

862 frequency and/or dose should be considered in patients with mild-to-moderate hepatic cirrhosis
863 (see CLINICAL PHARMACOLOGY, WARNINGS, and PRECAUTIONS).

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

867 **HOW SUPPLIED**

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

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

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

873

874 **MEDICATION GUIDE**

875 **WELLBUTRIN® (WELL byu-trin)** 876 **(bupropion hydrochloride) Tablets**

877

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

882

883 **IMPORTANT: Be sure to read the three sections of this Medication Guide. The first**
884 **section is about the risk of suicidal thoughts and actions with antidepressant medicines; the**
885 **second section is about the risk of changes in thinking and behavior, depression and**
886 **suicidal thoughts or actions with medicines used to quit smoking; and the third section is**
887 **entitled “What Other Important Information Should I Know About WELLBUTRIN?”**

888

889 **Antidepressant Medicines, Depression and Other Serious Mental Illnesses, and** 890 **Suicidal Thoughts or Actions**

891

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

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

897

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

- 900 **1. Antidepressant medicines may increase suicidal thoughts or actions in some children,**
901 **teenagers, and young adults within the first few months of treatment.**
- 902 **2. Depression and other serious mental illnesses are the most important causes of suicidal**
903 **thoughts and actions. Some people may have a particularly high risk of having suicidal**
904 **thoughts or actions.** These include people who have (or have a family history of) bipolar
905 illness (also called manic-depressive illness) or suicidal thoughts or actions.
- 906 **3. How can I watch for and try to prevent suicidal thoughts and actions in myself or a**
907 **family member?**
- 908 • Pay close attention to any changes, especially sudden changes, in mood, behaviors,
909 thoughts, or feelings. This is very important when an antidepressant medicine is started or
910 when the dose is changed.
 - 911 • Call the healthcare provider right away to report new or sudden changes in mood,
912 behavior, thoughts, or feelings.
 - 913 • Keep all follow-up visits with the healthcare provider as scheduled. Call the healthcare
914 provider between visits as needed, especially if you have concerns about symptoms.

915
916 **Call a healthcare provider right away if you or your family member has any of the**
917 **following symptoms, especially if they are new, worse, or worry you:**
918

- 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

919
920 **What else do I need to know about antidepressant medicines?**

- 921 • **Never stop an antidepressant medicine without first talking to a healthcare provider.**
922 Stopping an antidepressant medicine suddenly can cause other symptoms.
- 923 • **Antidepressants are medicines used to treat depression and other illnesses.** It is
924 important to discuss all the risks of treating depression and also the risks of not treating it.
925 Patients and their families or other caregivers should discuss all treatment choices with the
926 healthcare provider, not just the use of antidepressants.
- 927 • **Antidepressant medicines have other side effects.** Talk to the healthcare provider about the
928 side effects of the medicine prescribed for you or your family member.
- 929 • **Antidepressant medicines can interact with other medicines.** Know all of the medicines
930 that you or your family member takes. Keep a list of all medicines to show the healthcare
931 provider. Do not start new medicines without first checking with your healthcare provider.

- 932 • **Not all antidepressant medicines prescribed for children are FDA approved for use in**
933 **children.** Talk to your child's healthcare provider for more information.

934

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

937

938 **Quitting Smoking, Quit-Smoking Medications, Changes in Thinking and Behavior,** 939 **Depression, and Suicidal Thoughts or Actions**

940

941 This section of the Medication Guide is only about the risk of changes in thinking and behavior,
942 depression and suicidal thoughts or actions with drugs used to quit smoking.

943

944 Although WELLBUTRIN is not a treatment for quitting smoking, it contains the same active
945 ingredient (bupropion hydrochloride) as ZYBAN[®] which is used to help patients quit smoking.

946

947 Some people have had changes in behavior, hostility, agitation, depression, suicidal thoughts or
948 actions while taking bupropion to help them quit smoking. These symptoms can develop during
949 treatment with bupropion or after stopping treatment with bupropion.

950

951 If you, your family member, or your caregiver notice agitation, hostility, depression, or changes
952 in thinking or behavior that are not typical for you, or you have any of the following symptoms,
953 stop taking bupropion and call your healthcare provider right away:

954

- thoughts about suicide or dying
- attempts to commit suicide
- new or worse depression
- new or worse anxiety
- panic attacks
- feeling very agitated or restless
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- abnormal thoughts or sensations
- seeing or hearing things that are not there (hallucinations)
- feeling people are against you (paranoia)
- feeling confused
- other unusual changes in behavior or mood

955

956 When you try to quit smoking, with or without bupropion, you may have symptoms that may be
957 due to nicotine withdrawal, including urge to smoke, depressed mood, trouble sleeping,
958 irritability, frustration, anger, feeling anxious, difficulty concentrating, restlessness, decreased
959 heart rate, and increased appetite or weight gain. Some people have even experienced suicidal
960 thoughts when trying to quit smoking without medication. Sometimes quitting smoking can lead
961 to worsening of mental health problems that you already have, such as depression.

