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**PRESCRIBING INFORMATION**

**WELLBUTRIN SR<sup>®</sup>**  
**(bupropion hydrochloride)**  
**Sustained-Release Tablets**

**MEDICATION GUIDE**  
**WELLBUTRIN SR<sup>®</sup> (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 the section of this Medication Guide beginning with “What is the most important information I should know about WELLBUTRIN SR?” It contains important information about this medication. It immediately follows the next section called “About Using Antidepressants in Children and Teenagers.”**

**About Using Antidepressants in Children and Teenagers**

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

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

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

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

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

Antidepressants increase suicidal thoughts and actions in some children and teenagers. But suicidal thoughts and actions can also be caused by depression, a serious medical condition that

39 is commonly treated with antidepressants. Thinking about killing yourself or trying to kill  
40 yourself is called *suicidality* or *being suicidal*.

41

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

47

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

- 50 • Bipolar illness (sometimes called manic-depressive illness)
- 51 • A family history of bipolar illness
- 52 • A personal or family history of attempting suicide

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

55

## 56 **2. How to Try to Prevent Suicidal Thoughts and Actions**

57

58 To try to prevent suicidal thoughts and actions in your child, pay close attention to changes in her  
59 or his moods or actions, especially if the changes occur suddenly. Other important people in your  
60 child's life can help by paying attention as well (e.g., your child, brothers and sisters, teachers,  
61 and other important people). The changes to look out for are listed in Section 3, on what to watch  
62 for.

63

64 Whenever an antidepressant is started or its dose is changed, pay close attention to your child.  
65 After starting an antidepressant, your child should generally see his or her healthcare provider:

- 66 • Once a week for the first 4 weeks
- 67 • Every 2 weeks for the next 4 weeks
- 68 • After taking the antidepressant for 12 weeks
- 69 • After 12 weeks, follow your healthcare provider's advice about how often to come back
- 70 • More often if problems or questions arise (see Section 3)

71

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

73

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

75

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

- 78 • Thoughts about suicide or dying

- 79 • Attempts to commit suicide
- 80 • New or worse depression
- 81 • New or worse anxiety
- 82 • Feeling very agitated or restless
- 83 • Panic attacks
- 84 • Difficulty sleeping (insomnia)
- 85 • New or worse irritability
- 86 • Acting aggressive, being angry, or violent
- 87 • Acting on dangerous impulses
- 88 • An extreme increase in activity and talking
- 89 • Other unusual changes in behavior or mood

90

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

93

#### 94 **4. There are Benefits and Risks When Using Antidepressants**

95

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

101

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

103

104 Of all antidepressants, only fluoxetine (PROZAC<sup>®</sup>)\* has been FDA approved to treat pediatric  
105 depression.

106

107 For obsessive compulsive disorder in children and teenagers, FDA has approved only fluoxetine  
108 (PROZAC<sup>®</sup>)\*, sertraline (ZOLOFT<sup>®</sup>)\*, fluvoxamine (LUVOX<sup>®</sup>)\*, and clomipramine  
109 (ANAFRANIL<sup>®</sup>)\*.

110

111 Your healthcare provider may suggest other antidepressants based on the past experience of your  
112 child or other family members.

113

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

115

116 No. This is a warning about the risk of suicidality. Other side effects can occur with  
117 antidepressants. Be sure to ask your healthcare provider to explain all the side effects of the

118 particular drug he or she is prescribing. Also ask about drugs to avoid when taking an  
119 antidepressant. Ask your healthcare provider or pharmacist where to find more information.

120

### 121 **What is the most important information I should know about WELLBUTRIN SR?**

122

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

- 125 • with certain medical problems.
- 126 • who take certain medicines.

127

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

133

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

136

### 137 **What is important information I should know and share with my family about taking** 138 **antidepressants?**

139 Patients and their families should watch out for worsening depression or thoughts of suicide.  
140 Also watch out for sudden or severe changes in feelings such as feeling anxious, agitated,  
141 panicky, irritable, hostile, aggressive, impulsive, severely restless, overly excited and  
142 hyperactive, not being able to sleep, or other unusual changes in behavior. If this happens,  
143 especially at the beginning of antidepressant treatment or after a change in dose, call your doctor.  
144 For additional information, see section above entitled "About Using Antidepressants in Children  
145 and Teenagers." WELLBUTRIN SR has not been studied in children under the age of 18 and is  
146 not approved for use in children and teenagers.

147

### 148 **What is WELLBUTRIN SR?**

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

151

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

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

- 154 • have or had a seizure disorder or epilepsy.
- 155 • **are taking ZYBAN<sup>®</sup> (used to help people stop smoking) or any other medicines that**  
156 **contain bupropion hydrochloride, such as WELLBUTRIN<sup>®</sup> Tablets or WELLBUTRIN**  
157 **XL<sup>®</sup> Extended-Release Tablets.** Bupropion is the same active ingredient that is in  
158 WELLBUTRIN SR.

