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775
776 PHARMACIST-DETACH HERE AND GIVE INSTRUCTIONS TO PATIENT
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778

779 **PATIENT INFORMATION**

780
781 **LEXIVA[®]**

782 (lex-EE-vah)

783 **(fosamprenavir calcium)**

784 **Tablets and Oral Suspension**

785
786 Read the Patient Information that comes with LEXIVA before you start taking it and each time
787 you get a refill. There may be new information. This information does not take the place of
788 talking with your healthcare provider about your medical condition or treatment. It is important
789 to remain under a healthcare provider's care while taking LEXIVA. Do not change or stop
790 treatment without first talking with your healthcare provider. Talk to your healthcare provider or
791 pharmacist if you have any questions about LEXIVA.

792
793 **What is the most important information I should know about LEXIVA?**

794 LEXIVA can cause dangerous and life-threatening interactions if taken with certain other
795 medicines. Tell your healthcare provider about all the medicines you take, including prescription
796 and nonprescription medicines, vitamins, and herbal supplements.

- 797
- 798 • Some medicines cannot be taken at all with LEXIVA.
 - 799 • Some medicines will require dose changes if taken with LEXIVA.
 - 800 • Some medicines will require close monitoring if you take them with LEXIVA.

801 Know all the medicines you take, including prescription and nonprescription medicines,
802 vitamins, and herbal supplements. Keep a list of the medicines you take. Show this list to all your
803 healthcare providers and pharmacists anytime you get a new medicine or refill. Your healthcare
804 providers and pharmacists must know all the medicines you take. They will tell you if you can
805 take other medicines with LEXIVA. Do not start any new medicines while you are taking

806 LEXIVA without talking with your healthcare provider or pharmacist. You can ask your
807 healthcare provider or pharmacist for a list of medicines that can interact with LEXIVA.

808

809 **What is LEXIVA?**

810 LEXIVA is a medicine you take by mouth to treat HIV infection. HIV is the virus that causes
811 AIDS (acquired immune deficiency syndrome). LEXIVA belongs to a class of anti-HIV
812 medicines called protease inhibitors. LEXIVA is always used with other anti-HIV medicines.
813 When used in combination therapy, LEXIVA may help lower the amount of HIV found in your
814 blood, raise CD4+ (T) cell counts, and keep your immune system as healthy as possible, so it can
815 help fight infection. However, LEXIVA does not work in all patients with HIV.

816

817 **LEXIVA does not:**

- 818 • cure HIV infection or AIDS. We do not know if LEXIVA will help you live longer or have
819 fewer of the medical problems (opportunistic infections) that people get with HIV or AIDS.
820 Opportunistic infections are infections that develop because the immune system is weak.
821 Some of these conditions are pneumonia, herpes virus infections, and *Mycobacterium avium*
822 complex (MAC) infections. It is very important that you see your healthcare provider
823 regularly while you are taking LEXIVA. The long-term effects of LEXIVA are not known.
- 824 • lower the risk of passing HIV to other people through sexual contact, sharing needles, or
825 being exposed to your blood. For your health and the health of others, it is important to
826 always practice safer sex by using a latex or polyurethane condom to lower the chance of
827 sexual contact with semen, vaginal secretions, or blood. Never use or share dirty needles.

828

829 LEXIVA has not been fully studied in children under the age of 2 or in adults over the age of 65.

830

831 **Who should not take LEXIVA?**

832 **Do not take LEXIVA if you:**

- 833 • are taking certain other medicines. Read the section “What is the most important information I
834 should know about LEXIVA?” Do not take the following medicines* with LEXIVA. You
835 could develop serious or life-threatening problems.
 - 836 • HALCION® (triazolam; used for insomnia)
 - 837 • Ergot medicines: dihydroergotamine, ergonovine, ergotamine, and methylergonovine
838 such as CAFERGOT®, MIGRANAL®, D.H.E. 45®, ergotrate maleate, METHERGINE®,
839 and others (used for migraine headaches)
 - 840 • PROPULSID® (cisapride), used for certain stomach problems
 - 841 • VERSED® (midazolam), used for sedation
 - 842 • ORAP® (pimozide), used for Tourette’s disorder
- 843 • are allergic to LEXIVA or any of its ingredients. The active ingredient is fosamprenavir
844 calcium. See the end of this leaflet for a list of all the ingredients in LEXIVA.
- 845 • are allergic to AGENERASE (amprenavir).

