

Respiratory			
Pharyngitis	3%	11%	2%
Sinusitis	3%	1%	2%
Increased cough	1%	2%	1%
Skin			
Sweating	6%	5%	2%
Rash	5%	4%	1%
Pruritus	2%	4%	2%
Urticaria	2%	1%	0%
Special senses			
Tinnitus	6%	6%	2%
Taste perversion	2%	4%	—
Blurred vision or diplopia	3%	2%	2%
Urogenital			
Urinary frequency	2%	5%	2%
Urinary urgency	—	2%	0%
Vaginal hemorrhage [†]	0%	2%	—
Urinary tract infection	1%	0%	—

* Adverse events that occurred in at least 1% of patients treated with either 300 or 400 mg/day of the sustained-release formulation of bupropion, but equally or more frequently in the placebo group, were: abnormal dreams, accidental injury, acne, appetite increased, back pain, bronchitis, dysmenorrhea, dyspepsia, flatulence, flu syndrome, hypertension, neck pain, respiratory disorder, rhinitis, and tooth disorder.

[†] Incidence based on the number of female patients.

— Hyphen denotes adverse events occurring in greater than 0 but less than 0.5% of patients.

Additional events to those listed in Table 7 that occurred at an incidence of at least 1% in controlled clinical trials of the immediate-release formulation of bupropion (300 to 600 mg/day) and that were numerically more frequent than placebo were: cardiac arrhythmias (5% vs 4%), hypertension (4% vs 2%), hypotension (3% vs 2%), tachycardia (11% vs 9%), appetite increase (4% vs 2%), dyspepsia (3% vs 2%), menstrual complaints (5% vs 1%), akathisia (2% vs 1%), impaired sleep quality (4% vs 2%), sensory disturbance (4% vs 3%), confusion (8% vs 5%), decreased libido (3% vs 2%), hostility (6% vs 4%), auditory disturbance (5% vs 3%), and gustatory disturbance (3% vs 1%).

Incidence of Commonly Observed Adverse Events in Controlled Clinical Trials: Adverse events from Table 7 occurring in at least 5% of patients treated with the sustained-release formulation of bupropion and at a rate at least twice the placebo rate are listed below for the 300- and 400-mg/day dose groups.

300 mg/day of WELLBUTRIN SR: Anorexia, dry mouth, rash, sweating, tinnitus, and tremor.

400 mg/day of WELLBUTRIN SR: Abdominal pain, agitation, anxiety, dizziness, dry mouth, insomnia, myalgia, nausea, palpitation, pharyngitis, sweating, tinnitus, and urinary frequency.

Seasonal Affective Disorder: Adverse Events Leading to Discontinuation of

Treatment With WELLBUTRIN XL: In placebo-controlled clinical trials, 9% of patients treated with WELLBUTRIN XL and 5% of patients treated with placebo discontinued treatment due to adverse events. The adverse events in these trials that led to discontinuation in at least 1% of patients treated with WELLBUTRIN XL and at a rate numerically greater than the placebo rate are insomnia (2% vs <1%) and headache (1% vs <1%).

Adverse Events Occurring at an Incidence of 2% or More Among Patients Treated With WELLBUTRIN XL: Table 8 enumerates treatment-emergent adverse events that occurred among patients treated with WELLBUTRIN XL for up to approximately 6 months in 3 placebo-controlled trials. Events that occurred at an incidence of 2% or more and were more frequent than in the placebo group are included. Reported adverse events were classified using a MedDRA-based Dictionary.

Accurate estimates of the incidence of adverse events associated with the use of any drug are difficult to obtain. Estimates are influenced by drug dose, detection technique, setting, physician judgments, etc. The figures cited cannot be used to predict precisely the incidence of untoward events in the course of usual medical practice where patient characteristics and other factors differ from those that prevailed in the clinical trials. These incidence figures also cannot be compared with those obtained from other clinical studies involving related drug products as each group of drug trials is conducted under a different set of conditions; e.g., different patient populations, different treatment durations.

Finally, it is important to emphasize that the tabulation does not reflect the relative severity and/or clinical importance of the events. A better perspective on the serious adverse events associated with the use of bupropion is provided in the WARNINGS and PRECAUTIONS sections.

