

17.2 FDA-Approved Patient Labeling (Medication Guide)

MEDICATION GUIDE

APLENZIN (*phonetic transcription*) (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 with your doctor about your medical condition or your treatment. If you have any questions about APLENZIN, 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 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, 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:

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| • thoughts about suicide or dying | • trouble sleeping (insomnia) |
| • attempts to commit suicide | • new or worse irritability |
| • new or worse depression | • acting aggressive, being angry, or violent |
| • new or worse anxiety | • acting on dangerous impulses |
| • feeling very agitated or restless | • an extreme increase in activity and talking (mania) |
| • panic attacks | • other unusual changes in behavior or mood |
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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.

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

WHAT OTHER IMPORTANT INFORMATION SHOULD I KNOW ABOUT APLENZIN?

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 doctor before using APLENZIN?" 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 APLENZIN unless your doctor has said it is okay to take them.**

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

What is APLENZIN?

APLENZIN is a prescription medicine used to treat adults with a certain type of depression called major depressive disorder.

Who should not take APLENZIN?

Do not take APLENZIN 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, such as WELLBUTRIN[®] Tablets, or WELLBUTRIN SR[®] Sustained-Release Tablets, or WELLBUTRIN XL[®] Extended-Release Tablets.** Bupropion is the same active ingredient that is in APLENZIN.
- 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 APLENZIN, bupropion, 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 doctor before using APLENZIN?

- **Tell your doctor about your medical conditions.** Tell your doctor 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 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 APLENZIN.

How should I take APLENZIN?

- Take APLENZIN exactly as prescribed by your doctor.
- **Do not chew, cut, or crush APLENZIN tablets.** You must swallow the tablets whole. **Tell your doctor if you cannot swallow medicine tablets.**
- Take APLENZIN at the same time each day.
- Take your doses of APLENZIN at least 24 hours apart.

- 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 doctor 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 doctor. Call your doctor if you do not feel APLENZIN is working for you.
- Do not change your dose or stop taking APLENZIN without talking with your doctor first.

What should I avoid while taking APLENZIN?

- Do not drink a lot of alcohol while taking APLENZIN. 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 APLENZIN affects you. APLENZIN can impair your ability to perform these tasks.

What are possible side effects of APLENZIN?

- **Seizures.** Some patients may get seizures while taking APLENZIN. **If you have a seizure while taking APLENZIN, stop taking the tablets and call your doctor right away.** Do not take APLENZIN again if you have a seizure.
- **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.
- **Severe allergic reactions. Stop taking APLENZIN 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 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 doctor.

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 more often.

If you have nausea, take your medicine with food. If you have trouble 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 APLENZIN. For a complete list, ask your doctor or pharmacist.

How should I store APLENZIN?

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

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. Keep APLENZIN out of the reach of children.

This Medication Guide summarizes important information about APLENZIN. For more information, talk with your doctor. You can ask your doctor or pharmacist for information about APLENZIN that is written for health professionals or you can call toll-free [866-246-8245 (opt. 3)].

What are the ingredients in APLENZIN?

Active ingredient: bupropion hydrobromide.

Inactive ingredients: ethylcellulose aqueous dispersion, 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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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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