846
847 You should not take AGENERASE (amprenavir) and LEXIVA at the same time.

848
849 There are other medicines you should not take if you are taking LEXIVA and NORVIR®
850 (ritonavir) together. You could develop serious or life-threatening problems. Tell your healthcare
851 provider about all medicines you are taking before you begin taking LEXIVA and NORVIR
852 (ritonavir) together.

853
854 **What should I tell my healthcare provider before taking LEXIVA?**

855 Before taking LEXIVA, tell your healthcare provider about all of your medical conditions
856 including if you:

- 857 • are pregnant or planning to become pregnant. It is not known if LEXIVA can harm your
858 unborn baby. You and your healthcare provider will need to decide if LEXIVA is right for
859 you. If you use LEXIVA while you are pregnant, talk to your healthcare provider about how
860 you can be on the Antiretroviral Pregnancy Registry.
- 861 • are breastfeeding. You should not breastfeed if you are HIV-positive because of the chance of
862 passing the HIV virus to your baby through your milk. Also, it is not known if LEXIVA can
863 pass into your breast milk and if it can harm your baby. If you are a woman who has or will
864 have a baby, talk with your healthcare provider about the best way to feed your baby.
- 865 • have liver problems. You may be given a lower dose of LEXIVA or LEXIVA may not be
866 right for you.
- 867 • have kidney problems
- 868 • have diabetes. You may need dose changes in your insulin or other diabetes medicines.
- 869 • have hemophilia
- 870 • are allergic to sulfa medicines

871
872 Before taking LEXIVA, tell your healthcare provider about all the medicines you take, including
873 prescription and nonprescription medicines, vitamins, and herbal supplements. LEXIVA can
874 cause dangerous and life-threatening interactions if taken with certain other medicines. You may
875 need dose changes in some of your medicines or closer monitoring with some medicines if you
876 also take LEXIVA (see “What is the most important information I should know about
877 LEXIVA.”). Know all the medicines that you take and keep a list of them with you to show
878 healthcare providers and pharmacists.

879
880 Women who use birth control pills should choose a different kind of contraception. The use of
881 LEXIVA with NORVIR (ritonavir) in combination with birth control pills may be harmful to
882 your liver. The use of LEXIVA with or without NORVIR may decrease the effectiveness of birth
883 control pills. Talk to your healthcare provider about choosing an effective contraceptive.

884
885 **How should I take LEXIVA?**

- 886 • Take LEXIVA exactly as your healthcare provider prescribed.
- 887 • Do not take more or less than your prescribed dose of LEXIVA at any one time. Do not
- 888 change your dose or stop taking LEXIVA without talking with your healthcare provider.
- 889 • You can take LEXIVA Tablets with or without food.
- 890 • Adults should take LEXIVA Oral Suspension without food.
- 891 • Pediatric patients should take LEXIVA Oral Suspension with food. If vomiting occurs within
- 892 30 minutes after dosing, the dose should be repeated.
- 893 • Shake LEXIVA Oral Suspension vigorously before each use.
- 894 • When your supply of LEXIVA or other anti-HIV medicine starts to run low, get more from
- 895 your healthcare provider or pharmacy. The amount of HIV virus in your blood may increase if
- 896 one or more of the medicines are stopped, even for a short time.
- 897 • Stay under the care of a healthcare provider while using LEXIVA.
- 898 • It is important that you do not miss any doses. If you miss a dose of LEXIVA by more than
- 899 4 hours, wait and take the next dose at the regular time. However, if you miss a dose by fewer
- 900 than 4 hours, take your missed dose right away. Then take your next dose at the regular time.
- 901 • If you take too much LEXIVA, call your healthcare provider or poison control center right
- 902 away.

903

904 **What should I avoid while taking LEXIVA?**

- 905 • Do not use certain medicines while you are taking LEXIVA. See “What is the most important
- 906 information I should know about LEXIVA” and “Who should not take LEXIVA?”
- 907 • Do not breastfeed. See “Before taking LEXIVA, tell your healthcare provider”. Talk with
- 908 your healthcare provider about the best way to feed your baby.
- 909 • Avoid doing things that can spread HIV infection since LEXIVA doesn't stop you from
- 910 passing the HIV infection to others.
- 911 • Do not share needles or other injection equipment.
- 912 • Do not share personal items that can have blood or body fluids on them, like toothbrushes or
- 913 razor blades.
- 914 • Do not have any kind of sex without protection. Always practice safer sex by using a latex or
- 915 polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or
- 916 blood.

