

819 responded during 8 weeks of acute treatment with WELLBUTRIN SR were assigned randomly
820 to placebo or to the same dose of WELLBUTRIN SR (150 mg twice daily) during 44 weeks of
821 maintenance treatment as they had received during the acute stabilization phase, longer-term
822 efficacy was demonstrated (see CLINICAL TRIALS under CLINICAL PHARMACOLOGY).
823 Based on these limited data, it is unknown whether or not the dose of WELLBUTRIN SR needed
824 for maintenance treatment is identical to the dose needed to achieve an initial response. Patients
825 should be periodically reassessed to determine the need for maintenance treatment and the
826 appropriate dose for such treatment.

827 **Dosage Adjustment for Patients with Impaired Hepatic Function:** WELLBUTRIN SR
828 should be used with extreme caution in patients with severe hepatic cirrhosis. The dose should
829 not exceed 100 mg every day or 150 mg every other day in these patients. WELLBUTRIN SR
830 should be used with caution in patients with hepatic impairment (including mild to moderate
831 hepatic cirrhosis) and a reduced frequency and/or dose should be considered in patients with
832 mild to moderate hepatic cirrhosis (see CLINICAL PHARMACOLOGY, WARNINGS, and
833 PRECAUTIONS).

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

837 **HOW SUPPLIED**

838 WELLBUTRIN SR Sustained-Release Tablets, 100 mg of bupropion hydrochloride, are blue,
839 round, biconvex, film-coated tablets printed with "WELLBUTRIN SR 100" in bottles of 60
840 (NDC 0173-0947-55) tablets.

841 WELLBUTRIN SR Sustained-Release Tablets, 150 mg of bupropion hydrochloride, are
842 purple, round, biconvex, film-coated tablets printed with "WELLBUTRIN SR 150" in bottles of
843 60 (NDC 0173-0135-55) tablets.

844 WELLBUTRIN SR Sustained-Release Tablets, 200 mg of bupropion hydrochloride, are light
845 pink, round, biconvex, film-coated tablets printed with "WELLBUTRIN SR 200" in bottles of 60
846 (NDC 0173-0722-00) tablets.

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

849

850

MEDICATION GUIDE

851

WELLBUTRIN SR[®] (WELL byu-trin)

852

(bupropion hydrochloride) Sustained-Release Tablets

853

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

858
859 **IMPORTANT: Be sure to read the section of this Medication Guide beginning with “What**
860 **is the most important information I should know about WELLBUTRIN SR?” It contains**
861 **important information about this medication. It immediately follows the next section called**
862 **“About Using Antidepressants in Children and Teenagers.”**

863 **About Using Antidepressants in Children and Teenagers**

864
865
866 **What is the most important information I should know if my child is being prescribed an**
867 **antidepressant?**

868
869 Parents or guardians need to think about 4 important things when their child is prescribed an
870 antidepressant:

- 871 1. There is a risk of suicidal thoughts or actions
- 872 2. How to try to prevent suicidal thoughts or actions in your child
- 873 3. You should watch for certain signs if your child is taking an antidepressant
- 874 4. There are benefits and risks when using antidepressants

875 876 **1. There is a Risk of Suicidal Thoughts or Actions**

877
878 Children and teenager sometimes think about suicide, and many report trying to kill themselves.

879
880 Antidepressants increase suicidal thoughts and actions in some children and teenagers. But
881 suicidal thoughts and actions can also be caused by depression, a serious medical condition that
882 is commonly treated with antidepressants. Thinking about killing yourself or trying to kill
883 yourself is called *suicidality* or *being suicidal*.

884
885 A large study combined the results of 24 different studies of children and teenagers with
886 depression or other illnesses. In these studies, patients took either a placebo (sugar pill) or an
887 antidepressant for 1 to 4 months. ***No one committed suicide in these studies***, but some patients
888 became suicidal. On sugar pills, 2 out of every 100 became suicidal. On the antidepressants, 4
889 out of every 100 patients became suicidal.

890
891 **For some children and teenagers, the risks of suicidal actions may be especially high.** These
892 include patients with

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

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

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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)

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

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

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

- Thoughts about suicide or dying
- Attempts to commit suicide
- New or worse depression
- New or worse anxiety
- Feeling very agitated or restless
- Panic attacks
- Difficulty sleeping (insomnia)
- New or worse irritability
- Acting aggressive, being angry, or violent
- Acting on dangerous impulses
- An extreme increase in activity and talking
- Other unusual changes in behavior or mood

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

4. There are Benefits and Risks When Using Antidepressants

938
939 Antidepressants are used to treat depression and other illnesses. Depression and other illnesses
940 can lead to suicide. In some children and teenagers, treatment with an antidepressant increases
941 suicidal thinking or actions. It is important to discuss all the risks of treating depression and also
942 the risks of not treating it. You and your child should discuss all treatment choices with your
943 healthcare provider, not just the use of antidepressants.

