

802 Manufactured for



803 ViiV Healthcare
804 Research Triangle Park, NC 27709

805 by:



807 GlaxoSmithKline
808 Research Triangle Park, NC 27709

810
811 Lamivudine is manufactured under agreement from
812 **Shire Pharmaceuticals Group plc**
813 Basingstoke, UK

814
815 ©2012, ViiV Healthcare. All rights reserved.

816
817 EPZ:PI

818

819 **MEDICATION GUIDE**

820 **EPZICOM® (ep' zih com)**
821 (abacavir sulfate and lamivudine)
822 **Tablets**

823

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

828

829 **What is the most important information I should know about EPZICOM?**

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

836 **If you get a symptom from 2 or more of the following groups while**
837 **taking EPZICOM, call your healthcare provider right away to find out if**
838 **you should stop taking EPZICOM.**

	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

840
841 A list of these symptoms is on the Warning Card your pharmacist gives you.
842 **Carry this Warning Card with you at all times.**

843 **If you stop EPZICOM because of an allergic reaction, never take**
844 **EPZICOM (abacavir sulfate and lamivudine) or any other**
845 **abacavir-containing medicine (ZIAGEN and TRIZIVIR) again.** If you take
846 EPZICOM or any other abacavir-containing medicine again after you have had an
847 allergic reaction, **within hours** you may get **life-threatening symptoms** that
848 may include **very low blood pressure** or **death**. If you stop EPZICOM for any
849 other reason, even for a few days, and you are not allergic to EPZICOM, talk
850 with your healthcare provider before taking it again. Taking EPZICOM again can
851 cause a serious allergic or life-threatening reaction, even if you never had an
852 allergic reaction to it before.

853 **If your healthcare provider tells you that you can take EPZICOM again,**
854 **start taking it when you are around medical help or people who can call**
855 **a healthcare provider if you need one.**

856 **2. Lactic Acidosis (buildup of acid in the blood). Some human**
857 **immunodeficiency virus (HIV) medicines, including EPZICOM, can cause**
858 **a rare but serious condition called lactic acidosis. Lactic acidosis is a**
859 **serious medical emergency that can cause death and must be treated in**
860 **the hospital.**

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

- 863 • you feel very weak or tired
- 864 • you have unusual (not normal) muscle pain

- 865 • you have trouble breathing
- 866 • you have stomach pain with nausea and vomiting
- 867 • you feel cold, especially in your arms and legs
- 868 • you feel dizzy or light-headed
- 869 • you have a fast or irregular heartbeat

870 **3. Serious liver problems. Some people who have taken medicines like**
871 **EPZICOM have developed serious liver problems called hepatotoxicity,**
872 **with liver enlargement (hepatomegaly) and fat in the liver (steatosis).**
873 **Hepatomegaly with steatosis is a serious medical emergency that can**
874 **cause death.**

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

- 877 • your skin or the white part of your eyes turns yellow (jaundice)
- 878 • your urine turns dark
- 879 • your bowel movements (stools) turn light in color
- 880 • you don't feel like eating food for several days or longer
- 881 • you feel sick to your stomach (nausea)
- 882 • you have lower stomach area (abdominal) pain

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

886 **4. Use with interferon and ribavirin-based regimens.** Worsening of liver
887 disease (sometimes resulting in death) has occurred in patients infected with
888 both HIV and hepatitis C virus who are taking anti-HIV medicines and are also
889 being treated for hepatitis C with interferon with or without ribavirin. If you are
890 taking EPZICOM as well as interferon with or without ribavirin and you
891 experience side effects, be sure to tell your healthcare provider.

892 **5. If you have HIV and hepatitis B virus infection, your hepatitis B virus**
893 **infection may get worse if you stop taking EPZICOM.**

- 894 • Take EPZICOM exactly as prescribed.
- 895 • Do not run out of EPZICOM.
- 896 • Do not stop EPZICOM without talking to your healthcare provider.

