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MEDICATION GUIDE
WELLBUTRIN SR® (WELL byu-trin)
(bupropion hydrochloride) Sustained-Release Tablets

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

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

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

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

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

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

- 1. Antidepressant medicines may increase suicidal thoughts or actions in some children, teenagers, and young adults within the first few months of treatment.**
- 2. Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. Some people may have a particularly high risk of having suicidal thoughts or actions.** These include people who have (or have a family history of) bipolar illness (also called manic-depressive illness) or suicidal thoughts or actions.
- 3. How can I watch for and try to prevent suicidal thoughts and actions in myself or a family member?**

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

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

- 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

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What else do I need to know about antidepressant medicines?

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

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

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What other important information should I know about WELLBUTRIN SR?

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

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

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The chance of having seizures increases with higher doses of WELLBUTRIN SR. For more information, see the sections “Who should not take WELLBUTRIN SR?” and “What should I tell my doctor before using WELLBUTRIN SR?” Tell your doctor about all of your medical

921 conditions and all the medicines you take. **Do not take any other medicines while you are**
922 **using WELLBUTRIN SR unless your doctor has said it is okay to take them.**

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

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927 **What is WELLBUTRIN SR?**

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

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931 **Who should not take WELLBUTRIN SR?**

932 **Do not take WELLBUTRIN SR if you**

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

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

- 949 • **Tell your doctor about your medical conditions. Tell your doctor if you:**
 - 950 • **are pregnant or plan to become pregnant.** It is not known if WELLBUTRIN SR can
951 harm your unborn baby. If you can use WELLBUTRIN SR while you are pregnant, talk
952 to your doctor about how you can be on the Bupropion Pregnancy Registry.
 - 953 • **are breastfeeding.** WELLBUTRIN SR passes through your milk. It is not known if
954 WELLBUTRIN SR can harm your baby.
 - 955 • **have liver problems,** especially cirrhosis of the liver.
 - 956 • have kidney problems.
 - 957 • have an eating disorder such as anorexia nervosa or bulimia.
 - 958 • have had a head injury.
 - 959 • have had a seizure (convulsion, fit).
 - 960 • have a tumor in your nervous system (brain or spine).

- 961 • have had a heart attack, heart problems, or high blood pressure.
- 962 • are a diabetic taking insulin or other medicines to control your blood sugar.
- 963 • drink a lot of alcohol.
- 964 • abuse prescription medicines or street drugs.
- 965 • **Tell your doctor about all the medicines you take**, including prescription and non-
- 966 prescription medicines, vitamins, and herbal supplements. Many medicines increase your
- 967 chances of having seizures or other serious side effects if you take them while you are using
- 968 WELLBUTRIN SR.

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

- 971 • Take WELLBUTRIN SR exactly as prescribed by your doctor.
- 972 • **Do not chew, cut, or crush WELLBUTRIN SR Tablets.** You must swallow the tablets
- 973 whole. **Tell your doctor if you cannot swallow medicine tablets.**
- 974 • Take WELLBUTRIN SR at the same time each day.
- 975 • Take your doses of WELLBUTRIN SR at least 8 hours apart.
- 976 • You may take WELLBUTRIN SR with or without food.
- 977 • If you miss a dose, do not take an extra tablet to make up for the dose you forgot. Wait and
- 978 take your next tablet at the regular time. **This is very important.** Too much
- 979 WELLBUTRIN SR can increase your chance of having a seizure.
- 980 • If you take too much WELLBUTRIN SR, or overdose, call your local emergency room or
- 981 poison control center right away.
- 982 • **Do not take any other medicines while using WELLBUTRIN SR unless your doctor has**
- 983 **told you it is okay.**
- 984 • It may take several weeks for you to feel that WELLBUTRIN SR is working. Once you feel
- 985 better, it is important to keep taking WELLBUTRIN SR exactly as directed by your doctor.
- 986 Call your doctor if you do not feel WELLBUTRIN SR is working for you.
- 987 • Do not change your dose or stop taking WELLBUTRIN SR without talking with your doctor
- 988 first.

