

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **VIIBRYD**®

vilazodone hydrochloride tablets

Read this carefully before you start taking **VIIBRYD** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **VIIBRYD**.

Serious Warnings and Precautions

New and worsened emotional or behaviour problems:

- When you first start taking VIIBRYD or when your dose is adjusted, you may feel worse instead of better. You may feel new or worsened feelings of agitation, hostility, anxiety or impulsivity.
- During your treatment with VIIBRYD, it is important that you and your healthcare professional talk regularly about how you are feeling. They will closely monitor you for signs of new or worsened emotions or behaviours while you are taking VIIBRYD.
- You may find it helpful to tell a relative or close friend that you are depressed. Ask them to read this leaflet. You might ask them to tell you if they:
 - think your depression is getting worse, or
 - are worried about changes in your behaviour.
- If your depression worsens or you experience changes in your behaviour, tell your healthcare professional right away. Do not stop taking your medicine as it takes time for VIIBRYD to work.

Self-harm or suicide:

- Antidepressants, such as VIIBRYD, can increase the risk of suicidal thoughts and actions.
- If you have thoughts of harming or killing yourself at any time, tell your healthcare professional or go to a hospital right away. Close observation by a healthcare professional is necessary in this situation.

What is VIIBRYD used for?

VIIBRYD is used in adults to relieve symptoms of depression, which may include:

- feeling sad
- loss of interest in usual activities
- significant change in weight or appetite
- change in sleeping habits
- having a hard time concentrating
- feeling tired
- having suicidal thoughts

How does VIIBRYD work?

VIIBRYD is an antidepressant medication. It is thought to work by increasing the activity of serotonin in your brain. Serotonin is a brain chemical that helps to improve mood. It works at two different receptors in the brain.

What are the ingredients in VIIBRYD?

Medicinal ingredients: vilazodone hydrochloride

Non-medicinal ingredients: colloidal silicon dioxide, FD&C Blue #1 (40 mg only), FD&C Yellow #6 (20 mg only), FD&C Red #40 (10 mg only), lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc, and titanium dioxide.

VIIBRYD comes in the following dosage forms:

Tablets; 10 mg (pink), 20 mg (orange), 40 mg (blue)

Do not use VIIBRYD if:

- you are allergic to vilazodone or to any of the other ingredients in VIIBRYD.
- you take or have recently taken (in the last 14 days) medicines called Monoamine Oxidase Inhibitors (MAOIs).
 - Ask your healthcare professional or pharmacist if you are not sure if you take a MAOI.
 - Examples of MAOIs include linezolid which is an antibiotic, methylene blue which is a dye used in certain surgeries.
 - If you stopped taking a MAOI within the last 14 days, only start VIIBRYD if your healthcare professional tells you to.
 - Do not take a MAOI within 14 days of stopping VIIBRYD unless directed to do so by your healthcare professional.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take VIIBRYD. Talk about any health conditions or problems you may have, including if you:

- have high blood pressure that is not controlled by your medication or any heart problems
- have a history of drug abuse
- have a bleeding disorder
- take certain medicines which may affect blood clotting and increase bleeding, such as oral anticoagulants (e.g., warfarin, dabigatran), acetylsalicylic acid and other non-steroidal anti-inflammatory drugs (e.g., ibuprofen)
- have or had seizures or convulsions
- have glaucoma or increased pressure in your eyes
- have suicidal thoughts
- have a family history of mania or bipolar disorder

- are pregnant or plan to become pregnant. It is not known if VIIBRYD will harm your unborn baby. Talk to your healthcare professional 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 professional should decide if you should take VIIBRYD while breastfeeding.
- have any other medical conditions

Other warnings you should know about:

It is important to talk to your healthcare professional about the risks of treating depression and also the risk of not treating it. You should discuss all treatment options with your healthcare professional.

Effects on pregnancy and newborns: If you are pregnant or are planning to become pregnant while taking VIIBRYD, talk to your healthcare professional about the risks and benefits of various treatment options. It is very important that you keep taking VIIBRYD until your healthcare professional tells you to stop.

When pregnant women took medicines in the same group of medications as VIIBRYD, some newborn babies had complications at birth. This happened especially when the medication was taken in the last three months of pregnancy. Some newborns:

- required breathing support, tube feeding and a longer stay in the hospital
- had difficulty feeding or breathing, seizures, tense or overly relaxed muscles and were jittery and cried constantly
- had a serious condition called persistent pulmonary hypertension. This made the babies breathe faster and appear blue in color.

These symptoms normally go away over time. However, if your baby experiences any of these symptoms, consult your healthcare professional as soon as possible.

Effects on Sexual Function: Taking medicines like VIIBRYD may cause symptoms of sexual dysfunction. In some cases these symptoms have continued after stopping VIIBRYD treatment. Talk to your healthcare professional if you experience symptoms such as a decrease in sexual desire, performance or satisfaction.

Risk of breaking a bone: You should tell your healthcare professional if you:

- are elderly and had a recent bone fracture or
- were told you have osteoporosis or risk factors for osteoporosis.

Taking VIIBRYD may increase your risk of breaking a bone if you are elderly or have osteoporosis or have other major risk factors for breaking a bone. This is especially true when you first start taking VIIBRYD and soon after you stop taking it. Take extra care to avoid falling, especially if you get dizzy or have low blood pressure.

