Table 3. Dosing Regimen

Treatment Day	Total Daily Dose	Tablet Strength	Number of Tablets		
			Morning	Midday	Evening
1	200 mg	100 mg	1	0	1
4	300 mg	100 mg	1	1	1

Increasing the Dosage Above 300 mg/Day: As with other antidepressants, the full antidepressant effect of WELLBUTRIN may not be evident until 4 weeks of treatment or longer. An increase in dosage, up to a maximum of 450 mg/day, given in divided doses of not more than 150 mg each, may be considered for patients in whom no clinical improvement is noted after several weeks of treatment at 300 mg/day. Dosing above 300 mg/day may be accomplished using the 75- or 100-mg tablets. The 100-mg tablet must be administered 4 times daily with at least 4 hours between successive doses, in order not to exceed the limit of 150 mg in a single dose. WELLBUTRIN should be discontinued in patients who do not demonstrate an adequate response after an appropriate period of treatment at 450 mg/day.

Maintenance Treatment: The lowest dose that maintains remission is recommended. Although it is not known how long the patient should remain on WELLBUTRIN, it is generally recognized that acute episodes of depression require several months or longer of antidepressant drug treatment.

Dosage Adjustment for Patients with Impaired Hepatic Function: WELLBUTRIN should be used with extreme caution in patients with severe hepatic cirrhosis. The dose should not exceed 75 mg once a day in these patients. WELLBUTRIN should be used with caution in patients with hepatic impairment (including mild to moderate hepatic cirrhosis) and a reduced frequency and/or dose should be considered in patients with mild to moderate hepatic cirrhosis (see CLINICAL PHARMACOLOGY, WARNINGS, and PRECAUTIONS).

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

HOW SUPPLIED

WELLBUTRIN Tablets, 75 mg of bupropion hydrochloride, are yellow-gold, round, biconvex tablets printed with “WELLBUTRIN 75” in bottles of 100 (NDC 0173-0177-55).

WELLBUTRIN Tablets, 100 mg of bupropion hydrochloride, are red, round, biconvex tablets printed with “WELLBUTRIN 100” in bottles of 100 (NDC 0173-0178-55).

Store at 15° to 25°C (59° to 77°F). Protect from light and moisture.

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 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?"

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.

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

What else do I need to know about antidepressant medicines?

- **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.

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

What other important information should I know about WELLBUTRIN?

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

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

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

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

What is WELLBUTRIN?

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

Who should not take WELLBUTRIN?

Do not take WELLBUTRIN 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 SR Sustained-Release Tablets or WELLBUTRIN XL Extended-Release Tablets**. Bupropion is the same ingredient that is in WELLBUTRIN.
- 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, bupropion, or to any of the inactive ingredients. See the end of this leaflet for a complete list of ingredients in WELLBUTRIN.

What should I tell my doctor before using WELLBUTRIN?

- **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 can harm your unborn baby. If you can use WELLBUTRIN while you are pregnant, talk to your doctor about how you can be on the Bupropion Pregnancy Registry.
  - **are breastfeeding**. WELLBUTRIN passes through your milk. It is not known if WELLBUTRIN can harm your baby.
  - **have liver problems**, especially cirrhosis of the liver.
  - have kidney problems.
  - have an eating disorder, such as anorexia nervosa or bulimia.
  - have had a head injury.
  - have had a seizure (convulsion, fit).
  - have a tumor in your nervous system (brain or spine).
  - have had a heart attack, heart problems, or high blood pressure.
  - are a diabetic taking insulin or other medicines to control your blood sugar.
  - drink a lot of alcohol.
  - abuse prescription medicines or street drugs.

- **Tell your doctor about all the medicines you take**, including prescription and non-prescription medicines, vitamins, and herbal supplements. Many medicines increase your chances of having seizures or other serious side effects if you take them while you are using WELLBUTRIN.

How should I take WELLBUTRIN?

- Take WELLBUTRIN exactly as prescribed by your doctor.
- Take WELLBUTRIN at the same time each day.
- Take your doses of WELLBUTRIN at least 6 hours apart.
- You may take WELLBUTRIN with or without food.
- If you miss a dose, do not take an extra tablet to make up for the dose you forgot. Wait and take your next tablet at the regular time. **This is very important.** Too much WELLBUTRIN can increase your chance of having a seizure.
- If you take too much WELLBUTRIN, or overdose, call your local emergency room or poison control center right away.
- **Do not take any other medicines while using WELLBUTRIN unless your doctor has told you it is okay.**
- It may take several weeks for you to feel that WELLBUTRIN is working. Once you feel better, it is important to keep taking WELLBUTRIN exactly as directed by your doctor. Call your doctor if you do not feel WELLBUTRIN is working for you.
- Do not change your dose or stop taking WELLBUTRIN without talking with your doctor first.

What should I avoid while taking WELLBUTRIN?

- Do not drink a lot of alcohol while taking WELLBUTRIN. 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 risk of having seizures.
- Do not drive a car or use heavy machinery until you know how WELLBUTRIN affects you. WELLBUTRIN can impair your ability to perform these tasks.

What are possible side effects of WELLBUTRIN?

- **Seizures.** Some patients get seizures while taking WELLBUTRIN. **If you have a seizure while taking WELLBUTRIN, stop taking the tablets and call your doctor right away.** Do not take WELLBUTRIN again if you have a seizure.
- **Hypertension (high blood pressure).** Some patients get high blood pressure, sometimes severe, while taking WELLBUTRIN. The chance of high blood pressure may be increased if you also use nicotine replacement therapy (for example a nicotine patch) to help you stop smoking.
- **Severe allergic reactions. Stop taking WELLBUTRIN and call your doctor right away** if you get a rash, itching, hives, fever, swollen lymph glands, painful sores in the mouth or

around the eyes, swelling of the lips or tongue, chest pain, or have trouble breathing. These could be signs of a serious allergic reaction.

- **Unusual thoughts or behaviors.** Some patients have unusual thoughts or behaviors while taking WELLBUTRIN, including delusions (believe you are someone else), hallucinations (seeing or hearing things that are not there), paranoia (feeling that people are against you), or feeling confused. If this happens to you, call your doctor.

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

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

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

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

How should I store WELLBUTRIN?

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

General Information about WELLBUTRIN.

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

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

What are the ingredients in WELLBUTRIN?

Active ingredient: bupropion hydrochloride.

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

*The following are registered trademarks of their respective manufacturers: NARDIL®/Warner Lambert Company; MARPLAN®/Oxford Pharmaceutical Services, Inc.

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