

695 **PATIENT INFORMATION**

Rx only

696 **SUSTIVA**[®] (sus-TEE-vah)

697 **[efavirenz (eh-FAH-vih-rehnz)]**

698 **capsules and tablets**

699

700 **ALERT: Find out about medicines that should NOT be taken with SUSTIVA.**

701 Please also read the section "**MEDICINES YOU SHOULD NOT TAKE WITH**
702 **SUSTIVA.**"

703 Read this information before you start taking SUSTIVA. Read it again each time you
704 refill your prescription, in case there is any new information. This leaflet provides a
705 summary about SUSTIVA and does not include everything there is to know about your
706 medicine. This information is not meant to take the place of talking with your doctor.

707 **What is SUSTIVA?**

708 SUSTIVA is a medicine used in combination with other medicines to help treat infection
709 with Human Immunodeficiency Virus type 1 (HIV-1), the virus that causes AIDS
710 (acquired immune deficiency syndrome). SUSTIVA is a type of anti-HIV drug called a
711 "non-nucleoside reverse transcriptase inhibitor" (NNRTI). NNRTIs are not used in the
712 treatment of Human Immunodeficiency Virus type 2 (HIV-2) infection.

713 SUSTIVA works by lowering the amount of HIV-1 in the blood (viral load). SUSTIVA
714 must be taken with other anti-HIV medicines. When taken with other anti-HIV
715 medicines, SUSTIVA has been shown to reduce viral load and increase the number of
716 CD4+ cells, a type of immune cell in blood. SUSTIVA may not have these effects in
717 every patient.

718 SUSTIVA does not cure HIV or AIDS. People taking SUSTIVA may still develop other
719 infections and complications. Therefore, it is very important that you stay under the care
720 of your doctor.

721 SUSTIVA has not been shown to reduce the risk of passing HIV to others. Therefore,
722 continue to practice safe sex, and do not use or share dirty needles.

723 **What are the possible side effects of SUSTIVA?**

724 **Serious psychiatric problems.** A small number of patients experience severe depression,
725 strange thoughts, or angry behavior while taking SUSTIVA. Some patients have thoughts
726 of suicide and a few have actually committed suicide. These problems tend to occur more
727 often in patients who have had mental illness. Contact your doctor right away if you think
728 you are having these psychiatric symptoms, so your doctor can decide if you should
729 continue to take SUSTIVA (efavirenz).

730 **Common side effects.** Many patients have dizziness, trouble sleeping, drowsiness,
731 trouble concentrating, and/or unusual dreams during treatment with SUSTIVA. These
732 side effects may be reduced if you take SUSTIVA at bedtime on an empty stomach. They
733 also tend to go away after you have taken the medicine for a few weeks. If you have these
734 common side effects, such as dizziness, it does not mean that you will also have serious
735 psychiatric problems, such as severe depression, strange thoughts, or angry behavior. Tell
736 your doctor right away if any of these side effects continue or if they bother you. It is
737 possible that these symptoms may be more severe if SUSTIVA is used with alcohol or
738 mood altering (street) drugs.

739 If you are dizzy, have trouble concentrating, or are drowsy, avoid activities that may be
740 dangerous, such as driving or operating machinery.

741 Rash is common. Rashes usually go away without any change in treatment. In a small
742 number of patients, rash may be serious. If you develop a rash, call your doctor right
743 away. **Rash may be a serious problem in some children.** Tell your child's doctor right
744 away if you notice rash or any other side effects while your child is taking SUSTIVA.

745 Other common side effects include tiredness, upset stomach, vomiting, and diarrhea.

746 **Changes in body fat.** Changes in body fat develop in some patients taking anti-HIV
747 medicine. These changes may include an increased amount of fat in the upper back and
748 neck ("buffalo hump"), in the breasts, and around the trunk. Loss of fat from the legs,
749 arms, and face may also happen. The cause and long-term health effects of these fat
750 changes are not known.

751 Tell your doctor or healthcare provider if you notice any side effects while taking
752 SUSTIVA.

753 Contact your doctor before stopping SUSTIVA because of side effects or for any other
754 reason.

755 This is not a complete list of side effects possible with SUSTIVA. Ask your doctor or
756 pharmacist for a more complete list of side effects of SUSTIVA and all the medicines
757 you will take.

