

759 not exceed 75 mg once a day in these patients. WELLBUTRIN should be used with caution in  
760 patients with hepatic impairment (including mild to moderate hepatic cirrhosis) and a reduced  
761 frequency and/or dose should be considered in patients with mild to moderate hepatic cirrhosis  
762 (see CLINICAL PHARMACOLOGY, WARNINGS, and PRECAUTIONS).

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

## 766 HOW SUPPLIED

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

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

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

772

773

## MEDICATION GUIDE

774

**WELLBUTRIN<sup>®</sup> (WELL byu-trin)**

775

**(bupropion hydrochloride) Tablets**

776

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

781

782 **IMPORTANT: Be sure to read the section of this Medication Guide beginning with “What**  
783 **is the most important information I should know about WELLBUTRIN?” It contains**  
784 **important information about this medication. It immediately follows the next section called**  
785 **“About Using Antidepressants in Children and Teenagers.”**

786

787

### About Using Antidepressants in Children and Teenagers

788

789 **What is the most important information I should know if my child is being prescribed an**  
790 **antidepressant?**

791

792 Parents or guardians need to think about 4 important things when their child is prescribed an  
793 antidepressant:

794

1. There is a risk of suicidal thoughts or actions

795

2. How to try to prevent suicidal thoughts or actions in your child

796

3. You should watch for certain signs if your child is taking an antidepressant

797

4. There are benefits and risks when using antidepressants

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**1. There is a Risk of Suicidal Thoughts or Actions**

Children and teenagers sometimes think about suicide, and many report trying to kill themselves.

Antidepressants increase suicidal thoughts and actions in some children and teenagers. But suicidal thoughts and actions can also be caused by depression, a serious medical condition that is commonly treated with antidepressants. Thinking about killing yourself or trying to kill yourself is called *suicidality* or *being suicidal*.

A large study combined the results of 24 different studies of children and teenagers with depression or other illnesses. In these studies, patients took either a placebo (sugar pill) or an antidepressant for 1 to 4 months. ***No one committed suicide in these studies***, but some patients became suicidal. On sugar pills, 2 out of every 100 became suicidal. On the antidepressants, 4 out of every 100 patients became suicidal.

**For some children and teenagers, the risks of suicidal actions may be especially high.** These include patients with

- Bipolar illness (sometimes called manic-depressive illness)
- A family history of bipolar illness
- A personal or family history of attempting suicide

If any of these are present, make sure you tell your healthcare provider before your child takes an antidepressant.

**2. How to Try to Prevent Suicidal Thoughts and Actions**

To try to prevent suicidal thoughts and actions in your child, pay close attention to changes in her or his moods or actions, especially if the changes occur suddenly. Other important people in your child’s life can help by paying attention as well (e.g., your child, brothers and sisters, teachers, and other important people). The changes to look out for are listed in Section 3, on what to watch for.

Whenever an antidepressant is started or its dose is changed, pay close attention to your child. After starting an antidepressant, your child should generally see his or her healthcare provider:

- Once a week for the first 4 weeks
- Every 2 weeks for the next 4 weeks
- After taking the antidepressant for 12 weeks
- After 12 weeks, follow your healthcare provider’s advice about how often to come back
- More often if problems or questions arise (see Section 3)

838 You should call your child’s healthcare provider between visits if needed.

839

### 840 **3. You Should Watch For Certain Signs if Your Child is Taking an Antidepressant**

841

842 Contact your child’s healthcare provider *right away* if your child exhibits any of the following  
843 signs for the first time, or they seem worse, or worry you, your child, or your child’s teacher:

- 844 • Thoughts about suicide or dying
- 845 • Attempts to commit suicide
- 846 • New or worse depression
- 847 • New or worse anxiety
- 848 • Feeling very agitated or restless
- 849 • Panic attacks
- 850 • Difficulty sleeping (insomnia)
- 851 • New or worse irritability
- 852 • Acting aggressive, being angry, or violent
- 853 • Acting on dangerous impulses
- 854 • An extreme increase in activity and talking
- 855 • Other unusual changes in behavior or mood

856

857 Never let your child stop taking an antidepressant without first talking to his or her healthcare  
858 provider. Stopping an antidepressant suddenly can cause other symptoms.

859

### 860 **4. There are Benefits and Risks When Using Antidepressants**

861

862 Antidepressants are used to treat depression and other illnesses. Depression and other illnesses  
863 can lead to suicide. In some children and teenagers, treatment with an antidepressant increases  
864 suicidal thinking or actions. It is important to discuss all the risks of treating depression and also  
865 the risks of not treating it. You and your child should discuss all treatment choices with your  
866 healthcare provider, not just the use of antidepressants.

867

868 Other side effects can occur with antidepressants (see section below).

869

870 Of all antidepressants, only fluoxetine (PROZAC<sup>®</sup>)\* has been FDA approved to treat pediatric  
871 depression.

