

922 maintenance treatment as they had received during the acute stabilization phase, longer-term  
923 efficacy was demonstrated (see CLINICAL TRIALS under CLINICAL PHARMACOLOGY).  
924 Based on these limited data, it is unknown whether or not the dose of WELLBUTRIN SR needed  
925 for maintenance treatment is identical to the dose needed to achieve an initial response. Patients  
926 should be periodically reassessed to determine the need for maintenance treatment and the  
927 appropriate dose for such treatment.

928 **Dosage Adjustment for Patients with Impaired Hepatic Function:** WELLBUTRIN SR  
929 should be used with extreme caution in patients with severe hepatic cirrhosis. The dose should  
930 not exceed 100 mg every day or 150 mg every other day in these patients. WELLBUTRIN SR  
931 should be used with caution in patients with hepatic impairment (including mild-to-moderate  
932 hepatic cirrhosis) and a reduced frequency and/or dose should be considered in patients with  
933 mild-to-moderate hepatic cirrhosis (see CLINICAL PHARMACOLOGY, WARNINGS, and  
934 PRECAUTIONS).

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

## 938 **HOW SUPPLIED**

939 WELLBUTRIN SR Sustained-Release Tablets, 100 mg of bupropion hydrochloride, are blue,  
940 round, biconvex, film-coated tablets printed with “WELLBUTRIN SR 100” in bottles of 60  
941 (NDC 0173-0947-55) tablets.

942 WELLBUTRIN SR Sustained-Release Tablets, 150 mg of bupropion hydrochloride, are  
943 purple, round, biconvex, film-coated tablets printed with "WELLBUTRIN SR 150" in bottles of  
944 60 (NDC 0173-0135-55) tablets.

945 WELLBUTRIN SR Sustained-Release Tablets, 200 mg of bupropion hydrochloride, are light  
946 pink, round, biconvex, film-coated tablets printed with “WELLBUTRIN SR 200” in bottles of 60  
947 (NDC 0173-0722-00) tablets.

948 **Store at controlled room temperature, 20° to 25°C (68° to 77°F) [see USP]. Dispense in a**  
949 **tight, light-resistant container as defined in the USP.**

950

951

## **MEDICATION GUIDE**

952

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

953

### **(bupropion hydrochloride) Sustained-Release Tablets**

954

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

959

960 **IMPORTANT: Be sure to read the three sections of this Medication Guide. The first**  
961 **section is about the risk of suicidal thoughts and actions with antidepressant medicines; the**  
962 **second section is about the risk of changes in thinking and behavior, depression and**  
963 **suicidal thoughts or actions with medicines used to quit smoking; and the third section is**  
964 **entitled “What Other Important Information Should I Know About WELLBUTRIN SR?”**  
965

966 **Antidepressant Medicines, Depression and Other Serious Mental Illnesses, and**  
967 **Suicidal Thoughts or Actions**  
968

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

- 972 • all risks and benefits of treatment with antidepressant medicines
  - 973 • all treatment choices for depression or other serious mental illness
- 974

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

- 977 **1. Antidepressant medicines may increase suicidal thoughts or actions in some children,**  
978 **teenagers, and young adults within the first few months of treatment.**
  - 979 **2. Depression and other serious mental illnesses are the most important causes of suicidal**  
980 **thoughts and actions. Some people may have a particularly high risk of having suicidal**  
981 **thoughts or actions.** These include people who have (or have a family history of) bipolar  
982 illness (also called manic-depressive illness) or suicidal thoughts or actions.
  - 983 **3. How can I watch for and try to prevent suicidal thoughts and actions in myself or a**  
984 **family member?**
    - 985 • Pay close attention to any changes, especially sudden changes, in mood, behaviors,  
986 thoughts, or feelings. This is very important when an antidepressant medicine is started or  
987 when the dose is changed.
    - 988 • Call the healthcare provider right away to report new or sudden changes in mood,  
989 behavior, thoughts, or feelings.
    - 990 • Keep all follow-up visits with the healthcare provider as scheduled. Call the healthcare  
991 provider between visits as needed, especially if you have concerns about symptoms.
- 992

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

- 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

996

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

- 998 • **Never stop an antidepressant medicine without first talking to a healthcare provider.**

999 Stopping an antidepressant medicine suddenly can cause other symptoms.

- 1000 • **Antidepressants are medicines used to treat depression and other illnesses.** It is  
 1001 important to discuss all the risks of treating depression and also the risks of not treating it.  
 1002 Patients and their families or other caregivers should discuss all treatment choices with the  
 1003 healthcare provider, not just the use of antidepressants.

