

MEDICATION GUIDE

Vilazodone (vil-AZ-oh-done) Hydrochloride Tablets, for oral use

What is the most important information I should know about vilazodone hydrochloride tablets?

Vilazodone hydrochloride tablets may cause serious side effects, including:

- **Increased risk of suicidal thoughts or actions in some children, adolescents, and young adults.** Vilazodone hydrochloride tablets and other antidepressant medicines may increase suicidal thoughts or actions in some people 24 years of age and younger, **especially within the first few months of treatment or when the dose is changed. Vilazodone hydrochloride tablet is not for use in children.**
 - **Depression or other serious mental illnesses are the most important causes of suicidal thoughts or actions. Some people may have a higher risk of having suicidal thoughts or actions.** These include people who have (or have a family history of) depression, bipolar illness (also called manic-depressive illness) or have a history of suicidal thoughts or actions.

How can I watch for and try to prevent suicidal thoughts and actions?

- Pay close attention to any changes, especially sudden changes in mood, behavior, thoughts, or feelings, or if you develop suicidal thoughts or actions. 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 your healthcare provider between visits as needed, especially if you have concerns about symptoms.

Call your healthcare provider or get emergency medical help right away if you or your family member have any of the following symptoms, especially if they are new, worse, or worry you:

- attempts to commit suicide
- acting aggressive, being angry or violent
- new or worse depression
- panic attacks
- new or worse irritability
- an extreme increase in activity or talking (mania)
- acting on dangerous impulses
- thoughts about suicide or dying
- new or worse anxiety
- feeling agitated or restless
- trouble sleeping (insomnia)
- other unusual changes in behavior or mood

What is vilazodone hydrochloride tablet?

Vilazodone hydrochloride tablet is a prescription medicine used to treat a certain type of depression called Major Depressive Disorder (MDD) in adults. It is not known if vilazodone hydrochloride tablet is safe and effective for use in children for the treatment of MDD.

Who should not take vilazodone hydrochloride tablets?

Do not take vilazodone hydrochloride tablets if you:

- take a Monoamine Oxidase Inhibitor (MAOI)
- have stopped taking an MAOI in the last 14 days
- are being treated with the antibiotic linezolid or intravenous methylene blue

Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI, including the antibiotic linezolid or intravenous methylene blue.

Do not start taking an MAOI for at least 14 days after you stop treatment with vilazodone hydrochloride tablets.

Before taking vilazodone hydrochloride tablets, tell your healthcare provider about all your medical conditions, including if you:

- have or have a family history of suicide, depression, bipolar disorder, mania or hypomania
- have or had bleeding problems
- have or had seizures or convulsions
- have high pressure in the eye (glaucoma)
- have or had seizures or convulsions
- have low sodium levels in your blood
- drink alcohol
- are pregnant or plan to become pregnant. Taking Vilazodone hydrochloride tablets late in pregnancy may lead to an increased risk of certain problems in your newborn. Talk to your healthcare provider about the risks to your baby if you take vilazodone hydrochloride tablets during pregnancy. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with vilazodone hydrochloride tablets.
 - There is a pregnancy registry for females who are exposed to vilazodone hydrochloride tablets pregnancy. The purpose of the registry is to collect information about the health of females exposed to vilazodone hydrochloride tablets and their baby. If you become pregnant during treatment with vilazodone hydrochloride tablets, talk to your healthcare provider about registering with the National Pregnancy Registry for Antidepressants. You can register by calling 1-844-405-6185.
- are breastfeeding or plan to breastfeed. It is not known if vilazodone hydrochloride passes into breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with vilazodone hydrochloride tablets.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Vilazodone hydrochloride tablets and some medicines may affect each other causing possible serious side effects. Vilazodone hydrochloride tablets may affect the way other medicines work and other medicines may affect the way vilazodone hydrochloride tablets works.

Especially tell your healthcare provider if you take:

- MAOIs
- medicines used to treat migraine headaches known as triptans
- tricyclic antidepressants
- fentanyl
- lithium
- tramadol
- tryptophan
- buspirone
- amphetamines
- St. John's Wort
- medicines that can affect blood clotting such as aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs) and warfarin
- diuretics
- medicines used to treat mood, anxiety, psychotic or thought disorders, including selective serotonin reuptake inhibitors (SSRIs) and serotonin norepinephrine reuptake inhibitors (SNRIs)

Ask your healthcare provider if you are not sure if you are taking any of these medicines. Your healthcare provider can tell you if it is safe to take vilazodone hydrochloride tablets with your other medicines.

Do not start or stop any other medicines during treatment with vilazodone hydrochloride tablets without talking to your healthcare provider first. Stopping vilazodone hydrochloride tablets suddenly may cause you to have serious side effects. See, **“What are the possible side effects of vilazodone hydrochloride tablets?”**

Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine.

How should I take vilazodone hydrochloride tablets?

- Take vilazodone hydrochloride tablets exactly as your healthcare provider tell you to. Do not change your dose or stop taking vilazodone hydrochloride tablets without first talking to your healthcare provider.
- Your healthcare provider may need to change the dose of vilazodone hydrochloride tablets until it is the right dose for you.
- **Take vilazodone hydrochloride tablets 1 time each day with food.**
- If you miss a dose of vilazodone hydrochloride tablets, 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 vilazodone hydrochloride tablets at the same time.
- If you take too much vilazodone hydrochloride tablets, call your healthcare provider or poison control center at 1-800-222-1222 right away, or get emergency treatment right away.

