



## Patient Information Sheet

### Bupropion hydrochloride (marketed as the antidepressant Wellbutrin)

**5/2007: The suicidal thoughts or actions in children and adults issue has been addressed in product labeling.**

**Please see: <http://www.fda.gov/cder/drug/antidepressants/default.htm>**

This is a summary of the most important information about bupropion. For details, talk to your healthcare professional.

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#### FDA ALERT [07/2005] – Suicidal Thoughts or Actions in Children and Adults

Patients with depression or other mental illnesses often think about or attempt suicide. Closely watch anyone taking antidepressants, especially early in treatment or when the dose is changed. Patients who become irritable or anxious, or have new or increased thoughts of suicide or other changes in mood or behavior (or their care givers) should contact their healthcare professional right away.

##### Children

Taking antidepressants may increase suicidal thoughts and actions in about 1 out of 50 people 18 years or younger. Although bupropion is prescribed for children, FDA has not approved bupropion for use in children.

##### Adults

Several recent scientific publications report the possibility of an increased risk for suicidal behavior in adults who are being treated with antidepressant medications. Even before these reports became available, FDA began a complete review of all available data to determine whether there is an increased risk of suicidal thinking or behavior in adults being treated with antidepressant medications. It is expected that this review will take a year or longer to complete. In the meantime, FDA is highlighting that adults being treated with antidepressant medication, particularly those being treated for depression, should be watched closely for worsening of depression and for increased suicidal thinking or behavior.

*This information reflects FDA's preliminary analysis of data concerning this drug. FDA is considering, but has not reached a final conclusion about, this information. FDA intends to update this sheet when additional information or analyses become available.*

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#### What Is Bupropion?

Bupropion is a medicine that is used to treat depression.

#### Who Should Not Take Bupropion?

- **Never take bupropion if you are taking another drug used to treat depression, called a Monoamine Oxidase Inhibitor (MAOI), or if you have stopped taking a MAOI in the last 14 days. Taking bupropion close in time to a MAOI can result in serious, sometimes fatal, reactions, including:**
  - High body temperature
  - Coma
  - Seizures (convulsions)MAOI drugs include Nardil (phenelzine sulfate), Parnate (tranylcypromine sulfate), Marplan (isocarboxazid) and other brands.
- **Bupropion can cause seizures. Never take bupropion if you have any of the following because you have a higher chance of having seizures with bupropion:**
  - A seizure disorder
  - Take Zyban or any other medicine containing bupropion
  - A current or past eating disorder such as bulimia or anorexia nervosa
  - Stop suddenly, the use of alcohol or sedatives, including medicines for anxiety and sleeping problems called benzodiazepines.

#### What Are The Risks?

- **Suicidal Thoughts or Actions:** See FDA Alert.
- **Seizures:** Bupropion can cause seizures. See "Who should not take bupropion?" You also have a higher chance for seizures with bupropion if you take a higher dose, had a head injury, brain tumor, severe liver disease, abuse alcohol or drugs, or take certain medicines that interact with bupropion. **Stop bupropion if you have a seizure and never take it again.**
- **Possible liver damage**
- **Serious allergic reactions:** Call your healthcare professional right away if you get a skin rash, hives, chest pain, swelling, or trouble breathing.
- **Agitation, anxiety, and trouble sleeping**
- **Mental problems,** including psychosis, confusion and hallucinations.
- **Mania:** You may become hyperactive, excitable, or elated.
- **Weight and appetite change:** More people lose weight, than gain it, while taking bupropion.
- **High Blood Pressure (hypertension).** The chance for high blood pressure is increased if you also use nicotine replacement products to stop smoking.





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- **Other side effects** include agitation, dry mouth, trouble sleeping, headache and migraine, nausea and vomiting, constipation, and tremor
- **Tell your healthcare professional** about all your medical conditions, especially if you have liver, kidney, or heart disease. Tell your healthcare professional if you are pregnant or plan to become pregnant. Tell your healthcare professional if you are breast-feeding or plan to breast-feed your baby.

#### **Are There Any Interactions With Medicines Or Foods?**

- Bupropion may interact with medicines other than the ones already mentioned in this information sheet, causing serious side effects. Tell your healthcare professional about all the medicines, vitamins, and herbal supplements you take, especially those used for treating seizures, depression, mental illness, asthma, high blood pressure, or heart problems.
- If you plan to drink alcohol, talk to your healthcare professional.

#### **How Do I Take Bupropion?**

- Bupropion is taken by mouth, with or without food, exactly as prescribed by your doctor.
- Swallow tablets whole. Do not chew, crush, or divide bupropion tablets.

#### **Is There Anything Else I Need to Know?**

You can get more information about antidepressants at:

<http://www.fda.gov/cder/drug/antidepressants/default.htm>

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