- 1004 • **Antidepressant medicines have other side effects.** Talk to the healthcare provider about the  
 1005 side effects of the medicine prescribed for you or your family member.

- 1006 • **Antidepressant medicines can interact with other medicines.** Know all of the medicines  
 1007 that you or your family member takes. Keep a list of all medicines to show the healthcare  
 1008 provider. Do not start new medicines without first checking with your healthcare provider.

- 1009 • **Not all antidepressant medicines prescribed for children are FDA approved for use in**  
 1010 **children.** Talk to your child’s healthcare provider for more information.

1011  
 1012 WELLBUTRIN SR has not been studied in children under the age of 18 and is not approved for  
 1013 use in children and teenagers.

1014  
 1015 **Quitting Smoking, Quit-Smoking Medications, Changes in Thinking and Behavior,**  
 1016 **Depression, and Suicidal Thoughts or Actions**

1017  
 1018 This section of the Medication Guide is only about the risk of changes in thinking and behavior,  
 1019 depression and suicidal thoughts or actions with drugs used to quit smoking.

1020  
 1021 Although WELLBUTRIN SR is not a treatment for quitting smoking, it contains the same active  
 1022 ingredient (bupropion hydrochloride) as ZYBAN<sup>®</sup> which is used to help patients quit smoking.

1023  
 1024 Some people have had changes in behavior, hostility, agitation, depression, suicidal thoughts or  
 1025 actions while taking bupropion to help them quit smoking. These symptoms can develop during  
 1026 treatment with bupropion or after stopping treatment with bupropion.

1027

1028 If you, your family member, or your caregiver notice agitation, hostility, depression, or changes  
1029 in thinking or behavior that are not typical for you, or you have any of the following symptoms,  
1030 stop taking bupropion and call your healthcare provider right away:

- 1031
- 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

1032

1033 When you try to quit smoking, with or without bupropion, you may have symptoms that may be  
1034 due to nicotine withdrawal, including urge to smoke, depressed mood, trouble sleeping,  
1035 irritability, frustration, anger, feeling anxious, difficulty concentrating, restlessness, decreased  
1036 heart rate, and increased appetite or weight gain. Some people have even experienced suicidal  
1037 thoughts when trying to quit smoking without medication. Sometimes quitting smoking can lead  
1038 to worsening of mental health problems that you already have, such as depression.

1039

1040 Before taking bupropion, tell your healthcare provider if you have ever had depression or other  
1041 mental illnesses. You should also tell your doctor about any symptoms you had during other  
1042 times you tried to quit smoking, with or without bupropion.

1043

#### 1044 **What Other Important Information Should I Know About WELLBUTRIN SR?**

1045

1046 • **Seizures: There is a chance of having a seizure (convulsion, fit) with WELLBUTRIN SR,**  
1047 **especially in people:**

- 1048
- with certain medical problems.
  - who take certain medicines.
- 1049

1050

1051 The chance of having seizures increases with higher doses of WELLBUTRIN SR. For more  
1052 information, see the sections “Who should not take WELLBUTRIN SR?” and “What should  
1053 I tell my doctor before using WELLBUTRIN SR?” Tell your doctor about all of your  
1054 medical conditions and all the medicines you take. **Do not take any other medicines while  
1055 you are using WELLBUTRIN SR unless your doctor has said it is okay to take them.**

1056

1057 **If you have a seizure while taking WELLBUTRIN SR, stop taking the tablets and call**  
1058 **your doctor right away.** Do not take WELLBUTRIN SR again if you have a seizure.

