

MEDICATION GUIDE

BuPROPion Hydrochloride Extended-release Tablets USP (SR)

Rx only

Read this Medication Guide carefully before you start using bupropion hydrochloride extended-release tablets (SR) 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 bupropion hydrochloride extended-release tablets (SR), 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 bupropion hydrochloride extended-release tablets (SR)?”

Antidepressant Medicines, Depression and Other Serious Mental Illnesses, and Suicidal Thoughts or Actions

Although bupropion hydrochloride extended-release tablets (SR) are not a treatment for depression, they contain the same active ingredient as the antidepressant medications Wellbutrin[®], Wellbutrin SR[®], and Wellbutrin XL[®].

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.

Bupropion hydrochloride extended-release tablets (SR) have not been studied in children under the age of 18 and are not approved for use in children and teenagers.

What other important information should I know about bupropion hydrochloride extended-release tablets (SR)?

There is a chance of having a seizure (convulsion, fit) with bupropion hydrochloride extended-release tablets (SR), especially in people:

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

The chance of having seizures increases with higher doses of bupropion hydrochloride extended-release tablets (SR). For more information, see the sections "Who should not take bupropion hydrochloride extended-release tablets (SR)?" and "What should I tell my doctor before using bupropion hydrochloride extended-release tablets (SR)?" 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 bupropion hydrochloride extended-release tablets (SR) unless your doctor has said it is okay to take them.**

If you have a seizure while taking bupropion hydrochloride extended-release tablets (SR), stop taking the tablets and call your doctor right away. Do not take bupropion hydrochloride extended-release tablets (SR) again if you have a seizure.

What are bupropion hydrochloride extended-release tablets (SR)?

Bupropion hydrochloride extended-release tablets (SR) are a prescription medicine to help people quit smoking. Studies have shown that more than one third of people quit smoking for at least 1 month while taking bupropion hydrochloride extended-release tablets (SR) and participating in a patient support program. For many patients, bupropion hydrochloride extended-release tablets (SR) reduce withdrawal symptoms and the urge to smoke. Bupropion hydrochloride extended-release tablets (SR) should be used with a patient support program. It is to participate in the behavioral program, counseling, or other support program your healthcare professional recommends.

Who should not take bupropion hydrochloride extended-release tablets (SR)?

Do not take bupropion hydrochloride extended-release tablets (SR) if you:

- have or had a seizure disorder or epilepsy.
- **are taking Welbutrin[®], Welbutrin SR[®], Welbutrin XL[®], or any other medicines that contain bupropion hydrochloride, such as Wellbutrin[®] Tablets or Wellbutrin XL[®] Extended-Release Tablets.** Bupropion is the same active ingredient that is in bupropion hydrochloride extended-release tablets (SR).
- 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 bupropion hydrochloride extended-release tablets (SR), bupropion, or to any of the inactive ingredients. See the end of this leaflet for a complete list of ingredients in bupropion hydrochloride extended-release tablets (SR).

Can I take bupropion hydrochloride extended-release tablets (SR) if I have mild-to-moderate chronic bronchitis and/or emphysema (also called chronic obstructive pulmonary disease or COPD)?

Yes, bupropion hydrochloride extended-release tablets (SR) combined with a behavior modification program has been shown to help people with COPD quit smoking. It is important to participate in the behavior program, counseling, or other support program your healthcare professional recommends.

What should I tell my doctor before using bupropion hydrochloride extended-release tablets (SR)?

- **Tell your doctor about your medical conditions. Tell your doctor if you:**
 - **are pregnant or plan to become pregnant.** It is not known if bupropion hydrochloride extended-release tablets (SR) can harm your unborn baby.
 - **are breastfeeding.** Bupropion passes through your milk. It is not known if bupropion 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 nonprescription 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 bupropion hydrochloride extended-release tablets (SR).

How should I take bupropion hydrochloride extended-release tablets (SR)?

- Take bupropion hydrochloride extended-release tablets (SR) exactly as prescribed by your doctor.
- **Do not chew, cut, or crush bupropion hydrochloride extended-release tablets (SR).** You must swallow the tablets whole. **Tell your doctor if you cannot swallow medicine tablets.**
- Take bupropion hydrochloride extended-release tablets (SR) at the same time each day.
- Take your doses of bupropion hydrochloride extended-release tablets (SR) at least 8 hours apart.
- 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 many bupropion hydrochloride extended-release tablets (SR) can increase your chance of having a seizure.
- If you take too many bupropion hydrochloride extended-release tablets (SR), or overdose, call your local emergency room or poison control center right away.
- **Do not take any other medicines while using bupropion hydrochloride extended-release tablets (SR) unless your doctor has told you it is okay.**
- Do not change your dose or stop taking bupropion hydrochloride extended-release tablets (SR) without talking with your doctor first.