897 Your healthcare provider should monitor your health and do regular blood tests to
898 check your liver if you stop taking EPZICOM.

899 **What is EPZICOM?**

900 EPZICOM is a prescription medicine used to treat HIV infection. EPZICOM contains
901 2 medicines: abacavir (ZIAGEN) and lamivudine or 3TC (EPIVIR®). Both of these

902 medicines are called nucleoside analogue reverse transcriptase inhibitors (NRTIs).
903 When used together, they help lower the amount of HIV in your blood.

- 904 • **EPZICOM does not cure HIV infection or AIDS.**
- 905 • It is not known if EPZICOM will help you live longer or have fewer of the medical
906 problems that people get with HIV or AIDS.
- 907 • It is very important that you see your healthcare provider regularly while you
908 are taking EPZICOM.
- 909 • It is not known if EPZICOM is safe or effective in children under the age of 18.

910 **Who should not take EPZICOM?**

911 **Do not take EPZICOM if you:**

- 912 • **are allergic to abacavir or any of the ingredients in EPZICOM. See the**
913 **end of this Medication Guide for a complete list of ingredients in**
914 **EPZICOM.**
- 915 • **have certain liver problems.**

916 **What should I tell my healthcare provider before taking EPZICOM?**

917 **Before you take EPZICOM tell your healthcare provider if you:**

- 918 • **have been tested and know whether or not you have a particular gene**
919 **variation called HLA-B*5701.**
- 920 • **have hepatitis B virus infection or have other liver problems.**
- 921 • **have kidney problems.**
- 922 • **have heart problems, smoke, or have diseases that increase your risk of**
923 **heart disease such as high blood pressure, high cholesterol, or diabetes.**
- 924 • **are pregnant or plan to become pregnant.** It is not known if EPZICOM will
925 harm your unborn baby. Talk to your healthcare provider if you are pregnant or
926 plan to become pregnant.

927 **Pregnancy Registry.** If you take EPZICOM while you are pregnant, talk to your
928 healthcare provider about how you can take part in the Pregnancy Registry for
929 EPZICOM. The purpose of the pregnancy registry is to collect information about
930 the health of you and your baby.

- 931 • **are breastfeeding or plan to breastfeed. Do not breastfeed.** Lamivudine is
932 excreted in human breast milk. We do not know if abacavir can be passed to
933 your baby in your breast milk and whether it could harm your baby. Also,
934 mothers with HIV-1 should not breastfeed because HIV-1 can be passed to the
935 baby in the breast milk.

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

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

- 939 • alcohol
- 940 • medicines used to treat hepatitis viruses such as interferon or ribavirin.
- 941 • methadone
- 942 • ATRIPLA[®] (efavirenz/emtricitabine/tenofovir disoproxil fumarate)
- 943 • COMBIVIR[®] (lamivudine and zidovudine)
- 944 • COMPLERA[™] (emtricitabine/rilpivirine/tenofovir disoproxil fumarate)
- 945 • EMTRIVA[®] (emtricitabine)
- 946 • EPIVIR or EPIVIR-HBV[®] (lamivudine)
- 947 • TRIZIVIR (abacavir sulfate, lamivudine, and zidovudine)
- 948 • TRUVADA[®] (emtricitabine/tenofovir disoproxil fumarate)
- 949 • ZIAGEN (abacavir sulfate)

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

952 EPZICOM may affect the way other medicines work, and other medicines may affect
953 how EPZICOM works.

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

956 **How should I take EPZICOM?**

- 957 • **Take EPZICOM exactly as your healthcare provider tells you to take it.**
- 958 • EPZICOM may be taken with or without food.
- 959 • Do not skip doses.
- 960 • **Do not let your EPZICOM run out.**

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

965 **What are the possible side effects of EPZICOM?**

- 966 • **EPZICOM can cause serious side effects including allergic reactions,**
967 **lactic acidosis, and liver problems. See “What is the most important**
968 **information I should know about EPZICOM?”**