1059

- 1060 • **High blood pressure (hypertension).** Some people get high blood pressure, that can be  
1061 **severe, while taking WELLBUTRIN SR.** The chance of high blood pressure may be higher  
1062 if you also use nicotine replacement therapy (such as a nicotine patch) to help you stop  
1063 smoking.
- 1064 • **Severe allergic reactions. Some people have severe allergic reaction to**  
1065 **WELLBUTRIN SR. Stop taking WELLBUTRIN SR and call your doctor right away if**  
1066 you get a rash, itching, hives, fever, swollen lymph glands, painful sores in the mouth or  
1067 around the eyes, swelling of the lips or tongue, chest pain, or have trouble breathing. These  
1068 could be signs of a serious allergic reaction.
- 1069 • **Unusual thoughts or behaviors.** Some patients have unusual thoughts or behaviors while  
1070 taking WELLBUTRIN SR, including delusions (believe you are someone else),  
1071 hallucinations (seeing or hearing things that are not there), paranoia (feeling that people are  
1072 against you), or feeling confused. If this happens to you, call your doctor.

1073

#### 1074 **What is WELLBUTRIN SR?**

1075 WELLBUTRIN SR is a prescription medicine used to treat adults with a certain type of  
1076 depression called major depressive disorder.

1077

#### 1078 **Who should not take WELLBUTRIN SR?**

##### 1079 **Do not take WELLBUTRIN SR if you**

- 1080 • have or had a seizure disorder or epilepsy.
- 1081 • **are taking ZYBAN<sup>®</sup> (used to help people stop smoking) or any other medicines that**  
1082 **contain bupropion hydrochloride, such as WELLBUTRIN<sup>®</sup> Tablets or WELLBUTRIN**  
1083 **XL<sup>®</sup> Extended-Release Tablets.** Bupropion is the same active ingredient that is in  
1084 WELLBUTRIN SR.
- 1085 • drink a lot of alcohol and abruptly stop drinking, or use medicines called sedatives (these  
1086 make you sleepy) or benzodiazepines and you stop using them all of a sudden.
- 1087 • have taken within the last 14 days medicine for depression called a monoamine oxidase  
1088 inhibitor (MAOI), such as NARDIL<sup>®\*</sup> (phenelzine sulfate), PARNATE<sup>®</sup> (tranylcypromine  
1089 sulfate), or MARPLAN<sup>®\*</sup> (isocarboxazid).
- 1090 • have or had an eating disorder such as anorexia nervosa or bulimia.
- 1091 • are allergic to the active ingredient in WELLBUTRIN SR, bupropion, or to any of the  
1092 inactive ingredients. See the end of this leaflet for a complete list of ingredients in  
1093 WELLBUTRIN SR.

1094

#### 1095 **What should I tell my doctor before using WELLBUTRIN SR?**

1096 Tell your doctor if you have ever had depression, suicidal thoughts or actions, or other mental  
1097 health problems. See “Antidepressant Medicines, Depression and Other Serious Mental Illnesses,  
1098 and Suicidal Thoughts or Actions.”

- 1099 • **Tell your doctor about your other medical conditions including if you:**

- 1100 • **are pregnant or plan to become pregnant.** It is not known if WELLBUTRIN SR can
- 1101 harm your unborn baby.
- 1102 • **are breastfeeding.** WELLBUTRIN SR passes through your milk. It is not known if
- 1103 WELLBUTRIN SR can harm your baby.
- 1104 • **have liver problems,** especially cirrhosis of the liver.
- 1105 • have kidney problems.
- 1106 • have an eating disorder such as anorexia nervosa or bulimia.
- 1107 • have had a head injury.
- 1108 • have had a seizure (convulsion, fit).
- 1109 • have a tumor in your nervous system (brain or spine).
- 1110 • have had a heart attack, heart problems, or high blood pressure.
- 1111 • are a diabetic taking insulin or other medicines to control your blood sugar.
- 1112 • drink a lot of alcohol.
- 1113 • abuse prescription medicines or street drugs.
- 1114 • **Tell your doctor about all the medicines you take,** including prescription and non-
- 1115 prescription medicines, vitamins, and herbal supplements. Many medicines increase your
- 1116 chances of having seizures or other serious side effects if you take them while you are using
- 1117 WELLBUTRIN SR.

