

Medication Guide

Dispense with Medication Guide available at: www.epic-pharma.com/medguide/Venlafaxine-Hydrochloride-ER-Capsule.pdf

Venlafaxine Hydrochloride (ven" la fax' een hye" droe klor' ide) Extended-Release Capsules

Read the Medication Guide that comes with **venlafaxine hydrochloride extended-release capsules** before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or treatment. Talk with your healthcare provider if there is something you do not understand or want to learn more about.

What is the most important information I should know about venlafaxine hydrochloride extended-release capsules?

Venlafaxine hydrochloride extended-release capsules and other antidepressant medicines may cause serious side effects, including:

1. Suicidal thoughts or actions:

- **Venlafaxine hydrochloride extended-release capsules 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 **venlafaxine hydrochloride extended-release capsules** are 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, or call 911 if an emergency, 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
- other unusual changes in behavior or mood
- **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.

Call your healthcare provider right away if you have any of the following symptoms, or call 911 if an emergency. Venlafaxine hydrochloride extended-release capsules may be associated with these serious side effects:

2. Serotonin Syndrome

This condition can be life-threatening and may include:

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

3. Changes in blood pressure. Venlafaxine hydrochloride extended-release capsules may:

- increase your blood pressure. Control high blood pressure before starting treatment and monitor blood pressure regularly

4. Enlarged pupils (mydriasis).

5. Anxiety and insomnia.

6. Changes in appetite or weight.

7. Manic/hypomanic episodes:

- greatly increased energy
- severe trouble sleeping
- racing thoughts
- reckless behavior
- unusually grand ideas
- excessive happiness or irritability
- talking more or faster than usual

8. 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

9. Seizures or convulsions.

10. Abnormal bleeding: Venlafaxine hydrochloride extended-release capsules 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 (NSAIDs, like ibuprofen or naproxen), or aspirin.

11. Elevated cholesterol.

12. Lung disease and pneumonia: Venlafaxine hydrochloride extended-release capsules may cause rare lung problems. Symptoms include:

- worsening shortness of breath
- cough
- chest discomfort

13. Severe allergic reactions:

- trouble breathing
- swelling of the face, tongue, eyes or mouth
- rash, itchy welts (hives) or blisters, alone or with fever or joint pain.

14. Sexual Problems (dysfunction). Taking serotonin and norepinephrine reuptake inhibitors (SNRIs), including **venlafaxine hydrochloride extended-release capsules**, may cause sexual problems.

Symptoms in males may include:

- Delayed ejaculation or inability to have an ejaculation
- Decreased sex drive
- Problems getting or keeping an erection

Symptoms in females may include:

- Decreased sex drive
- 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 **venlafaxine hydrochloride extended-release capsules**. There may be treatments your healthcare provider can suggest.

Do not stop venlafaxine hydrochloride extended-release capsules without first talking to your healthcare provider. Stopping **venlafaxine hydrochloride extended-release capsules** too quickly may cause serious symptoms. Symptoms may include the following (some of which can be severe and last for a long time):

- anxiety, irritability, violent behavior
- feeling tired, restless or problems sleeping
- headache, sweating, dizziness
- electric shock-like sensations, shaking, confusion, nightmares
- vomiting, nausea, diarrhea
- problems with eyesight such as blurred vision or trouble focusing
- increased blood pressure

What are venlafaxine hydrochloride extended-release capsules?

Venlafaxine hydrochloride extended-release capsules are a prescription medicine used to treat depression. It is important to talk with your healthcare provider about the risks of treating depression and also the risks of not treating it. You should discuss all treatment choices with your healthcare provider. **Venlafaxine hydrochloride extended-release capsules** are also used to treat:

- Generalized Anxiety Disorder (GAD)
- Social Anxiety Disorder (SAD)
- Panic Disorder (PD)

Talk to your healthcare provider if you do not think that your condition is getting better with **venlafaxine hydrochloride extended-release capsules** treatment.

Who should not take venlafaxine hydrochloride extended-release capsules?

Do not take **venlafaxine hydrochloride extended-release capsules** if you:

- are allergic to **venlafaxine hydrochloride** or any of the ingredients in **venlafaxine hydrochloride extended-release capsules**. See the end of this Medication Guide for a complete list of ingredients in **venlafaxine hydrochloride extended-release capsules**.
- have uncontrolled angle-closure glaucoma
- 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 7 days of stopping **venlafaxine hydrochloride extended-release capsules** unless directed to do so by your physician.
 - Do not start **venlafaxine hydrochloride extended-release capsules** if you stopped taking an MAOI in the last 2 weeks unless directed to do so by your physician.

People who take venlafaxine hydrochloride extended-release capsules close in time to 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 venlafaxine hydrochloride extended-release capsules? Ask if you are not sure.