- 969 • **Changes in immune system (Immune Reconstitution Syndrome).** Your
970 immune system may get stronger and begin to fight infections that have been
971 hidden in your body for a long time. Tell your healthcare provider if you start
972 having new or worse symptoms of infection after you start taking EPZICOM.
- 973 • **Changes in body fat (fat redistribution).** Changes in body fat (lipoatrophy or
974 lipodystrophy) can happen in some people taking antiretroviral medicines
975 including EPZICOM.
- 976 These changes may include:
- 977 • more fat in or around your trunk, upper back and neck (buffalo hump),
978 breast, or chest
- 979 • loss of fat in your legs, arms, or face
- 980 • **Heart attack (myocardial infarction).** Some HIV medicines including
981 EPZICOM may increase your risk of heart attack.

982 **The most common side effects of EPZICOM include:**

- 983 • trouble sleeping
- 984 • depression
- 985 • headache
- 986 • tiredness
- 987 • dizziness
- 988 • nausea
- 989 • diarrhea
- 990 • rash
- 991 • fever

992 Tell your healthcare provider if you have any side effect that bothers you or that
993 does not go away.

994 These are not all the possible side effects of EPZICOM. For more information, ask
995 your healthcare provider or pharmacist.

996 Call your doctor for medical advice about side effects. You may report side effects
997 to FDA at 1-800-FDA-1088.

998 **How should I store EPZICOM?**

999 Store EPZICOM at 59°F to 86°F (15°C to 30°C).

1000 **Keep EPZICOM and all medicines out of the reach of children.**

1001 **General information for safe and effective use of EPZICOM.**

- 1002 Avoid doing things that can spread HIV infection to others.
- 1003 • **Do not share needles or other injection equipment.**
 - 1004 • **Do not share personal items that can have blood or body fluids on them,**
 - 1005 **like toothbrushes and razor blades.**
 - 1006 • **Do not have any kind of sex without protection.** Always practice safe sex
 - 1007 by using a latex or polyurethane condom to lower the chance of sexual contact
 - 1008 with semen, vaginal secretions, or blood.

1009 Medicines are sometimes prescribed for purposes other than those listed in a
1010 Medication Guide. Do not use EPZICOM for a condition for which it was not
1011 prescribed. Do not give EPZICOM to other people, even if they have the same
1012 symptoms that you have. It may harm them.

1013 This Medication Guide summarizes the most important information about EPZICOM.
1014 If you would like more information, talk with your healthcare provider. You can ask
1015 your healthcare provider or pharmacist for the information about EPZICOM that is
1016 written for healthcare professionals.

1017 For more information go to www.EPZICOM.com or call 1-877-844-8872.

1018 **What are the ingredients in EPZICOM?**

1019 Active ingredients: abacavir sulfate and lamivudine

1020 Inactive ingredients: magnesium stearate, microcrystalline cellulose, sodium starch
1021 glycolate, and OPADRY® orange YS-1-13065-A, a film coating made of FD&C Yellow
1022 No. 6, hypromellose, polyethylene glycol 400, polysorbate 80, and titanium dioxide.
1023

1024 This Medication Guide has been approved by the US Food and Drug Administration.

1025 COMBIVIR, EPIVIR, EPZICOM, TRIZIVIR, and ZIAGEN are registered trademarks of
1026 ViiV Healthcare.

1027 The brands listed are trademarks of their respective owners and are not trademarks
1028 of ViiV Healthcare. The makers of these brands are not affiliated with and do not
1029 endorse ViiV Healthcare or its products.

1030

1031

1032 Manufactured for:



1033

1034 ViiV Healthcare

1035 Research Triangle Park, NC 27709

1036 by:



1037

1038 GlaxoSmithKline

1039 Research Triangle Park, NC 27709

1040 Lamivudine is manufactured under agreement from

1041 **Shire Pharmaceuticals Group plc**

1042 Basingstoke, UK

1043

1044 ©2012, ViiV Healthcare. All rights reserved.

1045

1046 May 2012

1047 EPZ:MG

1048