944
945 Other side effects can occur with antidepressants (see section below).

946
947 Of all antidepressants, only fluoxetine (PROZAC[®])* has been FDA approved to treat pediatric
948 depression.

949
950 For obsessive compulsive disorder in children and teenagers, FDA has approved only fluoxetine
951 (PROZAC[®])*, sertraline (ZOLOFT[®])*, fluvoxamine (LUVOX[®])*, and clomipramine
952 (ANAFRANIL[®])*.

953
954 Your healthcare provider may suggest other antidepressants based on the past experience of your
955 child or other family members.

956
957 **Is this all I need to know if my child is being prescribed an antidepressant?**

958
959 No. This is a warning about the risk of suicidality. Other side effects can occur with
960 antidepressants. Be sure to ask your healthcare provider to explain all the side effects of the
961 particular drug he or she is prescribing. Also ask about drugs to avoid when taking an
962 antidepressant. Ask your healthcare provider or pharmacist where to find more information.

963
964 **What is the most important information I should know about WELLBUTRIN SR?**

965
966 **There is a chance of having a seizure (convulsion, fit) with WELLBUTRIN SR, especially**
967 **in people:**

- 968
- 969 • with certain medical problems.
 - 970 • who take certain medicines.

971
972 The chance of having seizures increases with higher doses of WELLBUTRIN SR. For more
973 information, see the sections “Who should not take WELLBUTRIN SR?” and “What should I
974 tell my doctor before using WELLBUTRIN SR?” Tell your doctor about all of your medical
975 conditions and all the medicines you take. **Do not take any other medicines while you are**
976 **using WELLBUTRIN SR unless your doctor has said it is okay to take them.**

977
978 **If you have a seizure while taking WELLBUTRIN SR, stop taking the tablets and call your**
doctor right away. Do not take WELLBUTRIN SR again if you have a seizure.

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

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

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

What is WELLBUTRIN SR?

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

Who should not take WELLBUTRIN SR?

Do not take WELLBUTRIN SR if you

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

What should I tell my doctor before using WELLBUTRIN SR?

- **Tell your doctor about your medical conditions. Tell your doctor if you:**
 - **are pregnant or plan to become pregnant.** It is not known if WELLBUTRIN SR can harm your unborn baby. If you can use WELLBUTRIN SR while you are pregnant, talk to your doctor about how you can be on the Bupropion Pregnancy Registry.
 - **are breastfeeding.** WELLBUTRIN SR passes through your milk. It is not known if WELLBUTRIN SR can harm your baby.

- 1019 • **have liver problems**, especially cirrhosis of the liver.
- 1020 • have kidney problems.
- 1021 • have an eating disorder such as anorexia nervosa or bulimia.
- 1022 • have had a head injury.
- 1023 • have had a seizure (convulsion, fit).
- 1024 • have a tumor in your nervous system (brain or spine).
- 1025 • have had a heart attack, heart problems, or high blood pressure.
- 1026 • are a diabetic taking insulin or other medicines to control your blood sugar.
- 1027 • drink a lot of alcohol.
- 1028 • abuse prescription medicines or street drugs.
- 1029
- 1030 • **Tell your doctor about all the medicines you take**, including prescription and non-
 1031 prescription medicines, vitamins, and herbal supplements. Many medicines increase your
 1032 chances of having seizures or other serious side effects if you take them while you are using
 1033 WELLBUTRIN SR.
- 1034

1035 **How should I take WELLBUTRIN SR?**

- 1036 • Take WELLBUTRIN SR exactly as prescribed by your doctor.
- 1037 • **Do not chew, cut, or crush WELLBUTRIN SR Tablets.** You must swallow the tablets
 1038 whole. **Tell your doctor if you cannot swallow medicine tablets.**
- 1039 • Take WELLBUTRIN SR at the same time each day.
- 1040 • Take your doses of WELLBUTRIN SR at least 8 hours apart.
- 1041 • You may take WELLBUTRIN SR with or without food.
- 1042 • If you miss a dose, do not take an extra tablet to make up for the dose you forgot. Wait and
 1043 take your next tablet at the regular time. **This is very important.** Too much
 1044 WELLBUTRIN SR can increase your chance of having a seizure.
- 1045 • If you take too much WELLBUTRIN SR, or overdose, call your local emergency room or
 1046 poison control center right away.
- 1047 • **Do not take any other medicines while using WELLBUTRIN SR unless your doctor has**
 1048 **told you it is okay.**
- 1049 • It may take several weeks for you to feel that WELLBUTRIN SR is working. Once you feel
 1050 better, it is important to keep taking WELLBUTRIN SR exactly as directed by your doctor.
 1051 Call your doctor if you do not feel WELLBUTRIN SR is working for you.
- 1052 • Do not change your dose or stop taking WELLBUTRIN SR without talking with your doctor
 1053 first.
- 1054

1055 **What should I avoid while taking WELLBUTRIN SR?**

- 1056 • Do not drink a lot of alcohol while taking WELLBUTRIN SR. If you usually drink a lot of
 1057 alcohol, talk with your doctor before suddenly stopping. If you suddenly stop drinking
 1058 alcohol, you may increase your chance of having seizures.

