MEDICATION GUIDE

Bupropion Hydrochloride Extended-Release Tablets, USP (XL)

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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 Bupropion Hydrochloride Extended-Release Tablets (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.

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 the risk of suicidal thoughts or actions in some children, teenagers, or young adults within the first few months of treatment.**
2. **Depression or 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 your healthcare provider right away to report new or sudden changes in mood, behavior, thoughts, or feelings.
   - Keep all follow up visits with your healthcare provider as scheduled. Call the healthcare provider between visits as needed, especially if you have concerns about symptoms.

Call your 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.

It is not known if bupropion hydrochloride extended-release tablets (XL) are safe and effective in children under the age of 18.

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 bupropion hydrochloride extended-release tablets (XL) are not a treatment for quitting smoking, it contains the same active ingredient (bupropion hydrochloride) as ZYBAN which is used to help patients quit smoking.

Talk to your healthcare provider or your family member's healthcare provider about:

- all risks and benefits of quit-smoking medicines.
- all treatment choices for quitting smoking.

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
- increased appetite
- 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.

Some people have had serious side effects while taking bupropion to help them quit smoking, including:

New or worse mental health problems, such as changes in behavior or thinking, aggression, hostility, agitation, depression, or suicidal thoughts or actions. Some people had these symptoms when they began taking bupropion, and others developed them after several weeks of treatment, or after stopping bupropion. These symptoms happened more often in people who had a history of mental health problems before taking bupropion than in people without a history of mental health problems.

Stop taking bupropion hydrochloride extended-release tablets (XL) and call your healthcare provider right away if you, your family, or caregiver notice any of these symptoms. Work with your healthcare provider to decide whether you should continue to take bupropion hydrochloride extended-release tablets (XL). In many people, these symptoms went away after stopping bupropion hydrochloride extended-release tablets (XL), but in some people symptoms continued after stopping bupropion hydrochloride extended-release tablets (XL). It is important for you to follow-up with your healthcare provider until your symptoms go away. **Before taking bupropion hydrochloride extended-release tablets (XL),** tell your healthcare provider if you have ever had depression or other mental health problems. You should also tell your healthcare provider 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 Bupropion Hydrochloride Extended-Release Tablets (XL)?

- **Seizures: There is a chance of having a seizure (convulsion, fit) with bupropion hydrochloride extended-release tablets (XL), 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 (XL). For more information, see the sections "Who should not take Bupropion Hydrochloride Extended-Release Tablets (XL)?" and "What should I tell my healthcare provider before taking Bupropion Hydrochloride Extended-Release Tablets (XL)?" Tell your healthcare provider about all of your medical conditions and all the medicines you take. **Do not take any other medicines while you are taking bupropion hydrochloride extended-release tablets (XL) unless your healthcare provider has said it is okay to take them.**

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

- **High blood pressure (hypertension). Some people get high blood pressure that can be severe, while taking bupropion hydrochloride extended-release tablets (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 (see the section of this Medication Guide called "How should I take Bupropion Hydrochloride Extended-Release Tablets (XL)?").

- **Manic episodes.** Some people may have periods of mania while taking bupropion hydrochloride extended-release tablets (XL), including:
  - Greatly increased energy
  - Severe trouble sleeping
  - Racing thoughts
  - Reckless behavior
  - Unusually grand ideas
  - Excessive happiness or irritability
  - Talking more or faster than usual

  If you have any of the above symptoms of mania, call your healthcare provider.

- **Unusual thoughts or behaviors.** Some patients have unusual thoughts or behaviors while taking bupropion hydrochloride extended-release tablets (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 healthcare provider.

- **Visual problems.**
  - eye pain
  - changes in vision
  - swelling or redness in or around the eye

  Only some people are at risk for these problems. You may want to undergo an eye examination to see if you are at risk and receive preventative treatment if you are.

