

740 **Table 3. Dosing Regimen**

Treatment Day	Total Daily Dose	Tablet Strength	Number of Tablets		
			Morning	Midday	Evening
1	200 mg	100 mg	1	0	1
4	300 mg	100 mg	1	1	1

741
 742 **Increasing the Dosage Above 300 mg/Day:** As with other antidepressants, the full
 743 antidepressant effect of WELLBUTRIN may not be evident until 4 weeks of treatment or longer.
 744 An increase in dosage, up to a maximum of 450 mg/day, given in divided doses of not more than
 745 150 mg each, may be considered for patients in whom no clinical improvement is noted after
 746 several weeks of treatment at 300 mg/day. Dosing above 300 mg/day may be accomplished
 747 using the 75- or 100-mg tablets. The 100-mg tablet must be administered 4 times daily with at
 748 least 4 hours between successive doses, in order not to exceed the limit of 150 mg in a single
 749 dose. WELLBUTRIN should be discontinued in patients who do not demonstrate an adequate
 750 response after an appropriate period of treatment at 450 mg/day.

751 **Maintenance Treatment:** The lowest dose that maintains remission is recommended.
 752 Although it is not known how long the patient should remain on WELLBUTRIN, it is generally
 753 recognized that acute episodes of depression require several months or longer of antidepressant
 754 drug treatment.

755 **Dosage Adjustment for Patients with Impaired Hepatic Function:** WELLBUTRIN
 756 should be used with extreme caution in patients with severe hepatic cirrhosis. The dose should
 757 not exceed 75 mg once a day in these patients. WELLBUTRIN should be used with caution in
 758 patients with hepatic impairment (including mild to moderate hepatic cirrhosis) and a reduced
 759 frequency and/or dose should be considered in patients with mild to moderate hepatic cirrhosis
 760 (see CLINICAL PHARMACOLOGY, WARNINGS, and PRECAUTIONS).

761 **Dosage Adjustment for Patients with Impaired Renal Function:** WELLBUTRIN
 762 should be used with caution in patients with renal impairment and a reduced frequency and/or
 763 dose should be considered (see CLINICAL PHARMACOLOGY and PRECAUTIONS).

764 **HOW SUPPLIED**

765 WELLBUTRIN Tablets, 75 mg of bupropion hydrochloride, are yellow-gold, round, biconvex
 766 tablets printed with “WELLBUTRIN 75” in bottles of 100 (NDC 0173-0177-55).

767 WELLBUTRIN Tablets, 100 mg of bupropion hydrochloride, are red, round, biconvex tablets
 768 printed with “WELLBUTRIN 100” in bottles of 100 (NDC 0173-0178-55).

769 **Store at 15° to 25°C (59° to 77°F). Protect from light and moisture.**
 770

771 **MEDICATION GUIDE**
 772 **WELLBUTRIN® (WELL byu-trin)**
 773 **(bupropion hydrochloride) Tablets**

774
775 Read this Medication Guide carefully before you start using WELLBUTRIN and each time you
776 get a refill. There may be new information. This information does not take the place of talking
777 with your doctor about your medical condition or your treatment. If you have any questions
778 about WELLBUTRIN, ask your doctor or pharmacist.

779
780 **IMPORTANT: Be sure to read both sections of this Medication Guide. The first section is**
781 **about the risk of suicidal thoughts and actions with antidepressant medicines; the second**
782 **section is entitled “What other important information should I know about**
783 **WELLBUTRIN?”**

784
785 **Antidepressant Medicines, Depression and Other Serious Mental Illnesses, and**
786 **Suicidal Thoughts or Actions**

787 This section of the Medication Guide is only about the risk of suicidal thoughts and actions
788 with antidepressant medicines. **Talk to your, or your family member’s, healthcare provider**
789 **about:**

- 790 • all risks and benefits of treatment with antidepressant medicines
791 • all treatment choices for depression or other serious mental illness

792
793 **What is the most important information I should know about antidepressant medicines,**
794 **depression and other serious mental illnesses, and suicidal thoughts or actions?**

- 795 **1. Antidepressant medicines may increase suicidal thoughts or actions in some children,**
796 **teenagers, and young adults within the first few months of treatment.**
797 **2. Depression and other serious mental illnesses are the most important causes of suicidal**
798 **thoughts and actions. Some people may have a particularly high risk of having suicidal**
799 **thoughts or actions.** These include people who have (or have a family history of) bipolar
800 illness (also called manic-depressive illness) or suicidal thoughts or actions.
801 **3. How can I watch for and try to prevent suicidal thoughts and actions in myself or a**
802 **family member?**
803 • Pay close attention to any changes, especially sudden changes, in mood, behaviors,
804 thoughts, or feelings. This is very important when an antidepressant medicine is started or
805 when the dose is changed.
806 • Call the healthcare provider right away to report new or sudden changes in mood,
807 behavior, thoughts, or feelings.
808 • Keep all follow-up visits with the healthcare provider as scheduled. Call the healthcare
809 provider between visits as needed, especially if you have concerns about symptoms.

