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## Vilazodone

pronounced as (vil az' oh done)

### IMPORTANT WARNING:

A small number of children, teenagers, and young adults (up to 24 years of age) who took antidepressants ('mood elevators') such as vilazodone during clinical studies became suicidal (thinking about harming or killing oneself or planning or trying to do so). Children, teenagers, and young adults who take antidepressants to treat depression or other mental illnesses may be more likely to become suicidal than children, teenagers, and young adults who do not take antidepressants to treat these conditions. However, experts are not sure about how great this risk is and how much it should be considered in deciding whether a child or teenager should take an antidepressant. Children younger than 18 years of age should not normally take vilazodone, but in some cases, a doctor may decide that vilazodone is the best medication to treat a child's condition.

You should know that your mental health may change in unexpected ways when you take vilazodone or other antidepressants, even if you are an adult over 24 years of age. You may become suicidal, especially at the beginning of your treatment and any time that your dose is increased or decreased. You, your family, or your caregiver should call your doctor right away if you experience any of the following symptoms: new or worsening depression; thinking about harming or killing yourself, or planning or trying to do so; extreme worry; agitation; panic attacks; difficulty falling asleep or staying asleep; aggressive behavior; irritability; acting without thinking; severe restlessness; frenzied abnormal excitement; or any other changes in your usual thoughts, mood, or behavior. Be sure that your family or caregiver knows which symptoms may be serious so they can call the doctor if you are unable to seek treatment on your own.

Your healthcare provider will want to see you often while you are taking vilazodone, especially at the beginning of your treatment. Be sure to keep all appointments for office visits with your doctor.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with vilazodone and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> [<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>] ) or the manufacturer's website to obtain the Medication Guide.

No matter your age, before you take an antidepressant, you, your parent, or your caregiver should talk to your doctor about the risks and benefits of treating your condition with an antidepressant or with other treatments. You should also talk about the risks and benefits of not treating your condition. You should know that having depression or another mental illness greatly increases the risk that you will become suicidal. This risk is higher if you or anyone in your family has or has ever had bipolar disorder (mood that changes from depressed to abnormally excited) or mania (frenzied, abnormally excited mood) or has thought about or attempted suicide. Talk to your doctor about your condition, symptoms, and personal and family medical history. You and your doctor will decide what type of treatment is right for you.

## Why is this medication prescribed?

Vilazodone is used to treat depression. Vilazodone is in a class of medications called serotonin modulators. It works by increasing the amount of serotonin, a natural substance in the brain that helps maintain mental balance.

## How should this medicine be used?

Vilazodone comes as a tablet to take by mouth. It is usually taken with food once a day. Take vilazodone at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take vilazodone exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Your doctor will probably start you on a low dose of vilazodone and gradually increase your dose, not more than once every 7 days.

Vilazodone controls depression but does not cure it. It may take several weeks before you feel the full benefit of vilazodone. Continue to take vilazodone even if you feel well. Do not stop taking vilazodone without talking to your doctor. Your doctor will probably decrease your dose gradually. If you suddenly stop taking vilazodone, you may experience withdrawal symptoms such as dizziness; nausea; headache; confusion; irritability; agitation; difficulty falling asleep or staying asleep; anxiety; extreme tiredness; seizures; pain, burning, or tingling in the hands or feet; frenzied or abnormally excited mood; or sweating. Tell your doctor if you experience any of these symptoms while you are decreasing your dose of vilazodone or soon after you stop taking vilazodone.

## Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

## What special precautions should I follow?

### Before taking vilazodone,

- tell your doctor and pharmacist if you are allergic to vilazodone, any other medications, or any of the ingredients in vilazodone tablets. Ask your pharmacist or check the Medication Guide for a list of the ingredients.

