

MEDICATION GUIDE

FORFIVO XL

Fore fye' voe Eks el

(bupropion hydrochloride extended-release tablets)

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

It is not known if FORFIVO XL is safe and effective in children.

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 FORFIVO XL is not a treatment for quitting smoking, it contains the same active ingredient (bupropion hydrochloride) as ZYBAN® which is used to help patients 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.

WHAT OTHER IMPORTANT INFORMATION SHOULD I KNOW ABOUT FORFIVO XL?

- **Activation of mania/hypomania:** Depression may be the early symptom of bipolar disorder. Using FORFIVO XL can trigger mania/hypomania if you have bipolar disorder. Tell your healthcare provider all of your symptoms, and if you or a family member has ever had depression, suicidal thoughts or actions, bipolar disorder or other mental health problems. Your healthcare provider may check you for bipolar disorder.
- **Seizures: There is a chance of having a seizure (convulsion, fit) with FORFIVO XL, especially in people:**
 - with certain medical problems.
 - who take certain medicines.

For more information, see the sections “Who should not take FORFIVO XL?” and “What should I tell my healthcare provider before using FORFIVO 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 using FORFIVO XL unless your healthcare provider has said it is okay to take them.**

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

- **High blood pressure (hypertension): Some people get high blood pressure that can be severe, while taking FORFIVO 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.
- **Severe allergic reactions: Some people have severe allergic reactions to FORFIVO XL. Stop taking FORFIVO 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.

- **Unusual thoughts or behaviors:** Some patients have unusual thoughts or behaviors while taking FORFIVO 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.

What is FORFIVO XL?

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

Who should not take FORFIVO XL?

Do not take FORFIVO XL 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 or APLENZIN EXTENDED-RELEASE TABLETS.** Bupropion is the same active ingredient that is in FORFIVO XL.
- 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 FORFIVO XL, bupropion, or to any of the inactive ingredients. See the end of this leaflet for a complete list of ingredients in FORFIVO XL.

What should I tell my healthcare provider before using FORFIVO XL?

- 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 Serious Mental Illnesses, and Suicidal Thoughts or Actions."

- **Tell your healthcare provider about your other medical conditions.**
Tell your healthcare provider if you:
 - **are pregnant or plan to become pregnant.** It is not known if FORFIVO XL can harm your unborn baby.
 - **are breastfeeding.** FORFIVO XL passes through your milk. It is not known if FORFIVO XL 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 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 other serious side effects if you take them while you are using FORFIVO XL.

How should I take FORFIVO XL?

- Take FORFIVO XL exactly as prescribed by your doctor.
- **Do not chew, cut, or crush FORFIVO XL 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.**
- You may take FORFIVO XL with or without food.
- If you take too much FORFIVO XL, or overdose, call your healthcare provider or go to the nearest hospital emergency room right away.
- **Do not take any other medicines while using FORFIVO XL unless your healthcare provider has told you it is okay.**
- If you are taking FORFIVO XL for the treatment of major depressive disorder, it may take several weeks for you to feel that FORFIVO XL is working. Once you feel better, it is important to keep taking FORFIVO XL exactly as directed by your doctor. Call your healthcare provider if you do not feel FORFIVO XL is working for you.
- Do not change your dose or stop taking FORFIVO XL without talking with your healthcare provider first.

What should I avoid while taking FORFIVO XL?

- Do not drink alcohol while taking FORFIVO XL.
- Do not drive a car or use heavy machinery until you know how FORFIVO XL affects you. FORFIVO XL can impair your ability to perform these tasks.

What are possible side effects of FORFIVO XL?

FORFIVO XL can cause serious side effects, including:

- See “What is the most important information I should know about FORFIVO XL?”

The most common side effects of FORFIVO XL include:

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

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

These are not all the side effects of FORFIVO XL. For a complete list, ask your healthcare provider or pharmacist.

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

How should I store FORFIVO XL?

- Store FORFIVO XL between 68 °F to 77 °F (20 °C to 25 °C).

Keep FORFIVO XL and all medicines out of the reach of children.

General Information about FORFIVO XL.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use FORFIVO XL for a condition for which it was not

prescribed. Do not give FORFIVO 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, FORFIVO XL may make the test result positive for amphetamines. If you tell the person giving you the drug screening test that you are taking FORFIVO XL, they can do a more specific drug screening test that should not have this problem.

This Medication Guide summarizes important information about FORFIVO XL. For more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about FORFIVO XL that is written for health professionals.

For more information, call 1-888-594-4332.

What are the ingredients in FORFIVO XL?

Active ingredient: bupropion hydrochloride.

Inactive ingredients: hydroxypropyl cellulose, hydrochloric acid, polyvinyl pyrrolidone and polyvinyl acetate blend, polyethylene oxide, stearic acid, colloidal silicon dioxide, magnesium stearate, hydroxypropylmethyl cellulose, triacetin, talc, methacrylic acid copolymer, polyethylene glycol 8000, titanium dioxide and carboxymethyl cellulose sodium. The tablets are printed with edible black ink.

The following are registered trademarks of their respective manufacturers: WELLBUTRIN[®] and WELLBUTRIN XL[®]/GlaxoSmithKline; ZYBAN[®]/GlaxoSmithKline; PARNATE[®]/GlaxoSmithKline; NARDIL[®]/Warner Lambert Company; MARPLAN[®]/Validus Pharmaceuticals LLC; KALETRA[®]/Abbott Laboratories.

Rx only

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Manufactured by:
Pillar5 Pharma Inc.
Arnprior, Ontario, K7S 0C9
Canada

For:

**Edgemont Pharmaceuticals, LLC
Austin, TX 78746**

Revised June 2014
FFO_V3