962

963 Before taking bupropion, tell your healthcare provider if you have ever had depression or other
964 mental illnesses. You should also tell your doctor about any symptoms you had during other
965 times you tried to quit smoking, with or without bupropion.

966

967 **What Other Important Information Should I Know About WELLBUTRIN?**

968

969 • **Seizures: There is a chance of having a seizure (convulsion, fit) with WELLBUTRIN,**
970 **especially in people:**

971

- with certain medical problems.

972

- who take certain medicines.

973

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

979

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

982

983 • **High blood pressure (hypertension). Some people get high blood pressure, that can be**
984 **severe, while taking WELLBUTRIN.** The chance of high blood pressure may be higher if
985 you also use nicotine replacement therapy (such as a nicotine patch) to help you stop
986 smoking.

987 • **Severe allergic reactions. Some people have severe allergic reaction to WELLBUTRIN.**
988 **Stop taking WELLBUTRIN and call your doctor right away** if you get a rash, itching,

989 hives, fever, swollen lymph glands, painful sores in the mouth or around the eyes, swelling of
990 the lips or tongue, chest pain, or have trouble breathing. These could be signs of a serious
991 allergic reaction.

992 • **Unusual thoughts or behaviors.** Some patients have unusual thoughts or behaviors while
993 taking WELLBUTRIN, including delusions (believe you are someone else), hallucinations
994 (seeing or hearing things that are not there), paranoia (feeling that people are against you), or
995 feeling confused. If this happens to you, call your doctor.

996

997 **What is WELLBUTRIN?**

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

1000

1001 **Who should not take WELLBUTRIN?**

1002 **Do not take WELLBUTRIN if you**

- 1003 • have or had a seizure disorder or epilepsy.
- 1004 • **are taking ZYBAN (used to help people stop smoking) or any other medicines that**
- 1005 **contain bupropion hydrochloride, such as WELLBUTRIN SR Sustained-Release**
- 1006 **Tablets or WELLBUTRIN XL Extended-Release Tablets.** Bupropion is the same active
- 1007 ingredient that is in WELLBUTRIN.
- 1008 • drink a lot of alcohol and abruptly stop drinking, or use medicines called sedatives (these
- 1009 make you sleepy) or benzodiazepines and you stop using them all of a sudden.
- 1010 • have taken within the last 14 days medicine for depression called a monoamine oxidase
- 1011 inhibitor (MAOI), such as NARDIL^{®*} (phenelzine sulfate), PARNATE[®] (tranylcypromine
- 1012 sulfate), or MARPLAN^{®*} (isocarboxazid).
- 1013 • have or had an eating disorder such as anorexia nervosa or bulimia.
- 1014 • are allergic to the active ingredient in WELLBUTRIN, bupropion, or to any of the inactive
- 1015 ingredients. See the end of this leaflet for a complete list of ingredients in WELLBUTRIN.
- 1016

1017 **What should I tell my doctor before using WELLBUTRIN?**

1018 Tell your doctor if you have ever had depression, suicidal thoughts or actions, or other mental
1019 health problems. See “Antidepressant Medicines, Depression and Other Serious Mental Illnesses,
1020 and Suicidal Thoughts or Actions.”

- 1021
- 1022 • **Tell your doctor about your other medical conditions including if you:**
- 1023 • **are pregnant or plan to become pregnant.** It is not known if WELLBUTRIN can harm
- 1024 your unborn baby.
- 1025 • **are breastfeeding.** WELLBUTRIN passes through your milk. It is not known if
- 1026 WELLBUTRIN can harm your baby.
- 1027 • **have liver problems,** especially cirrhosis of the liver.
- 1028 • have kidney problems.
- 1029 • have an eating disorder, such as anorexia nervosa or bulimia.
- 1030 • have had a head injury.
- 1031 • have had a seizure (convulsion, fit).
- 1032 • have a tumor in your nervous system (brain or spine).
- 1033 • have had a heart attack, heart problems, or high blood pressure.
- 1034 • are a diabetic taking insulin or other medicines to control your blood sugar.
- 1035 • drink a lot of alcohol.
- 1036 • abuse prescription medicines or street drugs.
- 1037 • **Tell your doctor about all the medicines you take,** including prescription and non-
- 1038 prescription medicines, vitamins, and herbal supplements. Many medicines increase your
- 1039 chances of having seizures or other serious side effects if you take them while you are using
- 1040 WELLBUTRIN.
- 1041