- **Severe allergic reactions. Some people can have severe allergic reactions to bupropion hydrochloride extended-release tablets (XL). Stop taking bupropion hydrochloride extended-release tablets (XL) and call your healthcare provider 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.

What are Bupropion Hydrochloride Extended-Release Tablets (XL)?

Bupropion hydrochloride extended-release tablets (XL) are a prescription medicine used to treat adults with a certain type of depression called major depressive disorder and for the prevention of autumn-winter seasonal depression (seasonal affective disorder).

Who should not take Bupropion Hydrochloride Extended-Release Tablets (XL)?

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

- have or had a seizure disorder or epilepsy.
- have or had an eating disorder such as anorexia nervosa or bulimia.
- **are taking any other medicines that contain bupropion, including WELLBUTRIN, WELLBUTRIN SR, APLENZIN®, ZYBAN, or FORFIVO XL.** Bupropion is the same active ingredient that is in bupropion hydrochloride extended-release tablets (XL).
- drink a lot of alcohol and abruptly stop drinking, or take medicines called sedatives (these make you sleepy), benzodiazepines, or anti-seizure medicines, and you stop taking them all of a sudden.
- take a monoamine oxidase inhibitor (MAOI). Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI, including the antibiotic linezolid.
  - **do not take an MAOI within 2 weeks of stopping bupropion hydrochloride extended-release tablets (XL) unless directed to do so by your healthcare provider.**
  - **do not start bupropion hydrochloride extended-release tablets (XL) if you stopped taking an MAOI in the last 2 weeks unless directed to do so by your healthcare provider.**
- are allergic to the active ingredient in bupropion hydrochloride extended-release tablets (XL), bupropion, or to any of the inactive ingredients. See the end of this Medication Guide for a complete list of ingredients in bupropion hydrochloride extended-release tablets (XL).

What should I tell my healthcare provider before taking Bupropion Hydrochloride Extended-Release Tablets (XL)?

Tell your healthcare provider if you have ever had depression, suicidal thoughts or actions, or other mental health problems. You should also tell your healthcare provider about any symptoms you had during other times you tried to quit smoking, with or without bupropion hydrochloride extended-release tablets (XL). See "Quitting Smoking, Quit-Smoking Medications, Changes in Thinking and Behavior, Depression, and Suicidal Thoughts or Actions."

- **Tell your healthcare provider about your other medical conditions, including if you:**
  - have liver problems, especially cirrhosis of the liver.
  - have kidney problems.
  - have, or have had, 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 alcohol.
  - abuse prescription medicines or street drugs.
  - are pregnant or plan to become pregnant. Talk to your healthcare provider about the risk to your unborn baby if you take bupropion hydrochloride extended-release tablets (XL) during pregnancy.
    - Tell your healthcare provider if you become pregnant or think you are pregnant during treatment with bupropion hydrochloride extended-release tablets (XL).
  - are breastfeeding or plan to breastfeed during treatment with bupropion hydrochloride extended-release tablets (XL). Bupropion hydrochloride extended-release tablets (XL) passes into your milk. Talk to your healthcare provider about the best way to feed your baby during treatment with bupropion hydrochloride extended-release tablets (XL).

Tell your healthcare provider about all the medicines you take, including prescription, over-the-counter 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 taking bupropion hydrochloride extended-release tablets (XL).

How should I take Bupropion Hydrochloride Extended-Release Tablets (XL)?