758 **How should I take SUSTIVA?**

759 **General Information**

- 760 • You should take SUSTIVA on an empty stomach, preferably at bedtime.
- 761 • Swallow SUSTIVA with water.
- 762 • Taking SUSTIVA with food increases the amount of medicine in your body, which
763 may increase the frequency of side effects.
- 764 • Taking SUSTIVA at bedtime may make some side effects less bothersome.
- 765 • SUSTIVA must be taken in combination with other anti-HIV medicines. If you take
766 only SUSTIVA, the medicine may stop working.
- 767 • Do not miss a dose of SUSTIVA. If you forget to take SUSTIVA, take the missed
768 dose right away, unless it is almost time for your next dose. Do not double the next
769 dose. Carry on with your regular dosing schedule. If you need help in planning the
770 best times to take your medicine, ask your doctor or pharmacist.
- 771 • Take the exact amount of SUSTIVA your doctor prescribes. Never change the dose
772 on your own. Do not stop this medicine unless your doctor tells you to stop.
- 773 • If you believe you took more than the prescribed amount of SUSTIVA, contact your
774 local Poison Control Center or emergency room right away.

- 775 • Tell your doctor if you start any new medicine or change how you take old ones.
776 Your doses may need adjustment.
- 777 • When your SUSTIVA supply starts to run low, get more from your doctor or
778 pharmacy. This is very important because the amount of virus in your blood may
779 increase if the medicine is stopped for even a short time. The virus may develop
780 resistance to SUSTIVA and become harder to treat.
- 781 • Your doctor may want to do blood tests to check for certain side effects while you
782 take SUSTIVA (efavirenz).

783 **Capsules**

- 784 • The dose of SUSTIVA capsules for adults is 600 mg (three 200-mg capsules, taken
785 together) once a day by mouth. The dose of SUSTIVA for children may be lower
786 (see **Can children take SUSTIVA?**).

787 **Tablets**

- 788 • The dose of SUSTIVA tablets for adults is 600 mg (one tablet) once a day by mouth.
789

790 **Can children take SUSTIVA?**

791 Yes, children who are able to swallow capsules can take SUSTIVA. Rash may be a
792 serious problem in some children. Tell your child's doctor right away if you notice rash
793 or any other side effects while your child is taking SUSTIVA. The dose of SUSTIVA for
794 children may be lower than the dose for adults. Capsules containing lower doses of
795 SUSTIVA are available. Your child's doctor will determine the right dose based on your
796 child's weight.

797 **Who should not take SUSTIVA?**

798 **Do not take SUSTIVA if you are allergic** to the active ingredient, efavirenz, or to any
799 of the inactive ingredients. Your doctor and pharmacist have a list of the inactive
800 ingredients.

801 **What should I avoid while taking SUSTIVA?**

- 802 • **Women taking SUSTIVA should not become pregnant.** Serious birth defects have
803 been seen in the offspring of animals and women treated with SUSTIVA during
804 pregnancy. It is not known whether SUSTIVA caused these defects. **Tell your doctor**
805 **right away if you are pregnant.** Also talk with your doctor if you want to become
806 pregnant.
- 807 • Women should not rely only on hormone-based birth control, such as pills, injections,
808 or implants, because SUSTIVA may make these contraceptives ineffective. Women
809 must use a reliable form of barrier contraception, such as a condom or diaphragm,
810 even if they also use other methods of birth control.
- 811 • **Do not breast-feed if you are taking SUSTIVA.** The Centers for Disease Control
812 and Prevention recommend that mothers with HIV not breast-feed because they can
813 pass the HIV through their milk to the baby. Also, SUSTIVA may pass through
814 breast milk and cause serious harm to the baby. Talk with your doctor if you are
815 breast-feeding. You may need to stop breast-feeding or use a different medicine.
- 816 • Taking SUSTIVA with alcohol or other medicines causing similar side effects as
817 SUSTIVA, such as drowsiness, may increase those side effects.
- 818 • Do not take any other medicines without checking with your doctor. These medicines
819 include prescription and nonprescription medicines and herbal products, especially
820 St. John's wort.

821 **Before using SUSTIVA, tell your doctor if you**

- 822 • **have problems with your liver or have hepatitis.** Your doctor may want to do tests
823 to check your liver while you take SUSTIVA.
- 824 • **have ever had mental illness or are using drugs or alcohol.**
- 825 • **have ever had seizures or are taking medicine for seizures** [for example, Dilantin[®]
826 (phenytoin), Tegretol[®] (carbamazepine), or phenobarbital]. Your doctor may want to
827 check drug levels in your blood from time to time.