- tell your doctor if you are taking a monoamine oxidase (MAO) inhibitor, such as isocarboxazid (Marplan), linezolid, methylene blue, phenelzine (Nardil), selegiline (Eldepryl, Emsam, Zelapar), and tranylcypromine (Parnate), or if you have stopped taking one of these medications within the past 14 days. Your doctor will probably tell you that you should not take vilazodone. If you stop taking vilazodone, your doctor will tell you that you should wait at least 14 days before you start to take an MAO inhibitor.
- tell your doctor and pharmacist what other prescription and nonprescription medications, and vitamins you are taking or plan to take. Be sure to mention any of the following: amphetamines such as amphetamine (in Adderall, in Mydayis), dextroamphetamine (Dexedrine, in Adderall), and methamphetamine (Desoxyn); anticoagulants ('blood thinners') such as warfarin (Coumadin, Jantoven); aspirin and other nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen (Advil, Motrin) and naproxen (Aleve, Naprosyn); buspirone; carbamazepine (Carbatrol, Equetro, Tegretol, others); clarithromycin; digoxin (Lanoxin); diuretics ('water pills'); fentanyl (Actiq, Duragesic, Fentora, Subsys); itraconazole (Sporanox); lithium (Lithobid); medications for anxiety, mental illness, or nausea; medications for migraine such as almotriptan, eletriptan (Relpax), frovatriptan (Frova), naratriptan (Amerge), rizatriptan (Maxalt), sumatriptan (Imitrex), and zolmitriptan (Zomig); phenytoin (Dilantin, Phenytek); rifampin (Rifadin, Rimactane); sedatives; selective serotonin reuptake inhibitors (SSRIs) such as citalopram (Celexa), escitalopram (Lexapro), fluoxetine (Prozac, Sarafem), fluvoxamine (Luvox), paroxetine (Paxil, Pexeva), and sertraline (Zoloft); selective serotonin and norepinephrine reuptake inhibitors (SNRIs) such as desvenlafaxine (Pristiq), duloxetine (Cymbalta), and venlafaxine (Effexor); sleeping pills; tramadol (Conzip, Qdola, Ultram, in Ultracet); tranquilizers; tricyclic antidepressants such as amitriptyline, amoxapine (Asendin), clomipramine (Anafranil), desipramine (Norpramin), doxepin (Sinequan), imipramine (Tofranil), nortriptyline (Pamelor), protriptyline, and trimipramine; and voriconazole (Vfend). Your doctor may need to change the doses of your medications or monitor you carefully for side effects. Many other medications may also interact with vilazodone, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list.
- tell your doctor what herbal products and nutritional supplements you are taking, especially St. John's wort and tryptophan.
- tell your doctor if you have a low level of sodium in your blood or glaucoma (increased pressure in the eye that may cause loss of sight), and if you drink or have ever drunk large amounts of alcohol, Also tell your doctor if you have or have ever had bleeding problems, seizures, or liver disease.
- tell your doctor if you are pregnant, especially if you are in the last few months of your pregnancy, or if you plan to become pregnant or are breast-feeding. If you become pregnant while taking vilazodone, call your doctor. Vilazodone may cause problems in newborns following delivery if it is taken during the last months of pregnancy.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking vilazodone.
- you should know that vilazodone may make you drowsy and affect your judgment and thinking. Do not drive a car or operate machinery until you know how this medication affects you.
- ask your doctor about the safe use of alcoholic beverages while you are taking vilazodone. Alcohol can make the side effects from vilazodone worse.
- you should know that vilazodone may cause angle-closure glaucoma (a condition where the fluid is suddenly blocked and unable to flow out of the eye causing a quick, severe increase in eye pressure which may lead to a loss of vision). Talk to your doctor about having an eye examination before you start taking this medication. If you have nausea, eye pain, changes in vision, such as seeing colored rings around lights, and swelling or redness in or around the eye, call your doctor or get emergency medical treatment right away.

## What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

## What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

## What side effects can this medication cause?

**Vilazodone may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:**

- dry mouth
- increased appetite
- heartburn
- gas
- dizziness
- pain, burning, or tingling in the hands or feet
- uncontrollable shaking of a part of the body
- unusual dreams
- tiredness
- joint pain
- sexual problems in males; decreased sex drive, inability to get or keep an erection, or delayed or absent ejaculation
- sexual problems in females; decreased sex drive, or delayed orgasm or unable to have an orgasm

**Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING or SPECIAL PRECAUTIONS sections, call your doctor immediately:**

- rash
- hives
- swelling
- difficulty breathing
- loss of consciousness
- seizures
- fever, sweating, confusion, fast or irregular heartbeat, and severe muscle stiffness or twitching, agitation, hallucinations, loss of coordination, nausea, vomiting, or diarrhea

- unusual bleeding or bruising
- nosebleeds
- small red or purple dots on the skin
- hallucinations (seeing things or hearing voices that do not exist)
- headache
- difficulty concentrating
- memory problems
- weakness
- problems with coordination
- increased falls
- fainting

Vilazodone may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>] ) or by phone (1-800-332-1088).

## What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>] ) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

## In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

## Symptoms of overdose may include the following:

- fever, sweating, confusion, fast or irregular heartbeat, and severe muscle stiffness or twitching, loss of coordination, nausea, vomiting, or diarrhea
- excessive tiredness
- hallucinations (seeing things or hearing voices that do not exist)
- lack of energy
- restlessness
- disorientation

## What other information should I know?

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

## Brand names

- Viibryd®

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