1118

#### 1119 **How should I take WELLBUTRIN SR?**

- 1120 • Take WELLBUTRIN SR exactly as prescribed by your doctor.
- 1121 • **Do not chew, cut, or crush WELLBUTRIN SR tablets.** If you do, the medicine will be
- 1122 released into your body too quickly. If this happens you may be more likely to get side
- 1123 effects including seizures. You must swallow the tablets whole. **Tell your doctor if you**
- 1124 **cannot swallow medicine tablets.**
- 1125 • Take WELLBUTRIN SR at the same time each day.
- 1126 • Take your doses of WELLBUTRIN SR at least 8 hours apart.
- 1127 • You may take WELLBUTRIN SR with or without food.
- 1128 • If you miss a dose, do not take an extra tablet to make up for the dose you forgot. Wait and
- 1129 take your next tablet at the regular time. **This is very important.** Too much
- 1130 WELLBUTRIN SR can increase your chance of having a seizure.
- 1131 • If you take too much WELLBUTRIN SR, or overdose, call your local emergency room or
- 1132 poison control center right away.
- 1133 • **Do not take any other medicines while using WELLBUTRIN SR unless your doctor has**
- 1134 **told you it is okay.**
- 1135 • It may take several weeks for you to feel that WELLBUTRIN SR is working. Once you feel
- 1136 better, it is important to keep taking WELLBUTRIN SR exactly as directed by your doctor.
- 1137 Call your doctor if you do not feel WELLBUTRIN SR is working for you.
- 1138 • Do not change your dose or stop taking WELLBUTRIN SR without talking with your doctor
- 1139 first.

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

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

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

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

The most common side effects of WELLBUTRIN SR are loss of appetite, dry mouth, skin rash, sweating, ringing in the ears, shakiness, stomach pain, agitation, anxiety, dizziness, trouble sleeping, muscle pain, nausea, fast heartbeat, sore throat, and urinating more often.

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

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

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

**How should I store WELLBUTRIN SR?**

- Store WELLBUTRIN SR at room temperature. Store out of direct sunlight. Keep WELLBUTRIN SR in its tightly closed bottle.
- WELLBUTRIN SR tablets may have an odor.

**General Information about WELLBUTRIN SR.**

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

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

1180 **What are the ingredients in WELLBUTRIN SR?**

1181 Active ingredient: bupropion hydrochloride.

1182

1183 Inactive ingredients: carnauba wax, cysteine hydrochloride, hypromellose, magnesium stearate,  
1184 microcrystalline cellulose, polyethylene glycol, polysorbate 80, and titanium dioxide. In  
1185 addition, the 100-mg tablet contains FD&C Blue No. 1 Lake, the 150-mg tablet contains FD&C  
1186 Blue No. 2 Lake and FD&C Red No. 40 Lake, and the 200-mg tablet contains FD&C Red No. 40  
1187 Lake. The tablets are printed with edible black ink.

1188

1189 WELLBUTRIN, WELLBUTRIN SR, WELLBUTRIN XL, ZYBAN, and PARNATE are  
1190 registered trademarks of GlaxoSmithKline.

1191 \*The following are registered trademarks of their respective manufacturers: NARDIL<sup>®</sup>/Warner  
1192 Lambert Company; MARPLAN<sup>®</sup>/Oxford Pharmaceutical Services, Inc.; KALETRA<sup>®</sup>/Abbott  
1193 Laboratories.

1194

1195 **R<sub>x</sub>only**

1196

1197 This Medication Guide has been approved by the U.S. Food and Drug Administration.

1198

1199 (Date of Issue)

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