810
811 **Call a healthcare provider right away if you or your family member has any of the**
812 **following symptoms, especially if they are new, worse, or worry you:**

813

- thoughts about suicide or dying
- attempts to commit suicide
- new or worse depression
- new or worse anxiety
- feeling very agitated or restless
- panic attacks
- trouble sleeping (insomnia)
- new or worse irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- other unusual changes in behavior or mood

814

815 **What else do I need to know about antidepressant medicines?**

- 816 • **Never stop an antidepressant medicine without first talking to a healthcare provider.**
 817 Stopping an antidepressant medicine suddenly can cause other symptoms.
- 818 • **Antidepressants are medicines used to treat depression and other illnesses.** It is
 819 important to discuss all the risks of treating depression and also the risks of not treating it.
 820 Patients and their families or other caregivers should discuss all treatment choices with the
 821 healthcare provider, not just the use of antidepressants.
- 822 • **Antidepressant medicines have other side effects.** Talk to the healthcare provider about the
 823 side effects of the medicine prescribed for you or your family member.
- 824 • **Antidepressant medicines can interact with other medicines.** Know all of the medicines
 825 that you or your family member takes. Keep a list of all medicines to show the healthcare
 826 provider. Do not start new medicines without first checking with your healthcare provider.
- 827 • **Not all antidepressant medicines prescribed for children are FDA approved for use in**
 828 **children.** Talk to your child’s healthcare provider for more information.

829

830 WELLBUTRIN has not been studied in children under the age of 18 and is not approved for use
 831 in children and teenagers.

832

833 **What other important information should I know about WELLBUTRIN?**

834

835 **There is a chance of having a seizure (convulsion, fit) with WELLBUTRIN, especially in**
 836 **people:**

- 837 • with certain medical problems.
 838 • who take certain medicines.

839

840 The chance of having seizures increases with higher doses of WELLBUTRIN. For more
 841 information, see the sections “Who should not take WELLBUTRIN?” and “What should I tell
 842 my doctor before using WELLBUTRIN?” Tell your doctor about all of your medical conditions
 843 and all the medicines you take. **Do not take any other medicines while you are using**
 844 **WELLBUTRIN unless your doctor has said it is okay to take them.**

845

846 **If you have a seizure while taking WELLBUTRIN, stop taking the tablets and call your**
847 **doctor right away.** Do not take WELLBUTRIN again if you have a seizure.

848

849 **What is WELLBUTRIN?**

850 WELLBUTRIN is a prescription medicine used to treat adults with a certain type of depression
851 called major depressive disorder.

852

853 **Who should not take WELLBUTRIN?**

854 **Do not take WELLBUTRIN if you**

- 855 • have or had a seizure disorder or epilepsy.
- 856 • **are taking ZYBAN (used to help people stop smoking) or any other medicines that**
857 **contain bupropion hydrochloride, such as WELLBUTRIN SR Sustained-Release**
858 **Tablets or WELLBUTRIN XL Extended-Release Tablets.** Bupropion is the same
859 ingredient that is in WELLBUTRIN.
- 860 • drink a lot of alcohol and abruptly stop drinking, or use medicines called sedatives (these
861 make you sleepy) or benzodiazepines and you stop using them all of a sudden.
- 862 • have taken within the last 14 days medicine for depression called a monoamine oxidase
863 inhibitor (MAOI), such as NARDIL^{®*} (phenelzine sulfate), PARNATE[®] (tranylcypromine
864 sulfate), or MARPLAN^{®*} (isocarboxazid).
- 865 • have or had an eating disorder such as anorexia nervosa or bulimia.
- 866 • are allergic to the active ingredient in WELLBUTRIN, bupropion, or to any of the inactive
867 ingredients. See the end of this leaflet for a complete list of ingredients in WELLBUTRIN.

868

869 **What should I tell my doctor before using WELLBUTRIN?**

- 870 • **Tell your doctor about your medical conditions.** Tell your doctor if you:
 - 871 • **are pregnant or plan to become pregnant.** It is not known if WELLBUTRIN can harm
872 your unborn baby. If you can use WELLBUTRIN while you are pregnant, talk to your
873 doctor about how you can be on the Bupropion Pregnancy Registry.
 - 874 • **are breastfeeding.** WELLBUTRIN passes through your milk. It is not known if
875 WELLBUTRIN can harm your baby.
 - 876 • **have liver problems,** especially cirrhosis of the liver.
 - 877 • have kidney problems.
 - 878 • have an eating disorder, such as anorexia nervosa or bulimia.
 - 879 • have had a head injury.
 - 880 • have had a seizure (convulsion, fit).
 - 881 • have a tumor in your nervous system (brain or spine).
 - 882 • have had a heart attack, heart problems, or high blood pressure.
 - 883 • are a diabetic taking insulin or other medicines to control your blood sugar.
 - 884 • drink a lot of alcohol.
 - 885 • abuse prescription medicines or street drugs.

- 886 • **Tell your doctor about all the medicines you take**, including prescription and non-
887 prescription medicines, vitamins, and herbal supplements. Many medicines increase your
888 chances of having seizures or other serious side effects if you take them while you are
889 using WELLBUTRIN.