Table 8. Treatment-Emergent Adverse Events* in Placebo-Controlled Trials of Seasonal Affective Disorder

System Organ Class/ Preferred Term	WELLBUTRIN XL (n = 537)	Placebo (n = 511)
Gastrointestinal Disorder		
Dry Mouth	26%	15%
Nausea	13%	8%
Constipation	9%	2%
Flatulence	6%	3%
Abdominal pain	2%	<1%
Nervous System Disorders		
Headache	34%	26%
Dizziness	6%	5%
Tremor	3%	<1%
Infections and Infestations		
Nasopharyngitis	13%	12%
Upper respiratory tract infection	9%	8%
Sinusitis	5%	4%
Psychiatric Disorders		
Insomnia	20%	13%

Anxiety	7%	5%
Abnormal dreams	3%	2%
Agitation	2%	<1%
Musculoskeletal and Connective Tissue Disorders		
Myalgia	3%	2%
Pain in extremity	3%	2%
Respiratory, Thoracic and Mediastinal Disorders		
Cough	4%	3%
General Disorders and Administration Site Conditions		
Feeling jittery	3%	2%
Skin and Subcutaneous Tissue Disorders		
Rash	3%	2%
Metabolism and Nutrition Disorders		
Decreased appetite	4%	1%
Reproductive System and Breast Disorders		
Dysmenorrhea	2%	<1%
Ear and Labyrinth Disorders		
Tinnitus	3%	<1%
Vascular Disorders		
Hypertension	2%	0%

* Adverse events that occurred in at least 2% of patients treated with WELLBUTRIN XL, but equally or more frequently in the placebo group, were: abdominal pain upper, arthralgia, back pain, diarrhea, dyspepsia, fatigue, gastroenteritis viral, hyperhidrosis, influenza, irritability, migraine, nasal congestion, neck pain, palpitations, pharyngolaryngeal pain, sinus congestion.

Incidence of Commonly Observed Adverse Events in Controlled Clinical Trials: Adverse events from Table 8 that occurred in at least 5% of patients treated with WELLBUTRIN XL and at a rate at least twice the placebo rate were constipation and flatulence.

Adverse Events During Taper or Following Discontinuation of WELLBUTRIN XL: Adverse events with onset during the 2 weeks following down-titration of WELLBUTRIN XL from 300 mg/day to 150 mg/day were reported by 14% of patients compared to 18% of patients who continued on placebo.

Adverse events with onset during the 2 weeks following discontinuation of WELLBUTRIN XL were reported by 9% of patients compared with 12% of patients following discontinuation of placebo.

Other Events Observed During the Clinical Development and Postmarketing

Experience of Bupropion: In addition to the adverse events noted above, the following events have been reported in clinical trials and postmarketing experience with the sustained-release formulation of bupropion in depressed patients and in nondepressed smokers, as well as in clinical trials and postmarketing clinical experience with the immediate-release formulation of bupropion.

Adverse events for which frequencies are provided below occurred in clinical trials with the sustained-release formulation of bupropion. The frequencies represent the proportion of patients who experienced a treatment-emergent adverse event on at least one occasion in placebo-controlled studies for depression (n = 987) or smoking cessation (n = 1,013), or patients who experienced an

adverse event requiring discontinuation of treatment in an open-label surveillance study with the sustained-release formulation of bupropion (n = 3,100). All treatment-emergent adverse events are included except those listed in Tables 2 through 8, those events listed in other safety-related sections, those adverse events subsumed under COSTART terms that are either overly general or excessively specific so as to be uninformative, those events not reasonably associated with the use of the drug, and those events that were not serious and occurred in fewer than 2 patients. Events of major clinical importance are described in the WARNINGS and PRECAUTIONS sections of the labeling.

Events are further categorized by body system and listed in order of decreasing frequency according to the following definitions of frequency: Frequent adverse events are defined as those occurring in at least 1/100 patients. Infrequent adverse events are those occurring in 1/100 to 1/1,000 patients, while rare events are those occurring in less than 1/1,000 patients.

Adverse events for which frequencies are not provided occurred in clinical trials or postmarketing experience with bupropion. Only those adverse events not previously listed for sustained-release bupropion are included. The extent to which these events may be associated with WELLBUTRIN XL is unknown.

Body (General): Infrequent were chills, facial edema, musculoskeletal chest pain, and photosensitivity. Rare was malaise. Also observed were arthralgia, myalgia, and fever with rash and other symptoms suggestive of delayed hypersensitivity. These symptoms may resemble serum sickness (see PRECAUTIONS).

Cardiovascular: Infrequent were postural hypotension, stroke, tachycardia, and vasodilation. Rare was syncope. Also observed were complete atrioventricular block, extrasystoles, hypotension, hypertension (in some cases severe, see PRECAUTIONS), myocardial infarction, phlebitis, and pulmonary embolism.