Before starting **venlafaxine hydrochloride extended-release capsules**, tell your healthcare provider if you:

- Are taking certain drugs such as:
 - Amphetamines
 - Medicines used to treat migraine headaches such as:
 - triptans
 - Medicines used to treat mood, anxiety, psychotic or thought disorders, such as:
 - tricyclic antidepressants
 - lithium
 - SSRIs
 - SNRIs
 - antipsychotic drugs
 - Medicines used to treat pain such as:
 - tramadol
 - Medicines used to thin your blood such as:
 - warfarin
 - Medicines used to treat heartburn such as:
 - Cimetidine
 - Over-the-counter medicines or supplements such as:
 - Aspirin or other NSAIDs
 - Tryptophan
 - St. John's Wort
 - have heart problems
 - have diabetes
 - have liver problems
 - have kidney problems
 - have thyroid problems
 - have or had seizures or convulsions
 - have bipolar disorder or mania
 - have low sodium levels in your blood
 - have high blood pressure
 - have high cholesterol
 - have or had bleeding problems
- are pregnant or plan to become pregnant. It is not known if **venlafaxine hydrochloride extended-release capsules** will harm your unborn baby. Talk to your healthcare provider about the benefits and risks of treating depression during pregnancy.
- are breast-feeding or plan to breast-feed. Some **venlafaxine hydrochloride** may pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby while taking **venlafaxine hydrochloride extended-release capsules**.

Tell your healthcare provider about all the medicines that you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. **Venlafaxine hydrochloride extended-release capsules** and some medicines may interact with each other, may not work as well, or may cause serious side effects.

Your healthcare provider or pharmacist can tell you if it is safe to take **venlafaxine hydrochloride extended-release capsules** with your other medicines. Do not start or stop any medicine while taking **venlafaxine hydrochloride extended-release capsules** without talking to your healthcare provider first.

If you take **venlafaxine hydrochloride extended-release capsules**, you should not take any other medicines that contain (venlafaxine) including: venlafaxine hydrochloride.

How should I take venlafaxine hydrochloride extended-release capsules?

- Take **venlafaxine hydrochloride extended-release capsules** exactly as prescribed. Your healthcare provider may need to change the dose of **venlafaxine hydrochloride extended-release capsules** until it is the right dose for you.
- **Venlafaxine hydrochloride extended-release capsules** are to be taken with food.
- If you miss a dose of **venlafaxine hydrochloride extended-release capsules**, 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 **venlafaxine hydrochloride extended-release capsules** at the same time.
- If you take too much **venlafaxine hydrochloride extended-release capsules**, call your healthcare provider or poison control center right away, or get emergency treatment.
- When switching from another antidepressant to **venlafaxine hydrochloride extended-release capsules** your doctor may want to lower the dose of the initial antidepressant first to avoid side effects

What should I avoid while taking venlafaxine hydrochloride extended-release capsules?

Venlafaxine hydrochloride extended-release capsules 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 **venlafaxine hydrochloride extended-release capsules** affect you. Do not

drink alcohol while using **venlafaxine hydrochloride extended-release capsules**.

What are the possible side effects of venlafaxine hydrochloride extended-release capsules?

Venlafaxine hydrochloride extended-release capsules may cause serious side effects, including:

- See "What is the most important information I should know about **venlafaxine hydrochloride extended-release capsules**?"
- Increased cholesterol- have your cholesterol checked regularly
- Newborns whose mothers take **venlafaxine hydrochloride extended-release capsules** in the third trimester may have problems right after birth including:
 - problems feeding and breathing
 - seizures
 - shaking, jitteriness or constant crying
- Angle-closure glaucoma

Common possible side effects in people who take **venlafaxine hydrochloride extended-release capsules** include:

- unusual dreams
- sexual problems
- loss of appetite, constipation, diarrhea, nausea or vomiting, or dry mouth
- feeling tired, fatigued or overly sleepy
- change in sleep habits, problems sleeping
- yawning
- tremor or shaking
- dizziness, blurred vision
- sweating
- feeling anxious, nervous or jittery
- headache
- increase in heart rate

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 **venlafaxine hydrochloride extended-release capsules**. For more information, ask your healthcare provider or pharmacist.

CALL YOUR DOCTOR FOR MEDICAL ADVICE ABOUT SIDE EFFECTS. YOU MAY REPORT SIDE EFFECTS TO THE FDA AT 1-800-FDA-1088.

How should I store venlafaxine hydrochloride extended-release capsules?

- Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].
- Keep **venlafaxine hydrochloride extended-release capsules** in a dry place.

Keep venlafaxine hydrochloride extended-release capsules and all medicines out of the reach of children.

General information about venlafaxine hydrochloride extended-release capsules

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

This Medication Guide summarizes the most important information about **venlafaxine hydrochloride extended-release capsules**. If you would like more information, talk with your healthcare provider. You may ask your healthcare provider or pharmacist for information about **venlafaxine hydrochloride extended-release capsules** that is written for healthcare professionals.

For more information about **venlafaxine hydrochloride extended-release capsules** call **1-888-374-2791**.

What are the ingredients in venlafaxine hydrochloride extended-release capsules?

Active ingredient: venlafaxine hydrochloride, USP

Inactive ingredients: empty hard gelatin capsules, ethylcellulose, hypromellose, povidone, sugar spheres (composed of corn starch and sucrose) and talc.

The 37.5 mg capsule shell contains red iron oxide, gelatin, and titanium dioxide. The 75 mg capsule shell contains black iron oxide, red iron oxide, gelatin, and titanium dioxide. The 150 mg capsule shell contains FD&C blue 1, FD&C red 3, FD&C yellow 6, gelatin, and titanium dioxide.

The imprinting ink contains black iron oxide, potassium hydroxide and shellac.

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

Manufactured by:

Yichang Humanwell Oral Solid Dosage Plant
Yichang, Hubei, China 443112

Distributed by:

Epic Pharma, LLC
Laurelton, NY 11413

LG0008

Rev. 08-2022-00