890

891 **How should I take WELLBUTRIN?**

- 892 • Take WELLBUTRIN exactly as prescribed by your doctor.
893 • Take WELLBUTRIN at the same time each day.
894 • Take your doses of WELLBUTRIN at least 6 hours apart.
895 • You may take WELLBUTRIN with or without food.
896 • If you miss a dose, do not take an extra tablet to make up for the dose you forgot. Wait and
897 take your next tablet at the regular time. **This is very important.** Too much WELLBUTRIN
898 can increase your chance of having a seizure.
899 • If you take too much WELLBUTRIN, or overdose, call your local emergency room or poison
900 control center right away.
901 • **Do not take any other medicines while using WELLBUTRIN unless your doctor has**
902 **told you it is okay.**
903 • It may take several weeks for you to feel that WELLBUTRIN is working. Once you feel
904 better, it is important to keep taking WELLBUTRIN exactly as directed by your doctor. Call
905 your doctor if you do not feel WELLBUTRIN is working for you.
906 • Do not change your dose or stop taking WELLBUTRIN without talking with your doctor
907 first.

908

909 **What should I avoid while taking WELLBUTRIN?**

- 910 • Do not drink a lot of alcohol while taking WELLBUTRIN. If you usually drink a lot of
911 alcohol, talk with your doctor before suddenly stopping. If you suddenly stop drinking
912 alcohol, you may increase your risk of having seizures.
913 • Do not drive a car or use heavy machinery until you know how WELLBUTRIN affects you.
914 WELLBUTRIN can impair your ability to perform these tasks.

915

916 **What are possible side effects of WELLBUTRIN?**

- 917 • **Seizures.** Some patients get seizures while taking WELLBUTRIN. **If you have a seizure**
918 **while taking WELLBUTRIN, stop taking the tablets and call your doctor right away.**
919 Do not take WELLBUTRIN again if you have a seizure.
920 • **Hypertension (high blood pressure).** Some patients get high blood pressure, sometimes
921 severe, while taking WELLBUTRIN. The chance of high blood pressure may be increased if
922 you also use nicotine replacement therapy (for example a nicotine patch) to help you stop
923 smoking.
924 • **Severe allergic reactions. Stop taking WELLBUTRIN and call your doctor right away**
925 **if you get a rash, itching, hives, fever, swollen lymph glands, painful sores in the mouth or**

926 around the eyes, swelling of the lips or tongue, chest pain, or have trouble breathing. These
927 could be signs of a serious allergic reaction.
928 • **Unusual thoughts or behaviors.** Some patients have unusual thoughts or behaviors while
929 taking WELLBUTRIN, including delusions (believe you are someone else), hallucinations
930 (seeing or hearing things that are not there), paranoia (feeling that people are against you), or
931 feeling confused. If this happens to you, call your doctor.

932
933 The most common side effects of WELLBUTRIN are nervousness, constipation, trouble
934 sleeping, dry mouth, headache, nausea, vomiting, and shakiness (tremor).

935
936 If you have nausea, you may want to take your medicine with food. If you have trouble sleeping,
937 do not take your medicine too close to bedtime.

938
939 Tell your doctor right away about any side effects that bother you.

940
941 These are not all the side effects of WELLBUTRIN. For a complete list, ask your doctor or
942 pharmacist.

943 944 **How should I store WELLBUTRIN?**

- 945 • Store WELLBUTRIN at room temperature. Store out of direct sunlight. Keep
946 WELLBUTRIN in its tightly closed bottle.

947 948 **General Information about WELLBUTRIN.**

- 949 • Medicines are sometimes prescribed for purposes other than those listed in a Medication
950 Guide. Do not use WELLBUTRIN for a condition for which it was not prescribed. Do not
951 give WELLBUTRIN to other people, even if they have the same symptoms you have. It may
952 harm them. Keep WELLBUTRIN out of the reach of children.

953
954 This Medication Guide summarizes important information about WELLBUTRIN. For more
955 information, talk to your doctor. You can ask your doctor or pharmacist for information about
956 WELLBUTRIN that is written for health professionals.

957 958 **What are the ingredients in WELLBUTRIN?**

959 Active ingredient: bupropion hydrochloride.

960
961 Inactive ingredients: 75-mg tablet – D&C Yellow No. 10 Lake, FD&C Yellow No. 6 Lake,
962 hydroxypropyl cellulose, hypromellose, microcrystalline cellulose, polyethylene glycol, talc, and
963 titanium dioxide; 100-mg tablet – FD&C Red No. 40 Lake, FD&C Yellow No. 6 Lake,
964 hydroxypropyl cellulose, hypromellose, microcrystalline cellulose, polyethylene glycol, talc, and
965 titanium dioxide.

966
967 *The following are registered trademarks of their respective manufacturers: NARDIL[®]/Warner
968 Lambert Company; MARPLAN[®]/Oxford Pharmaceutical Services, Inc.

969
970 **R_xonly**

971
972 This Medication Guide has been approved by the U.S. Food and Drug Administration.

973
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976 The logo for GlaxoSmithKline, featuring the lowercase letters 'gsk' in a white circle next to the text 'GlaxoSmithKline'.

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