

MEDICATION GUIDE

VIIBRYD [*vi-brid*] (vilazodone hydrochloride) **Tablets**

Read this Medication Guide carefully before you start taking VIIBRYD 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.

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

VIIBRYD and other antidepressant medicines may cause serious side effects.

Call your healthcare provider right away if you have any of the following symptoms, or call 911 if there is an emergency:

1. Suicidal thoughts or actions:

- **VIIBRYD 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 VIIBRYD 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, 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 (mania)
- other unusual changes in behavior or mood

2. Serotonin Syndrome or Neuroleptic Malignant Syndrome-like reactions:

- agitation, hallucinations, coma or other changes in mental status
- coordination problems or muscle twitching (overactive reflexes)
- fast heartbeat, high or low blood pressure
- sweating or fever
- nausea, vomiting, or diarrhea
- muscle stiffness or tightness

3. Abnormal bleeding: VIIBRYD and other antidepressant medicines may increase your risk of bleeding or bruising, especially if you take the blood thinner warfarin (Coumadin[®], Jantoven[®]), a non-steroidal anti-inflammatory drug (NSAID), or aspirin.

4. Seizures or convulsions.

5. 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

6. Low salt (sodium) levels in the blood.

Elderly people may be at greater risk for this. Symptoms may include:

- headache
- weakness or feeling unsteady
- confusion, problems concentrating or thinking or memory problems

Do not stop VIIBRYD without first talking to your healthcare provider.

Stopping VIIBRYD suddenly may cause serious symptoms including:

- anxiety, irritability, high or low mood, feeling restless or sleepy
- headache, sweating, nausea, dizziness
- electric shock-like sensations, tremor, confusion

What is VIIBRYD?

VIIBRYD is a prescription medicine used to treat a certain type of depression called Major Depressive Disorder (MDD). It is important to talk with your healthcare provider about the risks of treating depression and also the risk 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 VIIBRYD treatment.

It is not known if VIIBRYD is safe and effective in children.

Who should not take VIIBRYD?

Do not take VIIBRYD if you:

- Take an Monoamine Oxidase Inhibitor (MAOI). Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI.
 - Do not take an MAOI within 14 days of stopping VIIBRYD.
 - Do not start VIIBRYD if you stopped taking an MAOI in the last 14 days.

People who take VIIBRYD close in time to taking an MAOI may have serious or even life-threatening side effects. Get medical help right away if you have any of these symptoms:

- high fever

- uncontrolled muscle spasms
- stiff muscles
- rapid changes in heart rate or blood pressure
- confusion
- loss of consciousness (pass out)

What should I tell my healthcare provider before taking VIIBRYD?

Before starting VIIBRYD, tell your healthcare provider if you:

- have liver problems
- have kidney problems
- have or had seizures or convulsions
- have bipolar disorder (manic depression) or mania
- have low sodium levels in your blood
- have or had bleeding problems
- drink alcohol
- have any other medical conditions
- Are pregnant or plan to become pregnant. It is not known if VIIBRYD will harm your unborn baby. Talk to your healthcare provider about the benefits and risks of treating depression during pregnancy.
- Are breastfeeding or plan to breastfeed. It is not known if VIIBRYD passes into breast milk. You and your healthcare provider should decide if you should take VIIBRYD while breastfeeding.

Tell your healthcare provider about all the medicines that you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. VIIBRYD and some medicines may interact with each other, may not work as well, or may cause serious side effects when taken together.

Especially tell your healthcare provider if you take:

- triptans used to treat migraine headache
- medicines used to treat mood, anxiety, psychotic or thought disorders, including tricyclics, lithium, SSRIs, SNRIs, buspirone, or antipsychotics
- tramadol

- over-the-counter supplements such as tryptophan or St. John's Wort
- nonsteroidal anti-inflammatory drugs (NSAIDs)
- aspirin
- warfarin (Coumadin, Jantoven)
- mephenytoin (Mesantoin)
- diuretics

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

How should I take VIIBRYD?

- Take VIIBRYD exactly as prescribed. Your healthcare provider may need to change the dose of VIIBRYD until it is the right dose for you.
- **Take VIIBRYD with food.** VIIBRYD may not work as well if you take it on an empty stomach.
- If you miss a dose of VIIBRYD, take the missed dose as soon as you remember. If it is almost time for the next dose, skip the missed dose and take your next dose at the regular time. Do not take two doses of VIIBRYD at the same.
- If you take too much VIIBRYD, call your healthcare provider or poison control center right away, or get emergency treatment.

What should I avoid while taking VIIBRYD?

- VIIBRYD 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 VIIBRYD affects you.
- You should avoid drinking alcohol while taking VIIBRYD. See "What should I tell my healthcare provider before taking VIIBRYD?"

What are the possible side effects of VIIBRYD?

VIIBRYD may cause serious side effects, including:

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

Common side effects in people who take VIIBRYD include:

- diarrhea
- nausea or vomiting
- trouble sleeping

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 VIIBRYD. 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 VIIBRYD?

Store VIIBRYD at room temperature (59°F to 86°F or 15°C to 30°C).

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

General information about VIIBRYD.

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

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

For more information about VIIBRYD call 1-800-678-1605.

What are the ingredients in VIIBRYD?

Active ingredient: vilazodone hydrochloride
Inactive ingredients: lactose monohydrate, microcrystalline cellulose, magnesium stearate, colloidal silicon dioxide, polyvinyl

alcohol, titanium dioxide, polyethylene glycol, talc, and FD&C Blue #1 (40 mg only), FD&C Yellow #6 (20 mg only) and FD&C Red #40 (10 mg only).

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

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