Medication Guide
Venlafaxine (ven-la-fax-een) Tablets, USP

Read the Medication Guide that comes with venlafaxine tablets, USP 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 Tablets, USP?
Venlafaxine tablets, USP and other antidepressant medicines may cause serious side effects, including:

1. Suicidal thoughts or actions:
   - Venlafaxine tablets, USP 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 tablets, USP is 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

Call your healthcare provider right away if you have any of the following symptoms, or call 911 if an emergency. Venlafaxine Tablets, USP 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 Tablets, USP 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.
   - children and adolescents should have height and weight monitored during treatment

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 tablets, USP 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 tablets, USP 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. 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.

Do not stop Venlafaxine Tablets, USP without first talking to your healthcare provider. Stopping venlafaxine tablets, USP too quickly or changing from another antidepressant too quickly may cause serious symptoms including:
   - anxiety, irritability
   - feeling tired, restless or problems sleeping
   - headache, sweating, dizziness
   - electric shock-like sensations, shaking, confusion, nightmares
   - vomiting, nausea, diarrhea

What is Venlafaxine Tablets, USP?
Venlafaxine tablets, USP is 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. Talk to your healthcare provider if you do not think that your condition is getting better with venlafaxine tablets, USP treatment.

Who should not take Venlafaxine Tablets, USP?
Do not take venlafaxine tablets, USP if you:
- are allergic to venlafaxine tablets, USP or any of the ingredients in venlafaxine tablets, USP. See the end of this Medication Guide for a complete list of ingredients in venlafaxine tablets, USP.
- have uncontrolled narrow-angle 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 tablets, USP unless directed to do so by your physician.
- do not start venlafaxine tablets, USP if you stopped taking an MAOI in the last 2 weeks unless directed to do so by your physician.

People who take Venlafaxine Tablets, USP 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 Tablets, USP? Ask if you are not sure.
Before starting venlafaxine tablets, USP, tell your healthcare provider if you:

- Are taking certain drugs such as:
  - Amphetamines
  - Medicines used to treat migraine headaches such as:
    - O triptans
  - Medicines used to treat mood, anxiety, psychotic or thought disorders, such as:
    - O tricyclic antidepressants
    - O lithium
    - O SSRIs
    - O SNRIs
    - O antipsychotic drugs
  - Medicines used to treat pain such as:
    - O tramadol
  - Medicines used to thin your blood such as:
    - O warfarin
  - Medicines used to treat heartburn such as:
    - O Cimetidine
  - Over-the-counter medicines or supplements such as:
    - O Aspirin or other NSAIDs
    - O Tryptophan
    - O St. John’s Wort
- have high blood pressure
- have glaucoma
- have liver problems
- have diabetes
- have heart problems
- have sexual problems
- have changes in sleeping habits, problems sleeping
- have unusual dreams
- have sexual problems
- have loss of appetite, constipation, diarrhea, nausea or vomiting, or dry mouth
- have feeling tired, fatigued or overly sleepy
- have change in sleep habits, problems sleeping
- have yawning
- have tremor or shaking
- have dizziness, blurred vision
- have sweating
- have feeling anxious, nervous or jittery
- have feeling high, blood
- have blood
- have liver problems
- have diabetes
- have heart problems
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- have sweating
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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 tablets, USP. For more information, ask your healthcare provider or pharmacist.

General information about venlafaxine tablets, USP

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

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

To report SUSPECTED ADVERSE REACTIONS, contact NorthStar Rx LLC at 1-800-206-7821

What are the ingredients in Venlafaxine Tablets, USP?

Active ingredient: (venlafaxine)

Inactive ingredients:
- Tablets: microcrystalline cellulose, lactose monohydrate, pregelatinized starch, sodium starch glycolate, iron oxide red, iron oxide yellow, colloidal silicon dioxide, and magnesium stearate

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

Medication Guide available at www.northstarrxl.com/products or call 1-800-206-7821

Tablets:
- Microcrystalline cellulose, lactose monohydrate, pregelatinized starch, sodium starch glycolate, iron oxide red, iron oxide yellow, colloidal silicon dioxide, and magnesium stearate.