Wellbutrin (bupropion)

FDA ALERT [09/2007] - Suicidality and Antidepressant Drugs

Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of Wellbutrin or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Wellbutrin is not approved for use in pediatric patients.

Brand and Generic Names:

- Brand names = Wellbutrin®, Wellbutrin SR®, Wellbutrin XL™, Zyban®, Budeprion™, and Buproban™

Tablets (immediate release): 75 mg, 100 mg

Tablets (sustained release): 100 mg, 150 mg, 200 mg

Tablets (extended release): 150 mg, 300 mg

- Generic name = Bupropion
What is Wellbutrin® and what does it treat?

Bupropion is an antidepressant medication that works in the brain. It is approved for the treatment of Major Depressive Disorder (MDD), Seasonal Affective Disorder (SAD) and to help people quit smoking (smoking cessation).

MDD occurs when a person experiences several of the following symptoms concurrently, for at least two weeks: "low" or depressed mood (for example, sad, empty, tearful); decreased interest in most or all activities; changes in appetite (usually decreased); changes in sleep (usually poor sleep); loss of energy; feeling worthless/guilty/ hopeless/helpless; psychomotor agitation or retardation (i.e. thoughts/movements speeding up or slowing down); difficulty concentrating, and thoughts of death (suicidal thinking).

SAD is a type of depression that occurs mainly during the autumn-winter season.

What is the most important information I should know about Wellbutrin®?

After starting bupropion, symptoms gradually decrease over a period of weeks. Sleep and other physical symptoms may improve before there is noticeable improvement in mood or interest in activities. Once symptoms are under control, MDD usually requires long-term treatment to help prevent the return of depressive symptoms. Only your healthcare provider can determine the length of generic name treatment that is right for you.

Do not stop taking bupropion or change your dose without talking to with your healthcare provider first.

Because depression is also a part of Bipolar illness, people who take antidepressants may be at risk for "switching" from depression into mania. Symptoms of mania include "high" or irritable mood, very high self esteem, decreased need for sleep, pressure to keep talking, racing thoughts, being easily distracted, frequently involved in activities with a large risk for bad consequences (for example, excessive buying sprees).

Are there specific concerns about Wellbutrin® and pregnancy?

If you are planning on becoming pregnant, notify your healthcare provider so that he/she can best manage your medications. People living with MDD who wish to become pregnant face important decisions, each with risks and benefits. This is a complex decision as untreated MDD or depression relapse may have negative consequences for both the fetus and the mother. There are many dimensions to these choices, so be sure to confer with your doctor and caregivers.

The FDA has classified bupropion as a Category C pregnancy risk. This means that animal reproduction studies (rabbits and rats) have demonstrated adverse effects of bupropion on the fetus, however there are no well-controlled studies in humans.
Additionally, the benefits from use of bupropion may be acceptable despite potential risks.

Women who discontinue medication therapy are up to five times more likely to have a depression relapse than those who continue their antidepressant. Untreated depression or depression relapse may have negative consequences for both the fetus and the mother. If you are pregnant, please discuss the risks and benefits of this medication use with your healthcare provider.

**What should I discuss with my healthcare provider before taking Wellbutrin®?**

- The most bothersome symptoms of your condition
- If you have thoughts of suicide
- Medications you have taken in the past for your condition, whether they were effective or caused any adverse effects
- Any medical problems that you may have, especially seizures (or history of seizures), recent head injury, anorexia or bulimia
- All other medications you are currently taking and any medication allergies you have
- If you are pregnant, plan to become pregnant, or are breast-feeding
- If you drink alcohol, use drugs, or have a history of substance abuse or dependence

**How should I take Wellbutrin®?**

Bupropion is available in 3 different forms: Immediate Release (IR), Sustained Release (SR), or Extended Release (XL).

Bupropion IR is usually taken 2 or 3 times per day with 4-6 hours between doses. While the dose usually ranges from 100 mg twice daily to 150 mg three times daily, your health care provider will determine the dose that is right for you based on your response.

Bupropion SR is usually taken twice daily in the morning and mid-afternoon. The dose usually ranges from 100 mg twice daily up to 200 mg twice daily.

Bupropion XL is usually taken once daily in the morning. The dose ranges from 150 mg to 450 mg.

While there are dose ranges for each form, your health care provider will determine the form and dose that is right for you based on your response. Do not take more than your prescribed dose since higher doses may increase your risk of having a seizure. Since quickly increasing the dose of bupropion can cause seizures in some people, your doctor will slowly increase your dose.

You can take bupropion on an empty stomach or with food. The SR and XL forms should be swallowed whole—not chewed, crushed, or broken—so that the medication
can work correctly in your body and to reduce the risk of serious side effects. The tablet shell from the SR and XL forms may appear in your feces.

