EFFEXOR XR- venlafaxine hydrochloride capsule, extended release
Wyeth Pharmaceuticals Company, a subsidiary of Pfizer Inc.

Medication Guide

EFFEXOR XR (e-fex-or)
(venlafaxine hydrochloride)
(Extended-Release Capsules)

Read the Medication Guide that comes with **EFFEXOR XR** 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 EFFEXOR XR?

EFFEXOR XR and other antidepressant medicines may cause serious side effects, including:

1. Suicidal thoughts or actions:

- **EFFEXOR XR 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 **EFFEXOR XR** 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. EFFEXOR XR 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. EFFEXOR XR 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: **EFFEXOR XR** 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: **EFFEXOR XR** 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

Do not stop EFFEXOR XR without first talking to your healthcare provider. Stopping **EFFEXOR XR** 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 EFFEXOR XR?

EFFEXOR XR 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. **EFFEXOR XR** is 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 **EFFEXOR XR** treatment.

Who should not take EFFEXOR XR?

Do not take **EFFEXOR XR** if you:
- are allergic to **EFFEXOR XR** or any of the ingredients in **EFFEXOR XR**. See the end of this Medication Guide for a complete list of ingredients in **EFFEXOR XR**.
- 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 **EFFEXOR XR** unless directed to do so by your physician.
  - Do not start **EFFEXOR XR** if you stopped taking an MAOI in the last 2 weeks unless directed to do so by your physician.

  People who take EFFEXOR XR 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 EFFEXOR XR? Ask if you are not sure.

Before starting **EFFEXOR XR**, tell your healthcare provider if you:
- Are taking certain drugs such as:
  - 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 glaucoma
- 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 **EFFEXOR XR** 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 **EFFEXOR XR** may pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby while taking **EFFEXOR XR**.

Tell your healthcare provider about all the medicines that you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. **EFFEXOR XR** 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 **EFFEXOR XR** with your other medicines. Do not start or stop any medicine while taking **EFFEXOR XR** without talking to your healthcare provider first.

If you take **EFFEXOR XR**, you should not take any other medicines that contain (venlafaxine) including: venlafaxine HCl.

How should I take EFFEXOR XR?

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

What should I avoid while taking EFFEXOR XR?

EFFEXOR XR 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 **EFFEXOR XR** affects you. Do not drink alcohol while using **EFFEXOR XR**.

What are the possible side effects of EFFEXOR XR?

EFFEXOR XR may cause serious side effects, including:

- See "What is the most important information I should know about **EFFEXOR XR**?"
- Increased cholesterol- have your cholesterol checked regularly
- Newborns whose mothers take **EFFEXOR XR** in the third trimester may have problems right after birth including:
  - problems feeding and breathing
  - seizures
  - shaking, jitteriness or constant crying
- Narrow-angle glaucoma/enlarged pupils. Check eye pressure regularly if you:
  - have a history of increased eye pressure
  - are at risk for certain types of glaucoma

Common possible side effects in people who take **EFFEXOR XR** 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 **EFFEXOR XR**. 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 EFFEXOR XR?

- Store **EFFEXOR XR** at room temperature between 68°F and 77°F (20°C to 25°C).
- Keep **EFFEXOR XR** in a dry place.

Keep EFFEXOR XR and all medicines out of the reach of children.

General information about EFFEXOR XR

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

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

For more information about **EFFEXOR XR** call **1-800-934-5556** or go to www. **EFFEXORXR**.com.

What are the ingredients in EFFEXOR XR?

Active ingredient: (venlafaxine)

Inactive ingredients:

Extended-Release Capsules: cellulose, ethylcellulose, gelatin, hypromellose, iron oxide, and titanium dioxide

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

This product's label may have been updated. For current full prescribing information, please visit www.pfizer.com

LAB-0542-3.0

December 2012

Revised: 06/2013

Wyeth Pharmaceuticals Company, a subsidiary of Pfizer Inc.