MEDICATION GUIDE

Venlafaxine Hydrochloride Extended-Release Capsules

(ven'' la fax' een hye'' droe klor' ide)

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

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

- **Increased risk of suicidal thoughts and actions.** venlafaxine hydrochloride extended-release capsules and other antidepressant medicines may increase suicidal thoughts and actions in some children, adolescents, and young adults, **especially within the first few months of treatment or when the dose is changed venlafaxine hydrochloride extended-release capsules are not for use in children**.
  - Depression or other serious mental illnesses are the most important causes of suicidal thoughts or actions.

  How can I watch for and try to prevent suicidal thoughts and actions in myself or a family member?
  - Pay close attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings. 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 help right away if you or a 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)
  - thoughts about suicide or dying
  - acting on dangerous impulses
  - new or worse anxiety
  - feeling very agitated or restless
  - trouble sleeping
  - other unusual changes in behavior or mood

What is venlafaxine hydrochloride extended-release capsules?

Venlafaxine hydrochloride extended-release capsule is a prescription medicine used to treat adults with:

- a certain type of depression called Major Depressive Disorder (MDD)
- Generalized Anxiety Disorder (GAD)
- Social Anxiety Disorder (SAD)
- Panic Disorder (PD)

It is not known if Venlafaxine Hydrochloride Extended-Release Capsules are safe and effective for use in children.

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

- are allergic to venlafaxine hydrochloride, desvenlafaxine succinate, 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.
- 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 MAOIs such as linezolid or intravenous methylene blue.

Do not start taking an MAOI for at least 7 days after you stop treatment with venlafaxine hydrochloride extended-release capsules.

Before taking venlafaxine hydrochloride extended-release capsules tell your healthcare provider about all your medical conditions, including if you:

- have, or have a family history of suicide, bipolar disorder, depression, mania or hypomania

- have high blood pressure
- have heart problems
- have cerebrovascular problems or had a stroke
- have or have had bleeding problems
- have high pressure in the eye (glaucoma)
- have high cholesterol or high triglycerides
- have kidney or liver problems
- have or had seizures or convulsions
- have low sodium levels in your blood
- have lung problems
- drink alcohol
- are pregnant or plan to become pregnant. Venlafaxine hydrochloride extended-release capsules may harm your unborn baby. Talk to your healthcare provider about the risk to you and your unborn baby if you take venlafaxine hydrochloride extended-release capsules during pregnancy.
    - Tell your healthcare provider if you become pregnant or think you are pregnant during treatment with venlafaxine hydrochloride extended-release capsules.
    - **Pregnancy Exposure Registry.** There is a pregnancy registry for women who are exposed to venlafaxine hydrochloride extended-release capsules during pregnancy. The purpose of the registry is to collect information about the health of you and your baby. If you become pregnant during treatment with venlafaxine hydrochloride extended-release capsules, talk to your healthcare provider about registering with the National Pregnancy Registry for Antidepressants. You can register by calling 1-844-405-6185 or by visiting online at https://womensmentalhealth.org/research/pregnancyregistry/antidepressants.
- are breastfeeding or plan to breastfeed. Venlafaxine hydrochloride passes into your breast milk and may harm your baby. Talk to your healthcare provider about the best way to feed your baby during treatment with venlafaxine hydrochloride extended-release capsules.

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

Venlafaxine hydrochloride extended-release capsules and other medicines may affect each other causing possible serious side effects. Venlafaxine hydrochloride extended-release capsules may affect the way other medicines work and other medicines may affect the way venlafaxine hydrochloride extended-release capsules works.

Especially tell your healthcare provider if you take:

- medicines to treat migraine headaches known as triptans
- tricyclic antidepressants
- lithium
- tramadol, fentanyl, meperidine, methadone, or other opioids
- tryptophan
- buspirone
- amphetamines
- St. John's Wort
- phentermine
- other medicines containing desvenlafaxine or venlafaxine
- medicines that can affect blood clotting such as aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs), warfarin

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 venlafaxine hydrochloride extended-release capsules with your other medicines.

Do not start or stop any other medicines during treatment with venlafaxine hydrochloride extended-release

capsules without first talking to your healthcare provider. Stopping venlafaxine hydrochloride extended-release capsules suddenly may cause you to have serious side effects. **See "What are the possible side effects of venlafaxine hydrochloride extended-release capsules?"**

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 venlafaxine hydrochloride extended-release capsules?

- Take venlafaxine hydrochloride extended-release capsules exactly as your healthcare provider tells you to. Do not change your dose or stop taking venlafaxine hydrochloride extended-release capsules without first talking to your healthcare provider.
- Your healthcare provider may need to change the dose of venlafaxine hydrochloride extended-release capsules until it is the right dose for you.
- Take venlafaxine hydrochloride extended-release capsules 1 time each day with food.
- Venlafaxine hydrochloride may be taken either in the morning or in the evening, but take it the same way each time.
- Swallow venlafaxine hydrochloride extended-release capsules whole with fluid. Do not divide, crush, chew, or dissolve venlafaxine hydrochloride extended-release capsules.
- If you cannot swallow venlafaxine hydrochloride extended-release capsules whole, the venlafaxine hydrochloride extended-release capsules may be opened and the entire contents sprinkled on a spoonful of applesauce.
  - Swallow the venlafaxine hydrochloride extended-release capsules and applesauce mixture right away without chewing.
  - Follow with a glass of water to make sure you have swallowed all of the venlafaxine hydrochloride extended-release capsules pellets.
- If you take too much venlafaxine hydrochloride extended-release capsules, call your healthcare provider or poison control center at 1-800-222-1222 or go to the nearest hospital emergency room right away.