You should not take more than one product that contains bupropion, including the products that are used to quit smoking. Additionally, you should not take more than your prescribed dose since higher doses may increase your risk of having a seizure. Since quickly increasing the dose of bupropion can cause seizures in some people, your doctor will slowly increase your dose.

**What happens if I miss a dose of Wellbutrin®?**

For bupropion IR or SR, if you miss a dose, take it as soon as you remember. Take the remaining doses for the day at evenly spaced times at least 4 hours apart. DO NOT take 2 doses at once. You should not take more than your prescribed dose and doing so may increase your risk of having a seizure.

For the XL form, do not take an extra tablet to make up for the dose you forgot. Wait and take your next dose at your regular time the next day.

**What should I avoid while taking Wellbutrin®?**

Avoid drinking alcohol or using illegal drugs while you are taking bupropion because the beneficial effects of the medication may be decreased and the risk of seizures may be increased. Also, you should not suddenly stop alcohol or drugs if you are dependent on them since doing so may also increase your risk of having a seizure.

**What happens if I overdose with Wellbutrin®?**

If an overdose occurs, whether intentional or accidental, immediate medical attention may be necessary. Call your doctor or emergency medical service (911). You may also contact the poison control center (1-800-222-1222).

Symptoms of overdose include blurred vision, feeling lightheaded, hallucinations, seizures or loss of consciousness. A specific antidote does not exist.

**What are the possible side effects of Wellbutrin®?**

Side effects with bupropion are generally mild and often resolve over the first 1-2 weeks of treatment as you continue to take the medication. The most commonly reported side effects of bupropion are weight loss, nausea, loss of appetite, dry mouth, fast heartbeat, trouble sleeping, dizziness, headache and sore throat. Less than 10% of patients will experience skin rash, sweating, ringing in the ears, shakiness, stomach pain, muscle pain, and anxiety. If you experience these side effects and they are bothersome to you, contact your doctor or pharmacist.
Unlike many SSRIs, bupropion does not commonly cause sexual dysfunction and may be selected as an alternative treatment when antidepressant-induced sexual dysfunction is problematic.

In general the risk of seizures due to bupropion is low. The risk of having a seizure increases with higher than recommended doses of bupropion, a history of seizures or head injury, an eating disorder, alcohol or drug dependence, or taking other drugs that can also increase your risk of having a seizure.

**Are there any risks for taking Wellbutrin® for long periods of time?**

To date, there are no known problems associated with long term use bupropion. It is a safe and effective medication when used as directed.

**What other drugs may interact with Wellbutrin®?**

Bupropion should not be taken with or within two weeks of taking monoamine oxidase inhibitors (MAOIs). These include phenelzine (Nardil®), tranylcypromine (Parnate®), isocarboxazid (Marplan®) and selegeline (Emsam®).

There are several products with the active ingredient, bupropion. Do not take more than one product that contains bupropion since this may increase your risk of having a seizure.

Certain medications may increase your risk of having a seizure when combined with bupropion. These include other antidepressants, antipsychotics, theophylline, isoniazid, certain antibiotics (e.g. Cipro®), and abrupt discontinuation of benzodiazepines (e.g. Ativan®).

Notify your doctor and pharmacist if you are taking the anticonvulsant medications phenytoin (Dilantin®), carbamazepine (Tegretol®), or phenobarbital or the stomach medication cimetidine (Tagamet®). These particular drugs can change the way your body reacts to bupropion.

Always let your doctor know what other prescription, over-the-counter, and herbal medications you are taking.

**How long does it take for Wellbutrin® to work?**

While depressed mood and lack of interest in activities may need up to 4-6 weeks to improve, disturbances in sleep, energy, or appetite may show some improvement within the first 1-2 weeks. Improvement in these physical symptoms can be an important early signal that the medication is working.

*Updated by Sujin Lee, Pharm.D., BCPP*

*(March 2007)*
NAMI wishes to thank the College of Psychiatric and Neurological Pharmacists for producing this fact sheet.

Reviewed by Dr. Ken Duckworth, NAMI Medical Director

For further information please contact the pharmaceutical company listed below.

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Free or low-cost medications provided by pharmaceutical companies

Some pharmaceutical companies offer medication assistance programs to low-income individuals and families. These programs typically require a doctor’s consent and proof of financial status. They may also require that you have either no health insurance, or no prescription drug benefit through your health insurance. Please contact the pharmaceutical company directly for specific eligibility requirements and application information.

Wellbutrin Rx Assistance Program: 1-866-728-4368