917

918 **What are the possible side effects of LEXIVA?**

919 LEXIVA may cause the following side effects:

- 920 • skin rash. Skin rashes, some with itching, have happened in patients taking LEXIVA.
- 921 Swelling of the face, lips, and tongue (angioedema) has also been reported. Tell your
- 922 healthcare provider if you get a rash or develop facial swelling after starting LEXIVA.
- 923 • diabetes and high blood sugar (hyperglycemia). Some patients had diabetes before taking
- 924 LEXIVA while others did not. Some patients may need changes in their diabetes medicine.
- 925 Others may need a new diabetes medicine.

- 926 • increased bleeding problems in some patients with hemophilia.
927 • worse liver disease. Patients with liver problems, including hepatitis B or C, are more likely to
928 get worse liver disease when they take anti-HIV medicines like LEXIVA.
929 • changes in blood tests. Some people have changes in blood tests while taking LEXIVA. These
930 include increases seen in liver function tests and blood fat levels, and decreases in white blood
931 cells. Your healthcare provider may do regular blood tests to see if LEXIVA is affecting your
932 body.
933 • changes in body fat. These changes have happened in patients taking antiretroviral medicines
934 like LEXIVA. The changes may include an increased amount of fat in the upper back and
935 neck ("buffalo hump"), breast, and around the trunk. Loss of fat from the legs, arms, and face
936 may also happen. The cause and long-term health effects of these conditions are not known at
937 this time.

938

939 Common side effects of LEXIVA are nausea, vomiting, and diarrhea. Tell your healthcare
940 provider about any side effects that bother you or that won't go away.

941

942 This list of side effects of LEXIVA is not complete. For more information, ask your healthcare
943 provider or pharmacist.

944

945 **How should I store LEXIVA?**

- 946 • LEXIVA Tablets should be stored at room temperature between 59° and 86°F (15° to 30°C).
947 Keep the container of LEXIVA Tablets tightly closed.
948 • LEXIVA Oral Suspension may be stored at room temperature or refrigerated. Refrigeration of
949 LEXIVA Oral Suspension may improve taste for some patients. Do not freeze.
950 • Keep LEXIVA and all medicines out of the reach of children.
951 • Do not keep medicine that is out of date or that you no longer need. Be sure that if you throw
952 any medicine away, it is out of the reach of children.

953

954 **General information about LEXIVA**

955 Medicines are sometimes prescribed for conditions that are not mentioned in patient information
956 leaflets. Do not use LEXIVA for a condition for which it was not prescribed. Do not give
957 LEXIVA to other people, even if they have the same symptoms you have. It may harm them.

958

959 This leaflet summarizes the most important information about LEXIVA. If you would like more
960 information, talk with your healthcare provider. You can ask your pharmacist or healthcare
961 provider for information about LEXIVA that is written for health professionals. For more
962 information you can call toll-free 888-825-5249 or visit www.LEXIVA.com.

963

964 **What are the ingredients in LEXIVA?**

965 Tablets:

966 Active Ingredient: fosamprenavir calcium.

967 Inactive Ingredients: colloidal silicon dioxide, croscarmellose sodium, magnesium stearate,
968 microcrystalline cellulose, and povidone K30. The tablet film-coating contains the inactive
969 ingredients hypromellose, iron oxide red, titanium dioxide, and triacetin.

970

971 LEXIVA Tablets, 700 mg, are pink in color and are capsule-shaped, with the letters “GX LL7”
972 printed on one side of the tablet.



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974

975 Oral Suspension:

976 Active Ingredient: fosamprenavir calcium

977 Inactive ingredients: artificial grape-bubblegum flavor, calcium chloride dihydrate,
978 hypromellose, methylparaben, natural peppermint flavor, polysorbate 80, propylene glycol,
979 propylparaben, purified water, and sucralose.

980

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985 GlaxoSmithKline or its products.

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