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

- Do not drive, or operate heavy machinery, or do other dangerous activities until you know how venlafaxine hydrochloride extended-release capsules affects you. Venlafaxine hydrochloride extended-release capsules can make you drowsy.
- You should not drink alcohol during treatment with venlafaxine hydrochloride extended-release capsules. Drinking alcohol during treatment with venlafaxine hydrochloride extended-release capsules can increase your risk of having serious side effects.

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?"**
- **Serotonin syndrome.** Taking venlafaxine hydrochloride extended-release capsules can cause a potentially life-threatening problem called serotonin syndrome. The risk of developing serotonin syndrome is increased when venlafaxine hydrochloride extended-release capsules is taken with certain other medicines. **See "Do not take venlafaxine hydrochloride extended-release capsules if you:"** Stop taking venlafaxine hydrochloride extended-release capsules 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:
  - agitation
  - confusion
  - fast heartbeat
  - dizziness
  - flushing
  - tremors, stiff muscles, or muscle twitching
  - seeing or hearing things that are not real (hallucinations)
  - coma
  - changes in blood pressure
  - sweating
  - high body temperature (hyperthermia)
  - loss of coordination

- seizures
- nausea, vomiting, diarrhea

- **Increases in blood pressure.** Your healthcare provider should check your blood pressure before starting treatment and regularly during treatment with venlafaxine hydrochloride extended-release capsules. If you have high blood pressure, it should be controlled before you start treatment with venlafaxine hydrochloride extended-release capsules.
- **Increased risk of bleeding.** Taking venlafaxine hydrochloride extended-release capsules with aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs), or blood thinners may add to this risk. Tell your healthcare provider right away about any unusual bleeding or bruising.
- **Eye problems (angle-closure glaucoma).** Venlafaxine hydrochloride extended-release capsules may cause a certain type of eye problem called angle-closure glaucoma. 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 if you have eye pain, changes in your vision, or swelling or redness in or around the eye.
- **Manic episodes.** Manic episodes may happen in people with bipolar disorder who take venlafaxine hydrochloride extended-release capsules. Symptoms may include:
  - greatly increased energy
  - racing thoughts
  - unusually grand ideas
  - talking more or faster than usual
  - ere trouble sleeping
  - reckless behavior
  - excessive happiness or irritability
  -
- **Discontinuation syndrome.** Suddenly stopping venlafaxine hydrochloride extended-release capsules may cause you to have serious side effects. Your healthcare provider may want to decrease your dose slowly. Symptoms may include:
  - dizziness
  - irritability and agitation
  - anxiety
  - sweating
  - seizures
  - ringing in your ears (tinnitus)
  - nausea
  - problems sleeping
  - tiredness
  - confusion
  - electric shock sensation (paresthesia)
  - headache
  - diarrhea
  - abnormal dreams
  - changes in your mood
  - hypomania
- **Seizures (convulsions).**
- **Low sodium levels in your blood (hyponatremia).** Low sodium levels can happen during treatment with venlafaxine hydrochloride extended-release capsules. 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:
  - headache
  - difficulty concentrating
  - memory changes
  - confusion
  - weakness and unsteadiness on your feet which can lead to falls

  In severe or more sudden cases, signs and symptoms include:
  - hallucinations (seeing or hearing things that are not real)
  - fainting
  - seizures
  - coma
  - respiratory arrest
- **Lung problems.** Some people who have taken the medicine venlafaxine, which is the same kind of medicine as the medicine in venlafaxine hydrochloride extended-release capsules, have had lung problems. Symptoms of lung problems include difficulty breathing, cough, or chest discomfort. Tell your healthcare provider right away if you have any of these symptoms.
- **Sexual problems (dysfunction).** Taking selective serotonin 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.

Your healthcare provider may tell you to stop taking venlafaxine hydrochloride extended-release capsules if you develop serious side effects during treatment with venlafaxine hydrochloride extended-release capsules.

The most common side effects of venlafaxine hydrochloride extended-release capsules include:

- nausea
- dry mouth
- male and female sexual problems
- loss of appetite (anorexia)
- sleepiness
- sweating
- constipation

These are not all the possible side effects of venlafaxine hydrochloride extended-release capsules. 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 venlafaxine hydrochloride extended-release capsules?

- Store venlafaxine hydrochloride extended-release capsules at room temperature between 68°F to 77°F (20°C to 25°C).
- 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 the safe and effective use of 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 symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about venlafaxine hydrochloride extended-release capsules that is written for healthcare professionals.

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

Active ingredient: venlafaxine

Inactive ingredients: ethyl cellulose, hydroxypropyl methylcellulose, sugar spheres and talc. The empty capsule shells contain ferric oxide red, gelatin, sodium lauryl sulphate and titanium dioxide. In addition, the 37.5 mg empty capsule shells contain ferric oxide black, and 150 mg empty capsule shells contain ferric oxide yellow.

Capsules imprinting ink contains povidone, propylene glycol, shellac, sodium hydroxide and titanium dioxide. In addition, red imprinting ink used in 37.5 mg and 75 mg capsules contain FD & C Red#40 aluminium lake.

This Medication was approved by the U.S. Food and Drug Administration.

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