- 159 • drink a lot of alcohol and abruptly stop drinking, or use medicines called sedatives (these  
160 make you sleepy) or benzodiazepines and you stop using them all of a sudden.  
161 • have taken within the last 14 days medicine for depression called a monoamine oxidase  
162 inhibitor (MAOI), such as NARDIL<sup>®\*</sup> (phenelzine sulfate), PARNATE<sup>®</sup> (tranylcypromine  
163 sulfate), or MARPLAN<sup>®\*</sup> (isocarboxazid).  
164 • have or had an eating disorder such as anorexia nervosa or bulimia.  
165 • are allergic to the active ingredient in WELLBUTRIN SR, bupropion, or to any of the  
166 inactive ingredients. See the end of this leaflet for a complete list of ingredients in  
167 WELLBUTRIN SR.  
168

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

- 170 • **Tell your doctor about your medical conditions. Tell your doctor if you:**  
171 • **are pregnant or plan to become pregnant.** It is not known if WELLBUTRIN SR can  
172 harm your unborn baby. If you can use WELLBUTRIN SR while you are pregnant, talk  
173 to your doctor about how you can be on the Bupropion Pregnancy Registry.  
174 • **are breastfeeding.** WELLBUTRIN SR passes through your milk. It is not known if  
175 WELLBUTRIN SR can harm your baby.  
176 • **have liver problems,** especially cirrhosis of the liver.  
177 • have kidney problems.  
178 • have an eating disorder such as anorexia nervosa or bulimia.  
179 • have had a head injury.  
180 • have had a seizure (convulsion, fit).  
181 • have a tumor in your nervous system (brain or spine).  
182 • have had a heart attack, heart problems, or high blood pressure.  
183 • are a diabetic taking insulin or other medicines to control your blood sugar.  
184 • drink a lot of alcohol.  
185 • abuse prescription medicines or street drugs.  
186  
187 • **Tell your doctor about all the medicines you take,** including prescription and non-  
188 prescription medicines, vitamins, and herbal supplements. Many medicines increase your  
189 chances of having seizures or other serious side effects if you take them while you are using  
190 WELLBUTRIN SR.  
191

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

- 193 • Take WELLBUTRIN SR exactly as prescribed by your doctor.  
194 • **Do not chew, cut, or crush WELLBUTRIN SR Tablets.** You must swallow the tablets  
195 whole. **Tell your doctor if you cannot swallow medicine tablets.**  
196 • Take WELLBUTRIN SR at the same time each day.  
197 • Take your doses of WELLBUTRIN SR at least 8 hours apart.  
198 • You may take WELLBUTRIN SR with or without food.

- 199 • If you miss a dose, do not take an extra tablet to make up for the dose you forgot. Wait and  
200 take your next tablet at the regular time. **This is very important.** Too much  
201 WELLBUTRIN SR can increase your chance of having a seizure.
- 202 • If you take too much WELLBUTRIN SR, or overdose, call your local emergency room or  
203 poison control center right away.
- 204 • **Do not take any other medicines while using WELLBUTRIN SR unless your doctor has**  
205 **told you it is okay.**
- 206 • It may take several weeks for you to feel that WELLBUTRIN SR is working. Once you feel  
207 better, it is important to keep taking WELLBUTRIN SR exactly as directed by your doctor.  
208 Call your doctor if you do not feel WELLBUTRIN SR is working for you.
- 209 • Do not change your dose or stop taking WELLBUTRIN SR without talking with your doctor  
210 first.

211

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

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

218

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

- 220 • **Seizures.** Some patients get seizures while taking WELLBUTRIN SR. **If you have a seizure**  
221 **while taking WELLBUTRIN SR, stop taking the tablets and call your doctor right**  
222 **away.** Do not take WELLBUTRIN SR again if you have a seizure.
- 223 • **Hypertension (high blood pressure).** Some patients get high blood pressure, sometimes  
224 severe, while taking WELLBUTRIN SR. The chance of high blood pressure may be  
225 increased if you also use nicotine replacement therapy (for example, a nicotine patch) to help  
226 you stop smoking.
- 227 • **Severe allergic reactions: Stop taking WELLBUTRIN SR and call your doctor right**  
228 **away** if you get a rash, itching, hives, fever, swollen lymph glands, painful sores in the  
229 mouth or around the eyes, swelling of the lips or tongue, chest pain, or have trouble  
230 breathing. These could be signs of a serious allergic reaction.
- 231 • **Unusual thoughts or behaviors.** Some patients have unusual thoughts or behaviors while  
232 taking WELLBUTRIN SR, including delusions (believe you are someone else),  
233 hallucinations (seeing or hearing things that are not there), paranoia (feeling that people are  
234 against you), or feeling confused. If this happens to you, call your doctor.

235

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

239  
240 If you have nausea, you may want to take your medicine with food. If you have trouble sleeping,  
241 do not take your medicine too close to bedtime.

242  
243 Tell your doctor right away about any side effects that bother you.

244  
245 These are not all the side effects of WELLBUTRIN SR. For a complete list, ask your doctor or  
246 pharmacist.

247  
248 **How should I store WELLBUTRIN SR?**

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

252  
253 **General Information about WELLBUTRIN SR.**

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

258  
259 This Medication Guide summarizes important information about WELLBUTRIN SR. For more  
260 information, talk with your doctor. You can ask your doctor or pharmacist for information about  
261 WELLBUTRIN SR that is written for health professionals.

262  
263 **What are the ingredients in WELLBUTRIN SR?**

264 Active ingredient: bupropion hydrochloride.

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

271  
272 \*The following are registered trademarks of their respective manufacturers: PROZAC<sup>®</sup>/Eli Lilly  
273 and Company; ZOLOFT<sup>®</sup>/Pfizer Pharmaceuticals; LUVOX<sup>®</sup>/Solvay Pharmaceuticals, Inc;  
274 ANAFRANIL<sup>®</sup>/Mallinckrodt Inc; NARDIL<sup>®</sup>/Warner Lambert Company; MARPLAN<sup>®</sup>/Oxford  
275 Pharmaceutical Services, Inc.

276  
277 **R<sub>x</sub> only**

278  
279 **This Medication Guide has been approved by the U.S. Food and Drug Administration.**