872

873 For obsessive compulsive disorder in children and teenagers, FDA has approved only fluoxetine  
874 (PROZAC<sup>®</sup>)\*, sertraline (ZOLOFT<sup>®</sup>)\*, fluvoxamine (LUVOX<sup>®</sup>)\*, and clomipramine  
875 (ANAFRANIL<sup>®</sup>)\*.

876

877 Your healthcare provider may suggest other antidepressants based on the past experience of your  
878 child or other family members.

879

880 **Is this all I need to know if my child is being prescribed an antidepressant?**

881

882 No. This is a warning about the risk of suicidality. Other side effects can occur with  
883 antidepressants. Be sure to ask your healthcare provider to explain all the side effects of the  
884 particular drug he or she is prescribing. Also ask about drugs to avoid when taking an  
885 antidepressant. Ask your healthcare provider or pharmacist where to find more information.

886

887 **What is the most important information I should know about WELLBUTRIN?**

888

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

891

- with certain medical problems.
- who take certain medicines.

892

893

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

899

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

902

903 **What is important information I should know and share with my family about taking  
904 antidepressants?**

905

906 Patients and their families should watch out for worsening depression or thoughts of suicide.  
907 Also watch out for sudden or severe changes in feelings such as feeling anxious, agitated,  
908 panicky, irritable, hostile, aggressive, impulsive, severely restless, overly excited and  
909 hyperactive, not being able to sleep or other unusual changes in behavior. If this happens,  
909 especially at the beginning of antidepressant treatment or after a change in dose, call your doctor.

910

911 **For additional information, see section above** entitled "About Using Antidepressants in Children  
912 and Teenagers." WELLBUTRIN **has not been studied in children under the age of 18 and** is not  
913 approved for the use in children and teenagers.

913

914 **What is WELLBUTRIN?**

915

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

917

918 **Who should not take WELLBUTRIN?**

919 **Do not take WELLBUTRIN if you**

- 920 • have or had a seizure disorder or epilepsy.
- 921 • **are taking ZYBAN (used to help people stop smoking) or any other medicines that**
- 922 **contain bupropion hydrochloride, such as WELLBUTRIN SR Sustained-Release**
- 923 **Tablets or WELLBUTRIN XL Extended-Release Tablets.** Bupropion is the same
- 924 ingredient that is in WELLBUTRIN.
- 925 • drink a lot of alcohol and abruptly stop drinking, or use medicines called sedatives (these
- 926 make you sleepy) or benzodiazepines and you stop using them all of a sudden.
- 927 • have taken within the last 14 days medicine for depression called a monoamine oxidase
- 928 inhibitor (MAOI), such as NARDIL<sup>®\*</sup> (phenelzine sulfate), PARNATE<sup>®</sup> (tranylcypromine
- 929 sulfate), or MARPLAN<sup>®\*</sup> (isocarboxazid).
- 930 • have or had an eating disorder such as anorexia nervosa or bulimia.
- 931 • are allergic to the active ingredient in WELLBUTRIN, bupropion, or to any of the inactive
- 932 ingredients. See the end of this leaflet for a complete list of ingredients in WELLBUTRIN.
- 933

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

- 935 • **Tell your doctor about your medical conditions.** Tell your doctor if you:
- 936 • **are pregnant or plan to become pregnant.** It is not known if WELLBUTRIN can harm
- 937 your unborn baby. If you can use WELLBUTRIN while you are pregnant, talk to your
- 938 doctor about how you can be on the Bupropion Pregnancy Registry.
- 939 • **are breastfeeding.** WELLBUTRIN passes through your milk. It is not known if
- 940 WELLBUTRIN can harm your baby.
- 941 • **have liver problems,** especially cirrhosis of the liver.
- 942 • have kidney problems.
- 943 • have an eating disorder, such as anorexia nervosa or bulimia.
- 944 • have had a head injury.
- 945 • have had a seizure (convulsion, fit).
- 946 • have a tumor in your nervous system (brain or spine).
- 947 • have had a heart attack, heart problems, or high blood pressure.
- 948 • are a diabetic taking insulin or other medicines to control your blood sugar.
- 949 • drink a lot of alcohol.
- 950 • abuse prescription medicines or street drugs.
- 951 • **Tell your doctor about all the medicines you take,** including prescription and non-
- 952 prescription medicines, vitamins, and herbal supplements. Many medicines increase your
- 953 chances of having seizures or other serious side effects if you take them while you are using
- 954 WELLBUTRIN.
- 955

956 **How should I take WELLBUTRIN?**

- 957 • Take WELLBUTRIN exactly as prescribed by your doctor.
- 958 • Take WELLBUTRIN at the same time each day.
- 959 • Take your doses of WELLBUTRIN at least 6 hours apart.

