

946 **HOW SUPPLIED**

947 WELLBUTRIN XL Extended-Release Tablets, 150 mg of bupropion hydrochloride, are
948 creamy-white to pale yellow, round, tablets printed with “WELLBUTRIN XL 150” in bottles of
949 30 (NDC 0173-0730-01) and 90 (NDC 0173-0730-02).

950 WELLBUTRIN XL Extended-Release Tablets, 300 mg of bupropion hydrochloride, are
951 creamy-white to pale yellow, round, tablets printed with “WELLBUTRIN XL 300” in bottles of
952 30 (NDC 0173-0731-01).

953 **Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled**
954 **Room Temperature].**

955 **MEDICATION GUIDE**

956 **WELLBUTRIN XL® (WELL byu-trin)**

957 **(bupropion hydrochloride extended-release tablets)**

958

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

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

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969 **Antidepressant Medicines, Depression and Other Serious Mental Illnesses, and**
970 **Suicidal Thoughts or Actions**

971

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

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

977

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

- 980 **1. Antidepressant medicines may increase suicidal thoughts or actions in some children,**
981 **teenagers, and young adults within the first few months of treatment.**
- 982 **2. Depression and other serious mental illnesses are the most important causes of suicidal**
983 **thoughts and actions. Some people may have a particularly high risk of having suicidal**

984 **thoughts or actions.** These include people who have (or have a family history of) bipolar
985 illness (also called manic-depressive illness) or suicidal thoughts or actions.

986 **3. How can I watch for and try to prevent suicidal thoughts and actions in myself or a**
987 **family member?**

- 988 • Pay close attention to any changes, especially sudden changes, in mood, behaviors,
989 thoughts, or feelings. This is very important when an antidepressant medicine is started or
990 when the dose is changed.
- 991 • Call the healthcare provider right away to report new or sudden changes in mood,
992 behavior, thoughts, or feelings.
- 993 • Keep all follow-up visits with the healthcare provider as scheduled. Call the healthcare
994 provider between visits as needed, especially if you have concerns about symptoms.

995
996 **Call a healthcare provider right away if you or your family member has any of the**
997 **following symptoms, especially if they are new, worse, or worry you:**

- 998 • 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

999

1000 **What else do I need to know about antidepressant medicines?**

- 1001 • **Never stop an antidepressant medicine without first talking to a healthcare provider.**
1002 Stopping an antidepressant medicine suddenly can cause other symptoms.
- 1003 • **Antidepressants are medicines used to treat depression and other illnesses.** It is
1004 important to discuss all the risks of treating depression and also the risks of not treating it.
1005 Patients and their families or other caregivers should discuss all treatment choices with the
1006 healthcare provider, not just the use of antidepressants.
- 1007 • **Antidepressant medicines have other side effects.** Talk to the healthcare provider about the
1008 side effects of the medicine prescribed for you or your family member.
- 1009 • **Antidepressant medicines can interact with other medicines.** Know all of the medicines
1010 that you or your family member takes. Keep a list of all medicines to show the healthcare
1011 provider. Do not start new medicines without first checking with your healthcare provider.
- 1012 • **Not all antidepressant medicines prescribed for children are FDA approved for use in**
1013 **children.** Talk to your child's healthcare provider for more information.

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1015 WELLBUTRIN XL has not been studied in children under the age of 18 and is not approved for
1016 use in children and teenagers.

1017

1018 **What other important information should I know about WELLBUTRIN XL?**

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1020 **There is a chance of having a seizure (convulsion, fit) with WELLBUTRIN XL, especially**
1021 **in people:**

- 1022 • with certain medical problems.
- 1023 • who take certain medicines.

1024

1025 The chance of having seizures increases with higher doses of WELLBUTRIN XL. For more
1026 information, see the sections “Who should not take WELLBUTRIN XL?” and “What should I
1027 tell my doctor before using WELLBUTRIN XL?” Tell your doctor about all of your medical
1028 conditions and all the medicines you take. **Do not take any other medicines while you are**
1029 **using WELLBUTRIN XL unless your doctor has said it is okay to take them.**

1030

1031 **If you have a seizure while taking WELLBUTRIN XL, stop taking the tablets and call your**
1032 **doctor right away.** Do not take WELLBUTRIN XL again if you have a seizure.

1033

1034 **What is WELLBUTRIN XL?**

1035 WELLBUTRIN XL is a prescription medicine used to treat adults with a certain type of
1036 depression called major depressive disorder and for prevention of autumn-winter seasonal
1037 depression (seasonal affective disorder).