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

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

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

- 998 • **Seizures.** Some patients get seizures while taking WELLBUTRIN SR. **If you have a seizure**
- 999 **while taking WELLBUTRIN SR, stop taking the tablets and call your doctor right**
- 1000 **away.** Do not take WELLBUTRIN SR again if you have a seizure.

- 1001 • **Hypertension (high blood pressure).** Some patients get high blood pressure, sometimes
1002 severe, while taking WELLBUTRIN SR. The chance of high blood pressure may be
1003 increased if you also use nicotine replacement therapy (for example, a nicotine patch) to help
1004 you stop smoking.
- 1005 • **Severe allergic reactions: Stop taking WELLBUTRIN SR and call your doctor right**
1006 **away** if you get a rash, itching, hives, fever, swollen lymph glands, painful sores in the
1007 mouth or around the eyes, swelling of the lips or tongue, chest pain, or have trouble
1008 breathing. These could be signs of a serious allergic reaction.
- 1009 • **Unusual thoughts or behaviors.** Some patients have unusual thoughts or behaviors while
1010 taking WELLBUTRIN SR, including delusions (believe you are someone else),
1011 hallucinations (seeing or hearing things that are not there), paranoia (feeling that people are
1012 against you), or feeling confused. If this happens to you, call your doctor.

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1014 The most common side effects of WELLBUTRIN SR are loss of appetite, dry mouth, skin rash,
1015 sweating, ringing in the ears, shakiness, stomach pain, agitation, anxiety, dizziness, trouble
1016 sleeping, muscle pain, nausea, fast heartbeat, sore throat, and urinating more often.

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1018 If you have nausea, you may want to take your medicine with food. If you have trouble sleeping,
1019 do not take your medicine too close to bedtime.

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1021 Tell your doctor right away about any side effects that bother you.

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1023 These are not all the side effects of WELLBUTRIN SR. For a complete list, ask your doctor or
1024 pharmacist.

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1026 **How should I store WELLBUTRIN SR?**

- 1027 • Store WELLBUTRIN SR at room temperature. Store out of direct sunlight. Keep
1028 WELLBUTRIN SR in its tightly closed bottle.
- 1029 • WELLBUTRIN SR tablets may have an odor.

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1031 **General Information about WELLBUTRIN SR.**

- 1032 • Medicines are sometimes prescribed for purposes other than those listed in a Medication
1033 Guide. Do not use WELLBUTRIN SR for a condition for which it was not prescribed. Do
1034 not give WELLBUTRIN SR to other people, even if they have the same symptoms you have.
1035 It may harm them. Keep WELLBUTRIN SR out of the reach of children.

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1037 This Medication Guide summarizes important information about WELLBUTRIN SR. For more
1038 information, talk with your doctor. You can ask your doctor or pharmacist for information about
1039 WELLBUTRIN SR that is written for health professionals.

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1041 **What are the ingredients in WELLBUTRIN SR?**

1042 Active ingredient: bupropion hydrochloride.

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1044 Inactive ingredients: carnauba wax, cysteine hydrochloride, hypromellose, magnesium stearate,
1045 microcrystalline cellulose, polyethylene glycol, polysorbate 80, and titanium dioxide. In
1046 addition, the 100-mg tablet contains FD&C Blue No. 1 Lake, the 150-mg tablet contains FD&C
1047 Blue No. 2 Lake and FD&C Red No. 40 Lake, and the 200-mg tablet contains FD&C Red No. 40
1048 Lake. The tablets are printed with edible black ink.

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1051 Lambert Company; MARPLAN[®]/Oxford Pharmaceutical Services, Inc.

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1053 **R_x only**

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1055 This Medication Guide has been approved by the U.S. Food and Drug Administration.

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