

## Important Safety Information about WELLBUTRIN XL®

WELLBUTRIN XL® is indicated for the treatment of major depressive disorder.

### WARNING

#### Suicidality and Antidepressant Drugs

**Use in Treating Psychiatric Disorders:** 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 XL 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 XL is not approved for use in pediatric patients. (See **WARNINGS: Clinical Worsening and Suicide Risk in Treating Psychiatric Disorders, PRECAUTIONS: Information for Patients, and PRECAUTIONS: Pediatric Use.**)

**Use in Smoking Cessation Treatment:** WELLBUTRIN®, WELLBUTRIN SR®, and WELLBUTRIN XL are not approved for smoking cessation treatment, but bupropion under the name ZYBAN® is approved for this use. Serious neuropsychiatric events, including but not limited to depression, suicidal ideation, suicide attempt, and completed suicide have been reported in patients taking bupropion for smoking cessation. Some cases may have been complicated by the symptoms of nicotine withdrawal in patients who stopped smoking. Depressed mood may be a symptom of nicotine withdrawal. Depression, rarely including suicidal ideation, has been reported in smokers undergoing a smoking cessation attempt without medication. However, some of these symptoms have occurred in patients taking bupropion who continued to smoke.

All patients being treated with bupropion for smoking cessation treatment should be observed for neuropsychiatric symptoms including changes in behavior, hostility, agitation, depressed mood, and suicide-related events, including ideation, behavior, and attempted suicide. These symptoms, as well as worsening of pre-existing psychiatric illness and completed suicide, have been reported in some patients attempting to quit smoking while taking ZYBAN in the post-marketing experience. When symptoms were reported, most were during treatment with ZYBAN, but some were following discontinuation of treatment with ZYBAN. These events have occurred in patients with and without pre-existing psychiatric disease; some have experienced worsening of their psychiatric illnesses. Patients with serious psychiatric illness such as schizophrenia, bipolar disorder, and major depressive disorder did not participate in the pre-marketing studies of ZYBAN.

**Advise patients and caregivers that the patient using bupropion for smoking cessation should stop taking bupropion and contact a healthcare provider immediately if agitation, hostility, depressed mood, or changes in thinking or behavior that are not typical for the patient are observed, or if the patient develops suicidal ideation or suicidal behavior.** In many post-marketing cases, resolution of symptoms after discontinuation of ZYBAN was reported, although in some cases the symptoms persisted; therefore, ongoing monitoring and supportive care should be provided until symptoms resolve.

The risks of using bupropion for smoking cessation should be weighed against the benefits of its use. ZYBAN has been demonstrated to increase the likelihood of abstinence from smoking for as long as six months compared to treatment with placebo. The health benefits of quitting smoking are immediate and substantial. (See **WARNINGS: Neuropsychiatric Symptoms and Suicide Risk in Smoking Cessation Treatment and PRECAUTIONS: Information for Patients.**)

WELLBUTRIN XL® is not for everyone. There is a chance of having a seizure (convulsion, fit) with WELLBUTRIN XL®, especially in people with certain medical problems or who take certain medicines. The risk of having seizures increases with higher doses of WELLBUTRIN XL®. Tell your doctor about all of your medical conditions, especially if you have liver or kidney problems, and all the medicines you take. **Do not take any other medicines while you are using WELLBUTRIN XL® unless your doctor has said it is okay to take them. If you have a seizure while taking WELLBUTRIN XL®, stop taking the tablets and call your doctor right away.** Do not take WELLBUTRIN XL® again if you have a seizure.

Do not take with monoamine oxidase inhibitors (MAOIs), or medicines that contain bupropion like ZYBAN®, which is used to help patients stop smoking. Some people get high blood pressure that can be severe while taking WELLBUTRIN XL®. The risk for high blood pressure may be increased if you also use nicotine replacement therapy (such as a nicotine patch) to help you stop smoking.

#### Who should not take WELLBUTRIN XL®:

Do not take WELLBUTRIN XL® 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® Tablets or WELLBUTRIN SR® Sustained-Release Tablets. Bupropion is the same active ingredient that is in WELLBUTRIN XL®
- 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 XL®, bupropion, or to any of the inactive ingredients

#### Possible side effects of WELLBUTRIN XL®:

The most common adverse reactions reported with WELLBUTRIN XL® are weight loss, dry mouth, nausea, difficulty sleeping, dizziness, and sore throat. Other common side effects include loss of appetite, skin rash, sweating, ringing in the ears, shakiness, stomach pain, agitation, anxiety, muscle pain, fast heartbeat, and more frequent urination.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088. You may also contact BTA Pharmaceuticals directly at 1-866-246-8245 (opt. 3).

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