828 **What important information should I know about taking other**
829 **medicines with SUSTIVA?**

830 **SUSTIVA may change the effect of other medicines, including ones for HIV, and**
831 **cause serious side effects.** Your doctor may change your other medicines or change
832 their doses. Other medicines, including herbal products, may affect SUSTIVA. For this
833 reason, **it is very important to:**

- 834 • let all your doctors and pharmacists know that you take SUSTIVA.
835 • tell your doctors and pharmacists about all medicines you take. This includes those
836 you buy over-the-counter and herbal or natural remedies.

837 Bring all your prescription and nonprescription medicines as well as any herbal remedies
838 that you are taking when you see a doctor, or make a list of their names, how much you
839 take, and how often you take them. This will give your doctor a complete picture of the
840 medicines you use. Then he or she can decide the best approach for your situation.

841 Taking SUSTIVA with St. John's wort (*Hypericum perforatum*), an herbal product sold
842 as a dietary supplement, or products containing St. John's wort is not recommended. Talk
843 with your doctor if you are taking or are planning to take St. John's wort. Taking St.
844 John's wort may decrease SUSTIVA levels and lead to increased viral load and possible
845 resistance to SUSTIVA or cross-resistance to other anti-HIV drugs.

846 **MEDICINES YOU SHOULD NOT TAKE WITH SUSTIVA**

847 The following medicines may cause serious and life-threatening side effects when taken
848 with SUSTIVA. You should not take any of these medicines while taking SUSTIVA:

- 849 • Hismanal[®] (astemizole)
850 • Vascor[®] (bepidil)
851 • Propulsid[®] (cisapride)
852 • Versed[®] (midazolam)
853 • Orap[®] (pimozide)
854 • Halcion[®] (triazolam)
855 • Ergot medications (for example, Wigraine[®] and Cafergot[®])

856 The following medicine should not be taken with SUSTIVA since it may lose its effect or
857 may increase the chance of having side effects from SUSTIVA:

- 858 • Vfend[®] (voriconazole). Some doses of voriconazole can be taken at the same time as
859 a lower dose of SUSTIVA, but you must check with your doctor first.

860 **The following medicines may need to be replaced with another medicine when taken**
861 **with SUSTIVA:**

- 862 • Fortovase[®], Invirase[®] (saquinavir)
- 863 • Biaxin[®] (clarithromycin)
- 864 • Carbatrol[®], Tegretol[®] (carbamazepine)
- 865 • Sporanox[®] (itraconazole)

866 **The following medicines may require a change in the dose of either SUSTIVA or the**
867 **other medicine:**

- 868 • Calcium channel blockers such as Cardizem[®] or Tiazac[®] (diltiazem), Covera HS[®] or
869 Isoptin SR[®] (verapamil), and others.
- 870 • The cholesterol-lowering medicines Lipitor[®] (atorvastatin), PRAVACHOL[®]
871 (pravastatin), and Zocor[®] (simvastatin).
- 872 • Crixivan[®] (indinavir)
- 873 • Kaletra[®] (lopinavir/ritonavir)
- 874 • Methadone
- 875 • Mycobutin[®] (rifabutin)
- 876 • REYATAZ[®] (atazanavir sulfate). If you are taking SUSTIVA and REYATAZ, you
877 should also be taking Norvir[®] (ritonavir).
- 878 • Rifadin[®] (rifampin) or the rifampin-containing medicines Rifamate[®] and Rifater[®].
- 879 • Zoloft[®] (sertraline)

880 **These are not all the medicines that may cause problems if you take SUSTIVA. Be**
881 **sure to tell your doctor about all medicines that you take.**

882 **General advice about SUSTIVA:**

883 **Medicines are sometimes prescribed for conditions that are not mentioned in patient**
884 **information leaflets. Do not use SUSTIVA for a condition for which it was not**
885 **prescribed. Do not give SUSTIVA to other people, even if they have the same**
886 **symptoms you have. It may harm them.**

887 Keep SUSTIVA at room temperature (77° F) in the bottle given to you by your
888 pharmacist. The temperature can range from 59° to 86° F.

889 Keep SUSTIVA out of the reach of children.

890

891 This leaflet summarizes the most important information about SUSTIVA. If you would
892 like more information, talk with your doctor. You can ask your pharmacist or doctor for
893 the full prescribing information about SUSTIVA, or you can visit the SUSTIVA website
894 at <http://www.sustiva.com> or call 1-800-321-1335.

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902 Distributed by:

903 Bristol-Myers Squibb Company

904 Princeton, NJ 08543 USA

905 XX-XXXXXX-XX XXXXXXXXXXXX Revised _____