Digestive: Infrequent were abnormal liver function, bruxism, gastric reflux, gingivitis, glossitis, increased salivation, jaundice, mouth ulcers, stomatitis, and thirst. Rare was edema of tongue. Also observed were colitis, esophagitis, gastrointestinal hemorrhage, gum hemorrhage, hepatitis, intestinal perforation, liver damage, pancreatitis, and stomach ulcer.

Endocrine: Also observed were hyperglycemia, hypoglycemia, and syndrome of inappropriate antidiuretic hormone.

Hemic and Lymphatic: Infrequent was ecchymosis. Also observed were anemia, leukocytosis, leukopenia, lymphadenopathy, pancytopenia, and thrombocytopenia. Altered PT and/or INR, infrequently associated with hemorrhagic or thrombotic complications, were observed when bupropion was coadministered with warfarin.

Metabolic and Nutritional: Infrequent were edema and peripheral edema. Also observed was glycosuria.

Musculoskeletal: Infrequent were leg cramps. Also observed were muscle rigidity/fever/rhabdomyolysis and muscle weakness.

Nervous System: Infrequent were abnormal coordination, decreased libido, depersonalization, dysphoria, emotional lability, hostility, hyperkinesia, hypertonia, hypesthesia, suicidal ideation, and vertigo. Rare were amnesia, ataxia, derealization, and hypomania. Also observed were abnormal electroencephalogram (EEG), aggression, akinesia, aphasia, coma, completed suicide, delirium, delusions, dysarthria, dyskinesia, dystonia, euphoria, extrapyramidal syndrome, hallucinations, hypokinesia, increased libido, manic reaction, neuralgia, neuropathy, paranoid ideation, restlessness, suicide attempt, and unmasking tardive dyskinesia.

Respiratory: Rare was bronchospasm. Also observed was pneumonia.

Skin: Rare was maculopapular rash. Also observed were alopecia, angioedema, exfoliative dermatitis, and hirsutism.

Special Senses: Infrequent were accommodation abnormality and dry eye. Also observed were deafness, diplopia, increased intraocular pressure, and mydriasis.

Urogenital: Infrequent were impotence, polyuria, and prostate disorder. Also observed were abnormal ejaculation, cystitis, dyspareunia, dysuria, gynecomastia, menopause, painful erection, salpingitis, urinary incontinence, urinary retention, and vaginitis.

DRUG ABUSE AND DEPENDENCE

Controlled Substance Class: Bupropion is not a controlled substance.

Humans: Controlled clinical studies of bupropion (immediate-release formulation) conducted in normal volunteers, in subjects with a history of multiple drug abuse, and in depressed patients showed some increase in motor activity and agitation/excitement.

In a population of individuals experienced with drugs of abuse, a single dose of 400 mg of bupropion produced mild amphetamine-like activity as compared to placebo on the Morphine-Benzedrine Subscale of the Addiction Research Center Inventories (ARCI), and a score intermediate between placebo and amphetamine on the Liking Scale of the ARCI. These scales measure general feelings of euphoria and drug desirability.

Findings in clinical trials, however, are not known to reliably predict the abuse potential of drugs. Nonetheless, evidence from single-dose studies does suggest that the recommended daily dosage of bupropion when administered in divided doses is not likely to be especially reinforcing to amphetamine or stimulant abusers. However, higher doses that could not be tested because of the risk of seizure might be modestly attractive to those who abuse stimulant drugs.

Animals: Studies in rodents and primates have shown that bupropion exhibits some pharmacologic actions common to psychostimulants. In rodents, it has been shown to increase locomotor activity, elicit a mild stereotyped behavioral response, and increase rates of responding in several schedule-controlled behavior paradigms. In primate models to assess the positive reinforcing effects of psychoactive drugs, bupropion was self-administered intravenously. In rats, bupropion produced amphetamine-like and cocaine-like discriminative stimulus effects in drug discrimination paradigms used to characterize the subjective effects of psychoactive drugs.

OVERDOSAGE

Human Overdose Experience: Overdoses of up to 30 g or more of bupropion have been reported. Seizure was reported in approximately one third of all cases. Other serious reactions reported with overdoses of bupropion alone included hallucinations, loss of consciousness, sinus tachycardia, and ECG changes such as conduction disturbances (including QRS prolongation) or arrhythmias. Fever, muscle rigidity, rhabdomyolysis, hypotension, stupor, coma, and respiratory failure have been reported mainly when bupropion was part of multiple drug overdoses.

