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PRESCRIBING INFORMATION

WELLBUTRIN[®]
(bupropion hydrochloride)
Tablets

MEDICATION GUIDE
WELLBUTRIN[®] (WELL byu-trin)
(bupropion hydrochloride) Tablets

Read this Medication Guide carefully before you start using WELLBUTRIN 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, 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?” 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 teenagers 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®)* 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®)*, sertraline (ZOLOFT®)*, fluvoxamine (LUVOX®)*, and clomipramine
109 (ANAFRANIL®)*.

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?**

122
123 **There is a chance of having a seizure (convulsion, fit) with WELLBUTRIN, especially in**
124 **people:**

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

127
128 The chance of having seizures increases with higher doses of WELLBUTRIN. For more
129 information, see the sections “Who should not take WELLBUTRIN?” and “What should I tell
130 my doctor before using WELLBUTRIN?” Tell your doctor about all of your medical conditions
131 and all the medicines you take. **Do not take any other medicines while you are using**
132 **WELLBUTRIN unless your doctor has said it is okay to take them.**
133

134 **If you have a seizure while taking WELLBUTRIN, stop taking the tablets and call your**
135 **doctor right away.** Do not take WELLBUTRIN 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 has not been studied in children under the age of 18 and is not
146 approved for the use in children and teenagers.

147 148 **What is WELLBUTRIN?**

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

151 152 **Who should not take WELLBUTRIN?**

153 **Do not take WELLBUTRIN if you**

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

- 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^{®*} (phenelzine sulfate), PARNATE[®] (tranylcypromine
163 sulfate), or MARPLAN^{®*} (isocarboxazid).
- 164 • have or had an eating disorder such as anorexia nervosa or bulimia.
- 165 • are allergic to the active ingredient in WELLBUTRIN, bupropion, or to any of the inactive
166 ingredients. See the end of this leaflet for a complete list of ingredients in WELLBUTRIN.
167

168 **What should I tell my doctor before using WELLBUTRIN?**

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

190 **How should I take WELLBUTRIN?**

- 191 • Take WELLBUTRIN exactly as prescribed by your doctor.
- 192 • Take WELLBUTRIN at the same time each day.
- 193 • Take your doses of WELLBUTRIN at least 6 hours apart.
- 194 • You may take WELLBUTRIN with or without food.
- 195 • If you miss a dose, do not take an extra tablet to make up for the dose you forgot. Wait and
196 take your next tablet at the regular time. **This is very important.** Too much WELLBUTRIN
197 can increase your chance of having a seizure.
- 198 • If you take too much WELLBUTRIN, or overdose, call your local emergency room or poison
199 control center right away.

- 200 • **Do not take any other medicines while using WELLBUTRIN unless your doctor has**
201 **told you it is okay.**
- 202 • It may take several weeks for you to feel that WELLBUTRIN is working. Once you feel
203 better, it is important to keep taking WELLBUTRIN exactly as directed by your doctor. Call
204 your doctor if you do not feel WELLBUTRIN is working for you.
- 205 • Do not change your dose or stop taking WELLBUTRIN without talking with your doctor
206 first.
- 207

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

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

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

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

232 The most common side effects of WELLBUTRIN are nervousness, constipation, trouble
233 sleeping, dry mouth, headache, nausea, vomiting, and shakiness (tremor).

234

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

237

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

239

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

242

243 **How should I store WELLBUTRIN?**

- 244 • Store WELLBUTRIN at room temperature. Store out of direct sunlight. Keep
245 WELLBUTRIN in its tightly closed bottle.

246

247 **General Information about WELLBUTRIN.**

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

252

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

256

257 **What are the ingredients in WELLBUTRIN?**

258 Active ingredient: bupropion hydrochloride.

259

260 Inactive ingredients: 75-mg tablet – D&C Yellow No. 10 Lake, FD&C Yellow No. 6 Lake,
261 hydroxypropyl cellulose, hypromellose, microcrystalline cellulose, polyethylene glycol, talc, and
262 titanium dioxide; 100-mg tablet – FD&C Red No. 40 Lake, FD&C Yellow No. 6 Lake,
263 hydroxypropyl cellulose, hypromellose, microcrystalline cellulose, polyethylene glycol, talc, and
264 titanium dioxide.

265

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271 **R_x only**

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

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280 GlaxoSmithKline

281 Research Triangle Park, NC 27709