changes may include an increased amount of fat in the upper
868 back and neck ("buffalo hump"), breast, and around the back, chest, and stomach area. Loss
869 of fat from the legs, arms, and face may also happen. The cause and long-term health effects
870 of these conditions are not known.

871

872 Some HIV medicines including ZIAGEN may increase your risk of heart attack. If you have
873 heart problems, smoke, or suffer from diseases that increase your risk of heart disease such as
874 high blood pressure, high cholesterol, or diabetes, tell your doctor.

875

876 The most common side effects of ZIAGEN include nausea, vomiting, tiredness, headache,
877 diarrhea, trouble sleeping, fever and chills, and loss of appetite. Most of these side effects did not
878 cause people to stop taking ZIAGEN.

879

880 This list of side effects is not complete. Call your doctor for medical advice about side effects.

881 You may report side effects to FDA at 1-800-FDA-1088.

882

883 **How should I store ZIAGEN?**

- 884 • Store ZIAGEN at room temperature, between 68° to 77°F (20° to 25°C). Do not freeze
885 ZIAGEN.
886 • **Keep ZIAGEN and all medicines out of the reach of children.**
887

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

889 Medicines are sometimes prescribed for conditions that are not mentioned in Medication Guides.
890 Do not use ZIAGEN for a condition for which it was not prescribed. Do not give ZIAGEN to
891 other people, even if they have the same symptoms that you have. It may harm them.
892

893 This Medication Guide summarizes the most important information about ZIAGEN. If you
894 would like more information, talk with your doctor. You can ask your doctor or pharmacist for
895 the information that is written for healthcare professionals or call 1-888-825-5249.
896

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

898 **Tablets:** Each tablet contains abacavir sulfate equivalent to 300 mg of abacavir as active
899 ingredient and the following inactive ingredients: colloidal silicon dioxide, magnesium stearate,
900 microcrystalline cellulose, and sodium starch glycolate. The film-coating is made of
901 hypromellose, polysorbate 80, synthetic yellow iron oxide, titanium dioxide, and triacetin.

902 **Oral Solution:** Each milliliter (1 mL) of ZIAGEN Oral Solution contains abacavir sulfate
903 equivalent to 20 mg of abacavir (i.e., 20 mg/mL) as active ingredient and the following inactive
904 ingredients: artificial strawberry and banana flavors, citric acid (anhydrous), methylparaben and
905 propylparaben (added as preservatives), propylene glycol, saccharin sodium, sodium citrate
906 (dihydrate), sorbitol solution, and water.
907

908 *This Medication Guide has been approved by the US Food and Drug Administration.*
909
910



911 GlaxoSmithKline
912 Research Triangle Park, NC 27709
914

915 ©2008, GlaxoSmithKline. All rights reserved.

916
917 Month 200x
918 ZGN:xMG