- Take bupropion hydrochloride extended-release tablets (XL) exactly as prescribed by your healthcare provider. Do not change your dose or stop taking bupropion hydrochloride extended-release tablets (XL) without talking with your healthcare provider first.
- **Swallow bupropion hydrochloride extended-release tablets (XL) whole. Do not chew, cut, or crush bupropion hydrochloride extended-release tablets (XL).** If you do, the medicine will be released into your body too quickly. If this happens you may be more likely to get side effects including seizures. **Tell your healthcare provider if you cannot swallow tablets.**
- Bupropion hydrochloride extended-release tablets (XL) may have an odor. This is normal.
- Take your doses of bupropion hydrochloride extended-release tablets (XL) at least 24 hours apart.
- You may take bupropion hydrochloride extended-release tablets (XL) with or without food.
- If you miss a dose, do not take an extra dose to make up for the dose you missed. Wait and take your next dose at the regular time. **This is very important.** Too much bupropion hydrochloride extended-release tablets (XL) can increase your chance of having a seizure.
- If you take too much bupropion hydrochloride extended-release tablets (XL), or overdose, call your local emergency room or poison control center right away.
- **Do not take any other medicines while taking bupropion hydrochloride extended-release tablets (XL) unless your healthcare provider has told you it is okay.**
- If you are taking bupropion hydrochloride extended-release tablets (XL) for the treatment of major depressive disorder, it may take several weeks for you to feel that bupropion hydrochloride extended-release tablets (XL) are working. Once you feel better, it is important to keep taking bupropion hydrochloride extended-release tablets (XL) exactly as directed by your healthcare provider. Call your healthcare provider if you do not feel bupropion hydrochloride extended-release tablets (XL) are working for you.

What should I avoid while taking Bupropion Hydrochloride Extended-Release Tablets (XL)?

- Limit or avoid using alcohol during treatment with bupropion hydrochloride extended-release tablets (XL). If you usually drink a lot of alcohol, talk with your healthcare provider 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 (XL) affects you. Bupropion hydrochloride extended-release tablets (XL) can affect your ability to do these things safely.

What are possible side effects of Bupropion Hydrochloride Extended-Release Tablets (XL)?

Bupropion hydrochloride extended-release tablets (XL) can cause serious side effects. See the sections at the beginning of this Medication Guide for information about serious side effects of bupropion hydrochloride extended-release tablets (XL).

The most common side effects of bupropion hydrochloride extended-release tablets (XL) include:

- trouble sleeping
- stuffy nose
- dry mouth
- dizziness
- feeling anxious
- nausea
- constipation
- joint aches

If you have trouble sleeping, do not take bupropion hydrochloride extended-release tablets (XL) too close to bedtime.

Tell your healthcare provider right away about any side effects that bother you.

These are not all the possible side effects of bupropion hydrochloride extended-release tablets (XL). For more information, ask your healthcare provider or pharmacist.

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

You may also report side effects to Granules Pharmaceuticals Inc., at 1-877-770-3183.

How should I store Bupropion Hydrochloride Extended-Release Tablets (XL)?

Store bupropion hydrochloride extended-release tablets (XL) at room temperature 77°F (25°C).

Keep bupropion hydrochloride extended-release tablets (XL) and all medicines out of the reach of children.

General information about the safe and effective use of Bupropion Hydrochloride Extended-Release Tablets (XL).

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

If you take a urine drug screening test, bupropion hydrochloride extended-release tablets (XL) may make the test result positive for amphetamines. If you tell the person giving you the drug screening test that you are taking bupropion hydrochloride extended-release tablets (XL), they can do a more specific drug screening test that should not have this problem.

This Medication Guide summarizes important information about bupropion hydrochloride extended-release tablets (XL). If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about bupropion hydrochloride extended-release tablets (XL) that is written for health professionals.

For more information about bupropion hydrochloride extended-release tablets (XL), please contact Granules Pharmaceuticals Inc., at 1-877-770-3183.

What are the ingredients in Bupropion Hydrochloride Extended-Release Tablets (XL)?

Active ingredient: bupropion hydrochloride.

Inactive ingredients: ethyl alcohol, ethylcellulose, glyceryl dibehenate, isopropyl alcohol, methacrylic acid and ethyl acrylate copolymer dispersion, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, triethyl citrate. In addition, tablets are printed with black ink which contains ferrosoferric oxide, hypromellose, isopropyl alcohol and propylene glycol.

Manufactured by:
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Manufactured for:
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Chantilly, VA 20151

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