- 1059 • Do not drive a car or use heavy machinery until you know how WELLBUTRIN SR affects
1060 you. WELLBUTRIN SR can impair your ability to perform these tasks.

1061

1062 **What are possible side effects of WELLBUTRIN SR?**

- 1063 • **Seizures.** Some patients get seizures while taking WELLBUTRIN SR. **If you have a seizure**
1064 **while taking WELLBUTRIN SR, stop taking the tablets and call your doctor right**
1065 **away.** Do not take WELLBUTRIN SR again if you have a seizure.
- 1066 • **Hypertension (high blood pressure).** Some patients get high blood pressure, sometimes
1067 severe, while taking WELLBUTRIN SR. The chance of high blood pressure may be
1068 increased if you also use nicotine replacement therapy (for example, a nicotine patch) to help
1069 you stop smoking.
- 1070 • **Severe allergic reactions: Stop taking WELLBUTRIN SR and call your doctor right**
1071 **away** if you get a rash, itching, hives, fever, swollen lymph glands, painful sores in the
1072 mouth or around the eyes, swelling of the lips or tongue, chest pain, or have trouble
1073 breathing. These could be signs of a serious allergic reaction.
- 1074 • **Unusual thoughts or behaviors.** Some patients have unusual thoughts or behaviors while
1075 taking WELLBUTRIN SR, including delusions (believe you are someone else),
1076 hallucinations (seeing or hearing things that are not there), paranoia (feeling that people are
1077 against you), or feeling confused. If this happens to you, call your doctor.

1078

1079 The most common side effects of WELLBUTRIN SR are loss of appetite, dry mouth, skin rash,
1080 sweating, ringing in the ears, shakiness, stomach pain, agitation, anxiety, dizziness, trouble
1081 sleeping, muscle pain, nausea, fast heartbeat, sore throat, and urinating more often.

1082

1083 If you have nausea, you may want to take your medicine with food. If you have trouble sleeping,
1084 do not take your medicine too close to bedtime.

1085

1086 Tell your doctor right away about any side effects that bother you.

1087

1088 These are not all the side effects of WELLBUTRIN SR. For a complete list, ask your doctor or
1089 pharmacist.

1090

1091 **How should I store WELLBUTRIN SR?**

- 1092 • Store WELLBUTRIN SR at room temperature. Store out of direct sunlight. Keep
1093 WELLBUTRIN SR in its tightly closed bottle.
- 1094 • WELLBUTRIN SR tablets may have an odor.

1095

1096 **General Information about WELLBUTRIN SR.**

- 1097 • Medicines are sometimes prescribed for **purposes other than those listed in a Medication**
1098 **Guide.** Do not use WELLBUTRIN SR for a condition for which it was not prescribed. Do

1099 not give WELLBUTRIN SR to other people, even if they have the same symptoms you have.
1100 It may harm them. Keep WELLBUTRIN SR out of the reach of children.

1101
1102 This **Medication Guide** summarizes important information about WELLBUTRIN SR. For more
1103 information, talk with your doctor. You can ask your doctor or pharmacist for information about
1104 WELLBUTRIN SR that is written for health professionals.

1105
1106 **What are the ingredients in WELLBUTRIN SR?**

1107 Active ingredient: bupropion hydrochloride.

1108
1109 Inactive ingredients: carnauba wax, cysteine hydrochloride, hypromellose, magnesium stearate,
1110 microcrystalline cellulose, polyethylene glycol, polysorbate 80, and titanium dioxide. In
1111 addition, the 100-mg tablet contains FD&C Blue No. 1 Lake, the 150-mg tablet contains FD&C
1112 Blue No. 2 Lake and FD&C Red No. 40 Lake, and the 200-mg tablet contains FD&C Red No. 40
1113 Lake. The tablets are printed with edible black ink.

1114
1115 *The following are registered trademarks of their respective manufacturers: PROZAC[®]/Eli Lilly
1116 and Company; ZOLOFT[®]/Pfizer Pharmaceuticals; LUVOX[®]/Solvay Pharmaceuticals, Inc;
1117 ANAFRANIL[®]/Mallinckrodt Inc; NARDIL[®]/Warner Lambert Company; MARPLAN[®]/Oxford
1118 Pharmaceutical Services, Inc.

1119
1120 **R_x only**

1121
1122 **This Medication Guide has been approved by the U.S. Food and Drug Administration.**

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