Although most patients recovered without sequelae, deaths associated with overdoses of bupropion alone have been reported in patients ingesting large doses of the drug. Multiple uncontrolled seizures, bradycardia, cardiac failure, and cardiac arrest prior to death were reported in these patients.

Overdosage Management: Ensure an adequate airway, oxygenation, and ventilation. Monitor cardiac rhythm and vital signs. EEG monitoring is also recommended for the first 48 hours post-ingestion. General supportive and symptomatic measures are also recommended. Induction of emesis is not recommended.

Activated charcoal should be administered. There is no experience with the use of forced diuresis, dialysis, hemoperfusion, or exchange transfusion in the management of bupropion overdoses. No specific antidotes for bupropion are known.

Due to the dose-related risk of seizures with WELLBUTRIN XL, hospitalization following suspected overdose should be considered. Based on studies in animals, it is recommended that seizures be treated with intravenous benzodiazepine administration and other supportive measures, as appropriate.

In managing overdosage, consider the possibility of multiple drug involvement. The physician should consider contacting a poison control center for additional information on the treatment of any overdose. Telephone numbers for certified poison control centers are listed in the *Physicians' Desk Reference* (PDR).

DOSAGE AND ADMINISTRATION

General Dosing Considerations: It is particularly important to administer WELLBUTRIN XL Tablets in a manner most likely to minimize the risk of seizure (see WARNINGS). Gradual escalation in dosage is also important if agitation, motor restlessness, and insomnia, often seen during the initial days of treatment, are to be minimized. If necessary, these effects may be managed by temporary reduction of dose or the short-term administration of an intermediate to long-acting sedative hypnotic. A sedative hypnotic usually is not required beyond the first week of treatment. Insomnia may also be minimized by avoiding bedtime doses. If distressing, untoward effects supervene, dose escalation should be stopped. WELLBUTRIN XL should be swallowed whole and not crushed, divided, or chewed. WELLBUTRIN XL may be taken without regard to meals.

Major Depressive Disorder: Initial Treatment: The usual adult target dose for WELLBUTRIN XL Tablets is 300 mg/day, given once daily in the morning. Dosing with WELLBUTRIN XL Tablets should begin at 150 mg/day given as a single daily dose in the morning. If the 150-mg initial dose is adequately tolerated, an increase to the 300-mg/day target dose, given as once daily, may be made as early as day 4 of dosing. There should be an interval of at least 24 hours between successive doses.

Increasing the Dosage Above 300 mg/day: As with other antidepressants, the full antidepressant effect of WELLBUTRIN XL Tablets may not be evident until 4 weeks of treatment or longer. An increase in dosage to the maximum of 450 mg/day, given as a single dose, may be considered for patients in whom no clinical improvement is noted after several weeks of treatment at 300 mg/day.

Maintenance Treatment: It is generally agreed that acute episodes of depression require several months or longer of sustained pharmacological therapy beyond response to the acute episode. It is unknown whether or not the dose of WELLBUTRIN XL needed for maintenance treatment is identical to the dose needed to achieve an initial response. Patients should be periodically reassessed to determine the need for maintenance treatment and the appropriate dose for such treatment.

Seasonal Affective Disorder: For the prevention of seasonal major depressive episodes associated with seasonal affective disorder, WELLBUTRIN XL should generally be initiated in the autumn prior to the onset of depressive symptoms. Treatment should continue through the winter season and should be tapered and discontinued in early spring. The timing of initiation and duration of treatment should be individualized based on the patient's historical pattern of seasonal major depressive episodes. Patients whose seasonal depressive episodes are infrequent or not associated with significant impairment should not generally be treated prophylactically.

Dosing with WELLBUTRIN XL Tablets should begin at 150 mg/day given as a single daily dose in the morning. If the 150-mg initial dose is adequately tolerated, the dose of WELLBUTRIN XL should be increased to the 300-mg/day dose after 1 week. If the 300-mg dose is not adequately tolerated, the dose can be reduced to 150 mg/day. The usual adult target dose for WELLBUTRIN XL Tablets is 300 mg/day, given once daily in the morning.

For patients taking 300 mg/day during the autumn-winter season, the dose should be tapered to 150 mg/day for 2 weeks prior to discontinuation.

Doses of WELLBUTRIN XL above 300 mg/day have not been studied for the prevention of seasonal major depressive episodes.