1042 **How should I take WELLBUTRIN?**

- 1043 • Take WELLBUTRIN exactly as prescribed by your doctor.
- 1044 • Take WELLBUTRIN at the same time each day.
- 1045 • Take your doses of WELLBUTRIN at least 6 hours apart.
- 1046 • You may take WELLBUTRIN with or without food.
- 1047 • If you miss a dose, do not take an extra tablet to make up for the dose you forgot. Wait and
- 1048 take your next tablet at the regular time. **This is very important.** Too much WELLBUTRIN
- 1049 can increase your chance of having a seizure.
- 1050 • If you take too much WELLBUTRIN, or overdose, call your local emergency room or poison
- 1051 control center right away.
- 1052 • **Do not take any other medicines while using WELLBUTRIN unless your doctor has**
- 1053 **told you it is okay.**
- 1054 • It may take several weeks for you to feel that WELLBUTRIN is working. Once you feel
- 1055 better, it is important to keep taking WELLBUTRIN exactly as directed by your doctor. Call
- 1056 your doctor if you do not feel WELLBUTRIN is working for you.
- 1057 • Do not change your dose or stop taking WELLBUTRIN without talking with your doctor
- 1058 first.

1059

1060 **What should I avoid while taking WELLBUTRIN?**

- 1061 • Do not drink a lot of alcohol while taking WELLBUTRIN. If you usually drink a lot of
- 1062 alcohol, talk with your doctor before suddenly stopping. If you suddenly stop drinking
- 1063 alcohol, you may increase your risk of having seizures.
- 1064 • Do not drive a car or use heavy machinery until you know how WELLBUTRIN affects you.
- 1065 WELLBUTRIN can impair your ability to perform these tasks.

1066

1067 **What are possible side effects of WELLBUTRIN?**

1068 WELLBUTRIN can cause serious side effects. Read this entire Medication Guide for more
1069 information about these serious side effects.

1070

1071 The most common side effects of WELLBUTRIN are nervousness, constipation, trouble
1072 sleeping, dry mouth, headache, nausea, vomiting, and shakiness (tremor).

1073

1074 If you have nausea, take your medicine with food. If you have trouble sleeping, do not take your
1075 medicine too close to bedtime.

1076

1077 These are not all the side effects of WELLBUTRIN. For a complete list, ask your doctor or
1078 pharmacist.

1079

1080 Call your doctor for medical advice about side effects. You may report side effects to FDA at
1081 1-800-FDA-1088.

1082

1083 **How should I store WELLBUTRIN?**

- 1084 • Store WELLBUTRIN at room temperature. Store out of direct sunlight. Keep
1085 WELLBUTRIN in its tightly closed bottle.

1086

1087 **General Information about WELLBUTRIN.**

- 1088 • Medicines are sometimes prescribed for purposes other than those listed in a Medication
1089 Guide. Do not use WELLBUTRIN for a condition for which it was not prescribed. Do not
1090 give WELLBUTRIN to other people, even if they have the same symptoms you have. It may
1091 harm them. Keep WELLBUTRIN out of the reach of children.

1092

1093 This Medication Guide summarizes important information about WELLBUTRIN. For more
1094 information, talk to your doctor. You can ask your doctor or pharmacist for information about
1095 WELLBUTRIN that is written for health professionals.

1096

1097 **What are the ingredients in WELLBUTRIN?**

1098 Active ingredient: bupropion hydrochloride.

1099

1100 Inactive ingredients: 75-mg tablet – D&C Yellow No. 10 Lake, FD&C Yellow No. 6 Lake,
1101 hydroxypropyl cellulose, hypromellose, microcrystalline cellulose, polyethylene glycol, talc, and
1102 titanium dioxide; 100-mg tablet – FD&C Red No. 40 Lake, FD&C Yellow No. 6 Lake,
1103 hydroxypropyl cellulose, hypromellose, microcrystalline cellulose, polyethylene glycol, talc, and
1104 titanium dioxide.

1105

1106 WELLBUTRIN, WELLBUTRIN SR, WELLBUTRIN XL, and PARNATE are registered
1107 trademarks of GlaxoSmithKline.

1108 *The following are registered trademarks of their respective manufacturers: NARDIL[®]/Warner
1109 Lambert Company; MARPLAN[®]/Oxford Pharmaceutical Services, Inc; KALETRA[®]/Abbott
1110 Laboratories.

1111

1112 **R_x only**

1113

1114 This Medication Guide has been approved by the U.S. Food and Drug Administration.

1115

1116 (Date of Issue)

1117 WLT: 6MG

1118

1119



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