1038

1039 **Who should not take WELLBUTRIN XL?**

1040 **Do not take WELLBUTRIN XL if you:**

- 1041 • have or had a seizure disorder or epilepsy.
- 1042 • **are taking ZYBAN[®] (used to help people stop smoking) or any other medicines that**
1043 **contain bupropion hydrochloride, such as WELLBUTRIN[®] Tablets or**
1044 **WELLBUTRIN SR[®] Sustained-Release Tablets.** Bupropion is the same active ingredient
1045 that is in WELLBUTRIN XL.
- 1046 • drink a lot of alcohol and abruptly stop drinking, or use medicines called sedatives (these
1047 make you sleepy) or benzodiazepines and you stop using them all of a sudden.
- 1048 • have taken within the last 14 days medicine for depression called a monoamine oxidase
1049 inhibitor (MAOI), such as NARDIL^{®*} (phenelzine sulfate), PARNATE[®] (tranylcypromine
1050 sulfate), or MARPLAN^{®*} (isocarboxazid).
- 1051 • have or had an eating disorder such as anorexia nervosa or bulimia.
- 1052 • are allergic to the active ingredient in WELLBUTRIN XL, bupropion, or to any of the
1053 inactive ingredients. See the end of this leaflet for a complete list of ingredients in
1054 WELLBUTRIN XL.

1055

1056 **What should I tell my doctor before using WELLBUTRIN XL?**

- 1057 • **Tell your doctor about your medical conditions.** Tell your doctor if you:

- 1058 • **are pregnant or plan to become pregnant.** It is not known if WELLBUTRIN XL can
1059 harm your unborn baby. If you can use WELLBUTRIN XL while you are pregnant, talk
1060 to your doctor about how you can be on the Bupropion Pregnancy Registry.
- 1061 • **are breastfeeding.** WELLBUTRIN XL passes through your milk. It is not known if
1062 WELLBUTRIN XL can harm your baby.
- 1063 • **have liver problems,** especially cirrhosis of the liver.
- 1064 • have kidney problems.
- 1065 • have an eating disorder such as anorexia nervosa or bulimia.
- 1066 • have had a head injury.
- 1067 • have had a seizure (convulsion, fit).
- 1068 • have a tumor in your nervous system (brain or spine).
- 1069 • have had a heart attack, heart problems, or high blood pressure.
- 1070 • are a diabetic taking insulin or other medicines to control your blood sugar.
- 1071 • drink a lot of alcohol.
- 1072 • abuse prescription medicines or street drugs.
- 1073 • **Tell your doctor about all the medicines you take,** including prescription and non-
1074 prescription medicines, vitamins and herbal supplements. Many medicines increase your
1075 chances of having seizures or other serious side effects if you take them while you are using
1076 WELLBUTRIN XL.

1077

1078 **How should I take WELLBUTRIN XL?**

- 1079 • Take WELLBUTRIN XL exactly as prescribed by your doctor.
- 1080 • **Do not chew, cut, or crush WELLBUTRIN XL tablets.** You must swallow the tablets
1081 whole. **Tell your doctor if you cannot swallow medicine tablets.**
- 1082 • Take WELLBUTRIN XL at the same time each day.
- 1083 • Take your doses of WELLBUTRIN XL at least 24 hours apart.
- 1084 • You may take WELLBUTRIN XL with or without food.
- 1085 • If you miss a dose, do not take an extra tablet to make up for the dose you forgot. Wait and
1086 take your next tablet at the regular time. **This is very important.** Too much
1087 WELLBUTRIN XL can increase your chance of having a seizure.
- 1088 • If you take too much WELLBUTRIN XL, or overdose, call your local emergency room or
1089 poison control center right away.
- 1090 • The WELLBUTRIN XL tablet is covered by a shell that slowly releases the medicine inside
1091 your body. You may notice something in your stool that looks like a tablet. This is normal.
1092 This is the empty shell passing from your body.
- 1093 • **Do not take any other medicines while using WELLBUTRIN XL unless your doctor has**
1094 **told you it is okay.**
- 1095 • If you are taking WELLBUTRIN XL for the treatment of major depressive disorder, it may
1096 take several weeks for you to feel that WELLBUTRIN XL is working. Once you feel better,

1097 it is important to keep taking WELLBUTRIN XL exactly as directed by your doctor. Call
1098 your doctor if you do not feel WELLBUTRIN XL is working for you.
1099 • If you are taking WELLBUTRIN XL for the prevention of seasonal major depressive
1100 episodes associated with seasonal affective disorder, it is important to keep taking
1101 WELLBUTRIN XL through the autumn-winter season, or as directed by your doctor.
1102 • Do not change your dose or stop taking WELLBUTRIN XL without talking with your doctor
1103 first.

