

MEDICATION GUIDE
FORFIVO XL (Fore-fyel-voe Eks el)
(bupropion hydrochloride extended-release)Tablets

IMPORTANT: Be sure to read the three sections of this Medication Guide. The first section is about the risk of changes in thinking and behavior, depression and suicidal thoughts or actions with medicines used to quit smoking; the second section is about the risk of suicidal thoughts and actions with antidepressant medicines; 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.

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 FORFIVO XL is 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 FORFIVO XL is not a treatment for quitting smoking, it contains the same active ingredient (bupropion) 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 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 FORFIVO 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 FORFIVO XL. In many people, these symptoms went away after stopping bupropion, but in some people symptoms continued after stopping bupropion. It is important for you to follow-up with your healthcare provider until your symptoms go away. **Before taking FORFIVO 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 FORFIVO XL?

- **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.

The chance of having seizures increases with higher doses of FORFIVO XL. For more information, see the sections "Who should not take FORFIVO XL?" and "What should I tell my healthcare provider before taking 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 taking 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 (see the section of this Medication Guide called “How should I take FORFIVO XL?”).

- **Manic episodes.** Some people may have periods of mania while taking FORFIVO 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 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.

- **Severe allergic reactions. Some people can 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.

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.
- have or had an eating disorder such as anorexia nervosa or bulimia.
- **are taking any other medicines that contain bupropion, including WELLBUTRIN, WELLBUTRIN SR, WELLBUTRIN XL, ZYBAN, or APLENZIN®.** Bupropion is the same active ingredient that is in FORFIVO XL.
- 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 FORFIVO XL unless directed to do so by your healthcare provider.**
 - **do not start FORFIVO 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 FORFIVO XL, bupropion, or to any of the inactive ingredients. See the end of this Medication Guide for a complete list of ingredients in FORFIVO XL.

What should I tell my healthcare provider before taking FORFIVO 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. 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.
- are breastfeeding. FORFIVO XL passes into your milk in small amounts

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 FORFIVO XL.

How should I take FORFIVO XL?

- Take FORFIVO XL exactly as prescribed by your healthcare provider. Do not change your dose or stop taking FORFIVO XL without talking with your healthcare provider first.
- **Swallow FORFIVO XL tablets whole. 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. **Tell your healthcare provider if you cannot swallow tablets.**
- You may take FORFIVO 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 FORFIVO XL can increase your chance of having a seizure.
- If you take too much FORFIVO XL, or overdose, call your local emergency room or poison control center right away.

Do not take any other medicines while taking FORFIVO XL unless your healthcare provider has told you it is okay.

What should I avoid while taking FORFIVO XL?

- Avoid using alcohol during treatment with FORFIVO XL.
- Do not drive a car or use heavy machinery until you know how FORFIVO XL affects you. FORFIVO XL can affect your ability to do these things safely.

What are possible side effects of FORFIVO XL?

FORFIVO XL can cause serious side effects. See the sections at the beginning of this Medication Guide for information about serious side effects of FORFIVO XL.

The most common side effects of FORFIVO XL include:

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

If you have nausea, take FORFIVO XL with food.

If you have trouble sleeping, do not take FORFIVO 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 FORFIVO 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.

How should I store FORFIVO XL?

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

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

General information about the safe and effective use of 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. If you would like 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 about FORFIVO XL, go to www.forfivoxl.com or call 1-877-447-7979.

What are the ingredients in FORFIVO XL?

Active ingredient: bupropion hydrochloride

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

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