

Medication Guide

APLENZIN (*uh-PLÉN-zin*)
(bupropion hydrobromide)
extended-release tablets

Rx Only

Read this Medication Guide for APLENZIN before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or treatment. Talk with your healthcare provider if there is something you do not understand or want to learn more about.

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

APLENZIN and other antidepressant medicines may cause serious side effects, including:

1. Suicidal thoughts or actions:

- **APLENZIN and other antidepressant medicines may increase suicidal thoughts or actions** in some children, teenagers, or young adults within the **first few months of treatment or when the dose is changed**.
- Depression or other serious mental illnesses are the most important causes of suicidal thoughts or actions.
- Watch for these changes and call your healthcare provider right away if you notice:
 - New or sudden changes in mood, behavior, actions, thoughts, or feelings, especially if severe.
 - Pay particular attention to such changes when APLENZIN is started or when the dose is changed.

Keep all follow-up visits with your healthcare provider and call between visits if you are worried about symptoms.

Call your healthcare provider right away if you have any of the following symptoms, or call 911 if an emergency, especially if they are new, worse, or worry you:

- attempts to commit suicide
- acting on dangerous impulses
- acting aggressive or violent
- thoughts about suicide or dying
- new or worse depression
- new or worse anxiety or panic attacks
- feeling agitated, restless, angry or irritable
- trouble sleeping
- an increase in activity or talking more than what is normal for you
- other unusual changes in behavior or mood

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

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

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.

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.

Stop taking bupropion and call your healthcare provider right away or call 911 if an emergency, 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:

- 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.

3. 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 experienced 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.

4. Hypertension (high blood pressure). Some patients may get high blood pressure, sometimes severe, while taking Aplenzin. 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.

5. Severe allergic reactions. Stop taking Aplenzin and call your healthcare provider right away if you have any of the following reactions:

- chest pain
- trouble breathing
- swelling of the face, tongue, eyes or mouth or swollen lymph glands
- rash, itchy welts (hives) or blisters, alone or with fever or joint pain

6. Unusual thoughts or behaviors. Some patients 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.

7. Manic episodes:

- greatly increased energy
- severe trouble sleeping
- racing thoughts
- reckless behavior
- unusually grand ideas

- excessive happiness or irritability
- talking more or faster than usual

What is APLENZIN?

APLENZIN is a prescription medicine used to treat depression. It is important to talk with your healthcare provider about the risks of treating depression and also the risks of not treating it. You should discuss all treatment choices with your healthcare provider. Talk to your healthcare provider if you do not think that your condition is getting better with APLENZIN treatment.

Who should not take APLENZIN?

Do not take APLENZIN if you:

- have or had a seizure disorder or epilepsy.
- 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).
- have or had an eating disorder such as anorexia nervosa or bulimia.
- 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 taking APLENZIN? Ask if you are not sure.

Before starting APLENZIN, tell your healthcare provider if you:

- have ever had depression, suicidal thoughts or actions, or other mental health problems. See section "**Antidepressant Medicines, Depression, and Other Mental Illnesses, and Suicidal Thoughts or Actions.**"
- **Tell your healthcare provider about your medical conditions.** Tell your healthcare provider 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 that you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. APLENZIN and some medicines may interact with each other, may not work as well, may increase your chances of having seizures or cause other serious side effects.

Your healthcare provider or pharmacist can tell you if it is safe to take APLENZIN with your other medicines. Do not start or stop any medicine while taking APLENZIN without first talking to your healthcare provider.

If you take APLENZIN, you should not take any other medicines that contain (bupropion) including: (i.e., **ZYBAN®**, **WELLBUTRIN®** Tablets, **WELLBUTRIN® SR Sustained-Release Tablets**, or **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. Your healthcare provider may need to change the dose of APLENZIN until it is the right dose for you.
- **Do not chew, cut, or crush Aplenzin tablets.** You must swallow the tablets whole. **Tell your healthcare provider if you cannot swallow medicine tablets.**
- Take Aplenzin at the same time each day.
- Take your doses of Aplenzin at least 24 hours apart.
- APLENZIN may be taken 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.
- Do not change your dose or stop taking Aplenzin without first talking with your healthcare provider.

What should I avoid while taking APLENZIN?

APLENZIN can cause sleepiness or may affect your ability to make decisions, think clearly, or react quickly. You should not drive, operate heavy machinery, or do other dangerous activities until you know how APLENZIN affects you. Do not drink alcohol while using APLENZIN.

What are the possible side effects of APLENZIN?

APLENZIN may cause serious side effects, including all of those described in the section entitled "What is the most important information I should know about APLENZIN?"

Common possible side effects in people who take APLENZIN include:

- weight loss
- loss of appetite
- stomach pain
- nausea. If you have nausea take your medicine with food.
- feeling anxious or trouble sleeping. If you have trouble sleeping, do not take your medicine too close to bedtime.
- dry mouth
- skin rash
- sweating
- ringing in the ears
- shakiness
- agitation
- dizziness
- muscle pain
- fast heartbeat
- urinating more often

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. 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 THE 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 away from direct sunlight.
- Keep APLENZIN bottle closed tightly.

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 condition. 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.

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 call **1-800-633-1610** or go to www.APLENZIN.com.

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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Valeant Pharmaceuticals International, Inc.
Steinbach, MB
Canada R5G 1Z7

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sanofi-aventis U.S. LLC
Bridgewater, NJ 08807
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