Switching Patients from WELLBUTRIN Tablets or from WELLBUTRIN SR Sustained-Release Tablets: When switching patients from WELLBUTRIN Tablets to WELLBUTRIN XL or from WELLBUTRIN SR Sustained-Release Tablets to WELLBUTRIN XL, give the same total daily dose when possible. Patients who are currently being treated with WELLBUTRIN Tablets at 300 mg/day (for example, 100 mg 3 times a day) may be switched to WELLBUTRIN XL 300 mg once daily. Patients who are currently being treated with WELLBUTRIN SR Sustained-Release Tablets at 300 mg/day (for example, 150 mg twice daily) may be switched to WELLBUTRIN XL 300 mg once daily.

Dosage Adjustment for Patients With Impaired Hepatic Function: WELLBUTRIN XL should be used with extreme caution in patients with severe hepatic cirrhosis. The dose should not exceed 150 mg every other day in these patients. WELLBUTRIN XL 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 XL 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 XL Extended-Release Tablets, 150 mg of bupropion hydrochloride, are creamy-white to pale yellow, round, tablets printed with “WELLBUTRIN XL 150” in bottles of 30 (NDC 0173-0730-01) and 90 (NDC 0173-0730-02).

WELLBUTRIN XL Extended-Release Tablets, 300 mg of bupropion hydrochloride, are creamy-white to pale yellow, round, tablets printed with “WELLBUTRIN XL 300” in bottles of 30 (NDC 0173-0731-01).

Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature].

MEDICATION GUIDE

WELLBUTRIN XL[®] (WELL byu-trin) (bupropion hydrochloride extended-release tablets)

Read this Medication Guide carefully before you start using WELLBUTRIN XL 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 XL, ask your doctor or pharmacist.

IMPORTANT: Be sure to read the three sections of this Medication Guide. The first section is about the risk of suicidal thoughts and actions with antidepressant medicines; the second section is about the risk of changes in thinking and behavior, depression and suicidal thoughts or actions with medicines used to quit smoking; and the third section is entitled “What Other Important Information Should I Know About WELLBUTRIN XL?”

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

Quitting Smoking, Quit-Smoking Medications, Changes in Thinking and Behavior, Depression, and Suicidal Thoughts or Actions

This section of the Medication Guide is only about the risk of changes in thinking and behavior, depression and suicidal thoughts or actions with drugs used to quit smoking.

Although WELLBUTRIN XL is not a treatment for quitting smoking, it contains the same active ingredient (bupropion hydrochloride) as ZYBAN[®] which is used to help patients quit smoking.

Some people have had changes in behavior, hostility, agitation, depression, suicidal thoughts or actions while taking bupropion to help them quit smoking. These symptoms can develop during treatment with bupropion or after stopping treatment with bupropion.

If you, your family member, or your caregiver notice agitation, hostility, depression, or changes in thinking or behavior that are not typical for you, or you have any of the following symptoms, stop taking bupropion and call your healthcare provider right away:

- - thoughts about suicide or dying
 - attempts to commit suicide
 - new or worse depression
 - new or worse anxiety
 - panic attacks
 - feeling very agitated or restless
 - acting aggressive, being angry, or violent
 - acting on dangerous impulses
 - an extreme increase in activity and talking (mania)
 - abnormal thoughts or sensations
 - seeing or hearing things that are not there (hallucinations)
 - feeling people are against you (paranoia)
 - feeling confused
 - other unusual changes in behavior or mood

When you try to quit smoking, with or without bupropion, you may have symptoms that may be due to nicotine withdrawal, including urge to smoke, depressed mood, trouble sleeping, irritability, frustration, anger, feeling anxious, difficulty concentrating, restlessness, decreased heart rate, and increased appetite or weight gain. Some people have even experienced suicidal thoughts when trying to quit smoking without medication. Sometimes quitting smoking can lead to worsening of mental health problems that you already have, such as depression.

Before taking bupropion, tell your healthcare provider if you have ever had depression or other mental illnesses. You should also tell your doctor about any symptoms you had during other times you tried to quit smoking, with or without bupropion.

What Other Important Information Should I Know About WELLBUTRIN XL?

- **Seizures: There is a chance of having a seizure (convulsion, fit) with WELLBUTRIN XL, especially in people:**
 - with certain medical problems.
 - who take certain medicines.

The chance of having seizures increases with higher doses of WELLBUTRIN XL. For more information, see the sections “Who should not take WELLBUTRIN XL?” and “What should I tell my doctor before using WELLBUTRIN XL?” 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 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.