How long should I take bupropion hydrochloride extended-release tablets (SR)?

Most people should take bupropion hydrochloride extended-release tablets (SR) for at least 7 to 12 weeks. Some people may need to take bupropion hydrochloride extended-release tablets (SR) for a longer period of time to assist in their smoking cessation efforts. Follow your doctor's instructions.

When should I stop smoking?

It takes about 1 week for bupropion hydrochloride extended-release tablets (SR) to reach the right levels in your body to be effective. So, to maximize your chance of quitting, you should not stop smoking until you have been taking bupropion hydrochloride extended-release tablets (SR) for 1 week. You should set a date to stop smoking during the second week you're taking bupropion hydrochloride extended-release tablets (SR).

Can I smoke while taking bupropion hydrochloride extended-release tablets (SR)?

It is not physically dangerous to smoke and use bupropion hydrochloride extended-release tablets (SR) at the same time. However, continuing to smoke after the date you set to stop smoking will seriously reduce your chance of breaking your smoking habit.

Can bupropion hydrochloride extended-release tablets (SR) be used at the same time as nicotine patches?

Yes, bupropion hydrochloride extended-release tablets (SR) and nicotine patches can be used at the same time but should only be used together under the supervision of your doctor. Using bupropion hydrochloride extended-release tablets (SR) and nicotine patches together may raise your blood pressure, sometimes severely. Tell your doctor if you are planning to use nicotine replacement therapy because your doctor will probably want to check your blood pressure regularly to make sure that it stays within acceptable levels.

DO NOT SMOKE AT ANY TIME if you are using a nicotine patch or any other nicotine product along with bupropion hydrochloride extended-release tablets (SR). It is possible to get too much nicotine and have serious side effects.

What should I avoid while taking bupropion hydrochloride extended-release tablets (SR)?

- Do not drink a lot of alcohol while taking bupropion hydrochloride extended-release tablets (SR). 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 bupropion hydrochloride extended-release tablets (SR) affect you. Bupropion hydrochloride extended-release tablets (SR) can impair your ability to perform these tasks.

What are possible side effects of bupropion hydrochloride extended-release tablets (SR)?

- **Seizures.** Some patients get seizures while taking bupropion hydrochloride extended-release tablets (SR). **If you have a seizure while taking bupropion hydrochloride extended-release tablets (SR), stop taking the tablets and call your doctor right away.** Do not take bupropion hydrochloride extended-release tablets (SR) again if you have a seizure.
- **Hypertension (high blood pressure).** Some patients get high blood pressure, sometimes severe, while taking bupropion hydrochloride extended-release tablets (SR). 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 (see "Can bupropion hydrochloride extended-release tablets (SR) be used at the same time as nicotine patches?").
- **Severe allergic reactions: Stop taking bupropion hydrochloride extended-release tablets (SR) 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 bupropion hydrochloride extended-release tablets (SR), 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 bupropion hydrochloride extended-release tablets (SR) are dry mouth and difficulty sleeping. If you have difficulty 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 bupropion hydrochloride extended-release tablets (SR). For a complete list, ask your doctor or pharmacist.

How should I store bupropion hydrochloride extended-release tablets (SR)?

- Store bupropion hydrochloride extended-release tablets (SR) at room temperature. Store out of direct sunlight. Keep bupropion hydrochloride extended-release tablets (SR) in their tightly closed bottle.
- Bupropion hydrochloride extended-release tablets (SR) may have an odor.

General Information about bupropion hydrochloride extended-release tablets (SR).

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

This Medication Guide summarizes important information about bupropion hydrochloride extended-release tablets (SR). For more information, talk with your doctor. You can ask your doctor or pharmacist for information about bupropion hydrochloride extended-release tablets (SR) that is written for health professionals.

What are the ingredients in bupropion hydrochloride extended-release tablets (SR)?

Active ingredient: bupropion hydrochloride.

Issued: August 2008