Discontinuation Symptoms: If your healthcare professional recommends that you stop taking VIIBRYD, they will gradually lower the dose of VIIBRYD you are taking. This may help manage any symptoms of discontinuation, such as:

- dizziness, headache, ringing in the ears, seizures
- nausea, diarrhea, vomiting
- tingling, burning, or prickling sensation of your skin, excessive sweating

- feeling nervous, confused, irritated, restless, or having an unstable mood
- fatigue, insomnia (inability to sleep), nightmares

These symptoms will usually disappear without needing treatment. Tell your healthcare professional immediately if you have these or any other symptoms. Your healthcare professional may adjust the dosage of VIIBRYD to alleviate the symptoms.

Serotonin toxicity (also known as Serotonin syndrome): VIIBRYD can cause Serotonin toxicity, a rare but potentially life-threatening condition. It can cause serious changes in how your brain, muscles and digestive system work. You may develop Serotonin toxicity if you take VIIBRYD with certain anti-depressants or migraine medications.

Serotonin toxicity symptoms include:

- fever, sweating, shivering, diarrhea, nausea, vomiting;
- muscle shakes, jerks, twitches or stiffness, overactive reflexes, loss of coordination;
- fast heartbeat, changes in blood pressure;
- confusion, agitation, restlessness, hallucinations, mood changes, unconsciousness, and coma.

Driving and Using Machines: VIIBRYD can make you feel sleepy or may affect your ability to think clearly, make decisions or react quickly. Wait until you know how you feel after you have taken VIIBRYD before you drive or use heavy machines.

Angle-closure Glaucoma: VIIBRYD can cause an acute attack of glaucoma. Having your eyes examined before you take VIIBRYD could help identify if you are at risk of having angle-closure glaucoma. Seek immediate medical attention if you experience:

- eye pain
- changes in vision
- swelling or redness in or around the eye

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious Drug Interactions

Do not take VIIBRYD if you:

- are taking or have recently taken (in the last 14 days) any MAOIs such as phenelzine, tranylcypromine, linezolid, methylene blue as you may have serious side effects.

The following may also interact with VIIBRYD:

- other antidepressants
- other medicines that affect serotonin such as lithium, sibutramine, tryptophan, triptans, St. John's Wort
- certain medicines which may affect blood clotting and increase bleeding, such as oral anticoagulants (e.g., warfarin, dabigatran), acetylsalicylic acid and other non-steroidal anti-inflammatory drugs (e.g., ibuprofen)
- certain medicines used to treat pain, such as fentanyl (used in anaesthesia or to treat chronic pain), tramadol, tapentadol, meperidine, methadone, pentazocine
- certain medicines used to treat cough, such as dextromethorphan

- when taking certain medicines such as antifungals (e.g., ketoconazole); antibiotics (e.g., erythromycin) or medicines used to treat seizures (e.g., carbamazepine, mephenytoin). Your healthcare professional may adjust your dose of VIIBRYD when taking these medicines.
- digoxin, used to treat various heart conditions
- diuretics (also known as “water pills”)

You should avoid drinking alcohol while taking VIIBRYD.

How to take VIIBRYD:

It is important to take VIIBRYD exactly as your healthcare professional has told you. Your healthcare professional may need to change the dose until it is right for you.

- Always take VIIBRYD with food. VIIBRYD may not work as well if you take it on an empty stomach.
- Even if you feel better, do not stop taking VIIBRYD without talking to your healthcare professional.
- It is important to keep taking VIIBRYD as recommended by your healthcare professional.

Usual dose:

The usual adult dose is 20 mg to 40 mg once a day:

- For the first 7 days, the dose is one 10 mg tablet once a day.
- After 7 days, you will take a 20 mg tablet once a day.
- If you are still not feeling better, your healthcare professional may increase your dose to a 40 mg tablet taken once a day.

Overdose:

If you think you, or a person you are caring for, have taken too much VIIBRYD, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

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 time.

What are possible side effects from using VIIBRYD?

These are not all the possible side effects you may have when taking VIIBRYD. If you experience any side effects not listed here, tell your healthcare professional.

Common side effects in people who take VIIBRYD include:

- diarrhea
- nausea or vomiting
- trouble sleeping

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON			
Mania/Hypomania: elevated or irritated mood, decreased need for sleep, racing thoughts		✓	
Seizures: loss of consciousness with uncontrollable shaking			✓
RARE			
Serotonin toxicity (also known as serotonin syndrome): a reaction which may cause feelings of agitation or restlessness, flushing, muscle twitching, involuntary eye movements, heavy sweating, high body temperature (> 38°C), or rigid muscles			✓
Angle-closure glaucoma: eye pain, changes in vision, and swelling or redness in or around the eye.			✓
Glaucoma: increased pressure in the eyes, eye pain and blurred vision		✓	
Low sodium level in blood: symptoms of tiredness, weakness, confusion, combined with achy, stiff or uncoordinated muscles		✓	
UNKNOWN FREQUENCY			
Allergic reaction: red skin, hives, itching, swelling of the lips, face, tongue or throat, trouble breathing, wheezing, shortness of breath, skin rashes, blisters of the skin, sores or pain in the mouth or eyes			✓
Low platelets: bruising or unusual bleeding from the skin or other areas		✓	
New or worsened emotional or behavioural problems: feeling angry, aggressive, worried, agitated, hostile or impulsive. Feeling violent or suicidal. Thoughts of hurting yourself or other people. Feeling like you are not yourself or that you are less inhibited			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Swelling of the pancreas: symptoms include pain in your upper abdomen that may extend to your back, nausea and vomiting, fever, increased heart rate and loss of appetite			✓
Sleep paralysis: temporary inability to move or talk for up to several minutes while you are going to sleep or waking up		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store VIIBRYD at room temperature (15 - 30°C).
- Keep out of reach and sight of children.

If you want more information about VIIBRYD:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.abbvie.ca, or by calling 1-888-704-8271.

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