Medication Guide
APLENZIN (*uh-PLEN-zin*)
(bupropion hydrobromide)
Extended-Release tablets

Read this Medication Guide carefully before you start using APLENZIN and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment. If you have any questions about APLENZIN, ask your healthcare provider 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 APLENZIN?

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 healthcare provider 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, 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 or 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.

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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.

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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 APLENZIN is not a treatment for quitting smoking, it contains a form of the same active ingredient (bupropion hydrobromide) as ZYBAN® which is used to help people 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 healthcare provider about any symptoms you had during other times you tried to quit smoking, with or without bupropion.

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What Other Important Information Should I Know About APLENZIN?

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

The chance of having seizures increases with higher doses of APLENZIN. For more information, see the sections "**Who should not take APLENZIN?**" and "**What should I tell my healthcare provider before using APLENZIN?**" 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 using APLENZIN unless your healthcare provider has said it is okay to take them.**

If you have a seizure while taking APLENZIN, stop taking the tablets and call your healthcare provider right away. Do not take APLENZIN again if you have a seizure.

- **High blood pressure (hypertension): Some people get high blood pressure, that can be severe, while taking APLENZIN.** 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 APLENZIN. Stop taking APLENZIN 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 trouble breathing. These could be signs of a serious allergic reaction.

- **Unusual thoughts or behaviors:** Some people may have unusual thoughts or behaviors while taking APLENZIN, 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.

- **Manic episodes:** Some people may have periods of mania while taking APLENZIN, 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.

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What is APLENZIN?

APLENZIN is a prescription medicine used to treat people 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 APLENZIN?

Do not take APLENZIN if you:

- have or had a seizure disorder or epilepsy
- have or had an eating disorder such as anorexia nervosa or bulimia
- 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)
- are allergic to the active ingredient in APLENZIN, bupropion hydrobromide, or to any of the inactive ingredients. See the end of this leaflet for a complete list of ingredients in APLENZIN.

What should I tell my healthcare provider before using APLENZIN?

- Tell your healthcare provider if you have ever had depression, suicidal thoughts or actions, or other mental health problems. See “Antidepressant Medicines, Depression, and Other Mental Illnesses, and Suicidal Thoughts or Actions.”
- **Tell your healthcare provider about your other medical conditions including if you:**
  - **are pregnant or plan to become pregnant.** It is not known if APLENZIN can harm your unborn baby.
  - **are breastfeeding.** APLENZIN passes through your milk. It is not known if APLENZIN 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 healthcare provider 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 cause other serious side effects if you take them while you are using APLENZIN.

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If you take APLENZIN, you should not take any other medicines that contain bupropion including:

- **ZYBAN®, WELLBUTRIN® Tablets**
- **WELLBUTRIN® SR Sustained-Release Tablets**
- **WELLBUTRIN XL® Extended-Release Tablets.**

Bupropion is the same active ingredient that is in APLENZIN.

How should I take APLENZIN?

- Take APLENZIN exactly as prescribed by your healthcare provider.
- **Do not chew, cut, or crush APLENZIN tablets.** 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. You must swallow the tablets whole. **Tell your healthcare provider if you cannot swallow medicine tablets**.
- Take APLENZIN in the morning.
- You may take APLENZIN 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 APLENZIN can increase your chance of having a seizure.
- If you take too much APLENZIN, or overdose, call your local emergency room or poison control center right away.
- The APLENZIN 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 APLENZIN unless your healthcare provider has told you it is okay.**
- If you are taking APLENZIN for the treatment of major depressive disorder, it may take several weeks for you to feel that APLENZIN is working. Once you feel better, it is important to keep taking APLENZIN exactly as directed by your healthcare provider. Call your healthcare provider if you do not feel APLENZIN is working for you.
- If you are taking APLENZIN for the prevention of seasonal major depressive episodes associated with seasonal affective disorder, it is important to keep taking APLENZIN through the autumn-winter season, or as directed by your healthcare provider.
- Do not change your dose or stop taking APLENZIN without first talking with your healthcare provider first.

What should I avoid while taking APLENZIN?

- Do not drink alcohol while using APLENZIN. 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 APLENZIN affects you. APLENZIN can impair your ability to perform these tasks.

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What are the possible side effects of APLENZIN?

See "**What is the most important information I should know about APLENZIN?**"

APLENZIN may cause serious side effects, including:

The most common side effects of APLENZIN include:

- dry mouth
- nausea
- trouble sleeping
- dizziness
- sore throat
- stomach pain
- agitation
- anxiety
- shakiness
- fast heartbeat
- sweating
- ringing in the ears
- muscle pain
- anorexia
- urinating more often than normal for you
- rash

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

These are not all the possible side effects of APLENZIN. 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 Valeant Pharmaceuticals North America LLC at 1-877-361-2719.

How should I store APLENZIN?

Store APLENZIN at room temperature between 59°F and 86°F (15°C to 30°C).

Keep APLENZIN and all medicines out of the reach of children.

General information about APLENZIN

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

- If you take a urine drug screening test, APLENZIN may make the test result positive for amphetamines. If you tell the person giving you the drug screening test that you are taking APLENZIN, they can do a more specific drug screening test that should not have this problem.

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This Medication Guide summarizes the most important information about APLENZIN. If you would like more information, talk with your healthcare provider. You may ask your healthcare provider or pharmacist for information about APLENZIN that is written for healthcare professionals.

For more information about APLENZIN, go to www.APLENZIN.com or call **1-800-633-1610**.

What are the ingredients in APLENZIN?

Active ingredient: bupropion hydrobromide

Inactive ingredients: ethylcellulose, glyceryl behenate, polyvinyl alcohol, polyethylene glycol, povidone, and dibutyl sebacate. Carnauba wax is included in the 174 mg and 348 mg strengths. The tablets are printed with edible black ink.

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