What should I avoid while taking vilazodone hydrochloride tablets?

- Do not drive, operate heavy machinery, or do other dangerous activities until you know how vilazodone hydrochloride tablets affects you. Vilazodone hydrochloride tablets can cause sleepiness or may affect your ability to make decisions, think clearly, or react quickly.
- Avoid drinking alcohol during treatment with vilazodone hydrochloride tablets.

What are the possible side effects of vilazodone hydrochloride tablets?

Vilazodone hydrochloride tablets may cause serious side effects, including:

- See, **“What is the most important information I should know about vilazodone hydrochloride tablets?”**
- **Serotonin Syndrome.** A potentially life-threatening problem called serotonin syndrome can happen when vilazodone hydrochloride tablets is taken with certain other medicines. See, **“Who should not take vilazodone hydrochloride tablets?”** Stop taking vilazodone hydrochloride tablets and call your healthcare provider or go to the nearest hospital emergency room right away if you have any of the following signs and symptoms of serotonin syndrome:
 - o agitation
 - o confusion
 - o fast heart beat
 - o dizziness
 - o flushing
 - o tremors, stiff muscles, or muscle twitching
 - o seizures
 - o seeing or hearing things that are not real (hallucinations)
 - o coma
 - o blood pressure changes
 - o sweating
 - o high body temperature (hyperthermia)
 - o loss of coordination
 - o nausea, vomiting, diarrhea
- **Increased risk of bleeding.** Taking vilazodone hydrochloride tablets with aspirin, non-steroidal anti-inflammatory drugs (NSAIDs), warfarin or blood thinners may add to this risk. Tell your healthcare provider right away about any unusual bleeding or bruising.
- **Mania or hypomania (manic episodes)** in people who have a history of bipolar disorder. Symptoms may include:
 - o greatly increased energy
 - o racing thoughts
 - o unusually grand ideas
 - o talking more or faster than usual
 - o severe trouble sleeping
 - o reckless behavior
 - o excessive happiness or irritability

• **Discontinuation syndrome.** Suddenly stopping vilazodone hydrochloride tablets may cause you to have serious side effects. Your healthcare provider may want to decrease your dose slowly. Symptoms may include:

- o nausea
- o changes in your mood
- o irritability and agitation
- o dizziness
- o electric shock sensation (paresthesia)
- o anxiety
- o confusion
- o sweating
- o headache
- o tiredness
- o problems sleeping
- o hypomania
- o ringing in your ears (tinnitus)
- o seizures

• **Seizures (convulsions).**

• **Eye problems (angle-closure glaucoma):** Vilazodone hydrochloride tablets may cause a certain type of eye problem called angle-closure glaucoma. Call your healthcare provider if you have changes in your vision or eye pain.

• **Low sodium levels in your blood (hyponatremia).** Low sodium levels in your blood may be serious and may cause death. Elderly people may be at greater risk for this. Signs and Symptoms of low sodium levels in your blood may include:

- o headache
- o memory changes
- o weakness and unsteadiness on your feet which can lead to falls
- o difficulty concentrating
- o confusion

In severe or more sudden cases, signs and symptoms include:

- o hallucinations (seeing or hearing things that are not real)
- o seizures
- o respiratory arrest
- o fainting
- o coma
- o death

• **Sexual problems (dysfunction).** Taking selective serotonin reuptake inhibitors (SSRIs), including vilazodone hydrochloride tablets, may cause sexual problems.

Symptoms in males may include:

- o delayed ejaculation or inability to have an ejaculation
- o problems getting or keeping an erection
- o decreased sex drive

Symptoms in females may include:

- o decreased sex drive
- o delayed orgasm or inability to have an orgasm

Talk to your healthcare provider if you develop any changes in your sexual function or if you have any questions or concerns about sexual problems during treatment with vilazodone hydrochloride tablets. There may be treatments your healthcare provider can suggest.

The most common side effects of vilazodone hydrochloride tablets include diarrhea, nausea or vomiting, trouble sleeping.

These are not all the possible side effects of vilazodone hydrochloride tablets.

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 vilazodone hydrochloride tablets?

- Store vilazodone hydrochloride tablets at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F).
- **Keep vilazodone hydrochloride tablets and all medicines out of the reach of children.**

General information about the safe and effective use of vilazodone hydrochloride tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use vilazodone hydrochloride tablets for a condition for which it was not prescribed. Do not give vilazodone hydrochloride tablets to other people, even if they have the same symptoms that you have. It may harm them. You may ask your healthcare provider or pharmacist for information about vilazodone hydrochloride tablets that is written for healthcare professionals.

What are the ingredients in vilazodone hydrochloride tablets?

Active ingredient: vilazodone hydrochloride

Inactive ingredients: microcrystalline cellulose, colloidal silicon dioxide, sodium starch glycolate, magnesium stearate, polyvinyl alcohol, polyethylene glycol, talc, titanium dioxide, FD&C Red No. #40 Al Lake (10 mg only), FD&C Yellow No. #6 Al Lake (20 mg only) and FD&C Blue No. #1 Al Lake (40 mg only).

Medication Guide available at <http://www.alembicusa.com/medicationguide.aspx> or call 1-866-210-9797.

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

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