- **High blood pressure (hypertension). Some people get high blood pressure, that can be severe, while taking WELLBUTRIN XL.** The chance of high blood pressure may be higher if you also use nicotine replacement therapy (such as a nicotine patch) to help you stop smoking.
- **Severe allergic reactions. Some people have severe allergic reactions to WELLBUTRIN XL. Stop taking WELLBUTRIN XL 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 XL, 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.

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What is WELLBUTRIN XL?

WELLBUTRIN XL is a prescription medicine used to treat adults with a certain type of depression called major depressive disorder and for prevention of autumn-winter seasonal depression (seasonal affective disorder).

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. See the end of this leaflet for a complete list of ingredients in WELLBUTRIN XL.

What should I tell my doctor before using WELLBUTRIN XL?

- Tell your doctor if you have ever had depression, suicidal thoughts or actions, or other mental health problems. See “Antidepressant Medicines, Depression and Other Serious Mental Illnesses, and Suicidal Thoughts or Actions.”
- **Tell your doctor about your other medical conditions including if you:**
 - **are pregnant or plan to become pregnant.** It is not known if WELLBUTRIN XL can harm your unborn baby.
 - **are breastfeeding.** WELLBUTRIN XL passes through your milk. It is not known if WELLBUTRIN XL 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 XL.

How should I take WELLBUTRIN XL?

- Take WELLBUTRIN XL exactly as prescribed by your doctor.
- **Do not chew, cut, or crush WELLBUTRIN XL tablets.** You must swallow the tablets whole.
Tell your doctor if you cannot swallow medicine tablets.
- Take WELLBUTRIN XL at the same time each day.
- Take your doses of WELLBUTRIN XL at least 24 hours apart.
- You may take WELLBUTRIN XL 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 XL can increase your chance of having a seizure.
- If you take too much WELLBUTRIN XL, or overdose, call your local emergency room or poison control center right away.
- The WELLBUTRIN XL tablet is covered by a shell that slowly releases the medicine inside your body. You may notice something in your stool that looks like a tablet. This is normal. This is the empty shell passing from your body.
- **Do not take any other medicines while using WELLBUTRIN XL unless your doctor has told you it is okay.**
- If you are taking WELLBUTRIN XL for the treatment of major depressive disorder, it may take several weeks for you to feel that WELLBUTRIN XL is working. Once you feel better, it is important to keep taking WELLBUTRIN XL exactly as directed by your doctor. Call your doctor if you do not feel WELLBUTRIN XL is working for you.
- If you are taking WELLBUTRIN XL for the prevention of seasonal major depressive episodes associated with seasonal affective disorder, it is important to keep taking WELLBUTRIN XL through the autumn-winter season, or as directed by your doctor.
- Do not change your dose or stop taking WELLBUTRIN XL without talking with your doctor first.

What should I avoid while taking WELLBUTRIN XL?

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

What are possible side effects of WELLBUTRIN XL?

WELLBUTRIN XL can cause serious side effects. Read this entire Medication Guide for more information about these serious side effects.

Common side effects reported in studies of major depressive disorder include weight loss, loss of appetite, dry mouth, skin rash, sweating, ringing in the ears, shakiness, stomach pain, agitation, anxiety, dizziness, trouble sleeping, muscle pain, nausea, fast heartbeat, sore throat, and urinating

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more often. In studies of seasonal affective disorder, common side effects included weight loss, constipation, and gas.

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

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

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store WELLBUTRIN XL?

- Store WELLBUTRIN XL at room temperature. Store out of direct sunlight. Keep WELLBUTRIN XL in its tightly closed bottle.
- WELLBUTRIN XL tablets may have an odor.

General Information about WELLBUTRIN XL.

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

This Medication Guide summarizes important information about WELLBUTRIN XL. For more information, talk with your doctor. You can ask your doctor or pharmacist for information about WELLBUTRIN XL that is written for health professionals or you can visit www.wellbutrin-xl.com or call toll-free 888-825-5249.

What are the ingredients in WELLBUTRIN XL?

Active ingredient: bupropion hydrochloride.

Inactive ingredients: ethylcellulose aqueous dispersion (NF), glyceryl behenate, methacrylic acid copolymer dispersion (NF), polyvinyl alcohol, polyethylene glycol, povidone, silicon dioxide, and triethyl citrate. The tablets are printed with edible black ink.

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Rx Only

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

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