- 960 • You may take WELLBUTRIN with or without food.  
961 • If you miss a dose, do not take an extra tablet to make up for the dose you forgot. Wait and  
962 take your next tablet at the regular time. **This is very important.** Too much WELLBUTRIN  
963 can increase your chance of having a seizure.  
964 • If you take too much WELLBUTRIN, or overdose, call your local emergency room or poison  
965 control center right away.  
966 • **Do not take any other medicines while using WELLBUTRIN unless your doctor has**  
967 **told you it is okay.**  
968 • It may take several weeks for you to feel that WELLBUTRIN is working. Once you feel  
969 better, it is important to keep taking WELLBUTRIN exactly as directed by your doctor. Call  
970 your doctor if you do not feel WELLBUTRIN is working for you.  
971 • Do not change your dose or stop taking WELLBUTRIN without talking with your doctor  
972 first.  
973

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

- 975 • Do not drink a lot of alcohol while taking WELLBUTRIN. If you usually drink a lot of  
976 alcohol, talk with your doctor before suddenly stopping. If you suddenly stop drinking  
977 alcohol, you may increase your risk of having seizures.  
978 • Do not drive a car or use heavy machinery until you know how WELLBUTRIN affects you.  
979 WELLBUTRIN can impair your ability to perform these tasks.  
980

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

- 982 • **Seizures.** Some patients get seizures while taking WELLBUTRIN. **If you have a seizure**  
983 **while taking WELLBUTRIN, stop taking the tablets and call your doctor right away.**  
984 Do not take WELLBUTRIN again if you have a seizure.  
985 • **Hypertension (high blood pressure).** Some patients get high blood pressure, sometimes  
986 severe, while taking WELLBUTRIN. The chance of high blood pressure may be increased if  
987 you also use nicotine replacement therapy (for example a nicotine patch) to help you stop  
988 smoking.  
989 • **Severe allergic reactions. Stop taking WELLBUTRIN and call your doctor right away**  
990 **if you get a rash, itching, hives, fever, swollen lymph glands, painful sores in the mouth or**  
991 **around the eyes, swelling of the lips or tongue, chest pain, or have trouble breathing. These**  
992 **could be signs of a serious allergic reaction.**  
993 • **Unusual thoughts or behaviors.** Some patients have unusual thoughts or behaviors while  
994 taking WELLBUTRIN, including delusions (believe you are someone else), hallucinations  
995 (seeing or hearing things that are not there), paranoia (feeling that people are against you), or  
996 feeling confused. If this happens to you, call your doctor.  
997

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

1000  
1001 If you have nausea, you may want to take your medicine with food. If you have trouble sleeping,  
1002 do not take your medicine too close to bedtime.

1003  
1004 Tell your doctor right away about any side effects that bother you.

1005  
1006 These are not all the side effects of WELLBUTRIN. For a complete list, ask your doctor or  
1007 pharmacist.

1008  
1009 **How should I store WELLBUTRIN?**

- 1010 • Store WELLBUTRIN at room temperature. Store out of direct sunlight. Keep  
1011 WELLBUTRIN in its tightly closed bottle.

1012  
1013 **General Information about WELLBUTRIN.**

- 1014 • Medicines are sometimes prescribed for **purposes other than those listed in a Medication**  
1015 **Guide.** Do not use WELLBUTRIN for a condition for which it was not prescribed. Do not  
1016 give WELLBUTRIN to other people, even if they have the same symptoms you have. It may  
1017 harm them. Keep WELLBUTRIN out of the reach of children.

1018  
1019 This **Medication Guide** summarizes important information about WELLBUTRIN. For more  
1020 information, talk to your doctor. You can ask your doctor or pharmacist for information about  
1021 WELLBUTRIN that is written for health professionals.

1022  
1023 **What are the ingredients in WELLBUTRIN?**

1024 Active ingredient: bupropion hydrochloride.

1025  
1026 Inactive ingredients: 75-mg tablet – D&C Yellow No. 10 Lake, FD&C Yellow No. 6 Lake,  
1027 hydroxypropyl cellulose, hypromellose, microcrystalline cellulose, polyethylene glycol, talc, and  
1028 titanium dioxide; 100-mg tablet – FD&C Red No. 40 Lake, FD&C Yellow No. 6 Lake,  
1029 hydroxypropyl cellulose, hypromellose, microcrystalline cellulose, polyethylene glycol, talc, and  
1030 titanium dioxide.

1031  
1032 \*The following are registered trademarks of their respective manufacturers: PROZAC<sup>®</sup>/Eli Lilly  
1033 and Company; ZOLOFT<sup>®</sup>/Pfizer Pharmaceuticals; LUVOX<sup>®</sup>/Solvay Pharmaceuticals, Inc;  
1034 ANAFRANIL<sup>®</sup>/Mallinckrodt Inc; NARDIL<sup>®</sup>/Warner Lambert Company; MARPLAN<sup>®</sup>/Oxford  
1035 Pharmaceutical Services, Inc.

1036  
1037 **R<sub>x</sub> only**

1038  
1039 **This Medication Guide has been approved by the U.S. Food and Drug Administration.**

1040  
1041 September 2006

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Manufactured by DSM Pharmaceuticals, Inc.

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Greenville, NC 27834 for

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GlaxoSmithKline

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Research Triangle Park, NC 27709

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