1104

1105 **What should I avoid while taking WELLBUTRIN XL?**

- 1106 • Do not drink a lot of alcohol while taking WELLBUTRIN XL. If you usually drink a lot of
1107 alcohol, talk with your doctor before suddenly stopping. If you suddenly stop drinking
1108 alcohol, you may increase your chance of having seizures.
- 1109 • Do not drive a car or use heavy machinery until you know how WELLBUTRIN XL affects
1110 you. WELLBUTRIN XL can impair your ability to perform these tasks.

1111

1112 **What are possible side effects of WELLBUTRIN XL?**

- 1113 • **Seizures.** Some patients get seizures while taking WELLBUTRIN XL. **If you have a seizure**
1114 **while taking WELLBUTRIN XL, stop taking the tablets and call your doctor right**
1115 **away.** Do not take WELLBUTRIN XL again if you have a seizure.
- 1116 • **Hypertension (high blood pressure).** Some patients get high blood pressure, sometimes
1117 severe, while taking WELLBUTRIN XL. The chance of high blood pressure may be
1118 increased if you also use nicotine replacement therapy (for example, a nicotine patch) to help
1119 you stop smoking.
- 1120 • **Severe allergic reactions. Stop taking WELLBUTRIN XL and call your doctor right**
1121 **away** if you get a rash, itching, hives, fever, swollen lymph glands, painful sores in the
1122 mouth or around the eyes, swelling of the lips or tongue, chest pain, or have trouble
1123 breathing. These could be signs of a serious allergic reaction.
- 1124 • **Unusual thoughts or behaviors.** Some patients have unusual thoughts or behaviors while
1125 taking WELLBUTRIN XL, including delusions (believe you are someone else),
1126 hallucinations (seeing or hearing things that are not there), paranoia (feeling that people are
1127 against you), or feeling confused. If this happens to you, call your doctor.

1128

1129 Common side effects reported in studies of major depressive disorder include weight loss, loss of
1130 appetite, dry mouth, skin rash, sweating, ringing in the ears, shakiness, stomach pain, agitation,
1131 anxiety, dizziness, trouble sleeping, muscle pain, nausea, fast heartbeat, sore throat, and urinating
1132 more often. In studies of seasonal affective disorder, common side effects included weight loss,
1133 constipation, and gas.

1134

1135 If you have nausea, take your medicine with food. If you have trouble sleeping, do not take your
1136 medicine too close to bedtime.

1137

1138 Tell your doctor right away about any side effects that bother you.

1139

1140 These are not all the side effects of WELLBUTRIN XL. For a complete list, ask your doctor or
1141 pharmacist.

1142

1143 **How should I store WELLBUTRIN XL?**

- 1144 • Store WELLBUTRIN XL at room temperature. Store out of direct sunlight. Keep
1145 WELLBUTRIN XL in its tightly closed bottle.
- 1146 • WELLBUTRIN XL tablets may have an odor.

1147

1148 **General Information about WELLBUTRIN XL.**

- 1149 • Medicines are sometimes prescribed for purposes other than those listed in a Medication
1150 Guide. Do not use WELLBUTRIN XL for a condition for which it was not prescribed. Do
1151 not give WELLBUTRIN XL to other people, even if they have the same symptoms you have.
1152 It may harm them. Keep WELLBUTRIN XL out of the reach of children.

1153

1154 This Medication Guide summarizes important information about WELLBUTRIN XL. For more
1155 information, talk with your doctor. You can ask your doctor or pharmacist for information about
1156 WELLBUTRIN XL that is written for health professionals or you can visit
1157 www.wellbutrin-xl.com or call toll-free 888-825-5249.

1158

1159 **What are the ingredients in WELLBUTRIN XL?**

1160 Active ingredient: bupropion hydrochloride.

1161

1162 Inactive ingredients: ethylcellulose aqueous dispersion (NF), glyceryl behenate, methacrylic acid
1163 copolymer dispersion (NF), polyvinyl alcohol, polyethylene glycol, povidone, silicon dioxide,
1164 and triethyl citrate. The tablets are printed with edible black ink.

1165

1166 *The following are registered trademarks of their respective manufacturers: NARDIL[®]/Warner
1167 Lambert Company; MARPLAN[®]/Oxford Pharmaceutical Services, Inc.

1168

1169 **Rx Only**

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1171 This Medication Guide has been approved by the U.S. Food and Drug Administration.

1172

1173 June 2007

WXL:4MG

1174

1175 Manufactured by:

1176 Biovail Corporation

1177 Mississauga, ON L5N 8M5, Canada for
1178



GlaxoSmithKline

1179
1180 GlaxoSmithKline
1181 Research Triangle Park, NC 27709
1182
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