

Effexor (venlafaxine)

FDA ALERT [09/2007] - Suicidality and Antidepressant Drugs

Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of Effexor or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Effexor is not approved for use in pediatric patients.

Brand/Generic Names

- Brand name: Effexor[®], Effexor XR[®]

Tablets (immediate release): 25 mg, 37.5 mg, 50 mg, 75 mg, 100 mg

Capules (extended release): 37.5 mg, 75 mg, 150 mg

- Generic name: Venlafaxine

Tablets (immediate release): 25 mg, 37.5 mg, 50 mg, 75 mg, 100 mg

What is Effexor® and what does it treat?

Venlafaxine is an antidepressant medication that works in the brain on the neurotransmitters serotonin and norepinephrine. It is approved for the treatment of Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD), panic disorder and social anxiety disorder (social phobia).

MDD occurs when a person experiences several of the following symptoms concurrently, for at least two weeks: "low" or depressed mood (for example, sad, empty, tearful); decreased interest in most or all activities; changes in appetite (usually decreased); changes in sleep (usually poor sleep); loss of energy; feeling worthless/guilty/ hopeless/helpless; psychomotor agitation or retardation (i.e. thoughts/movements speeding up or slowing down); difficulty concentrating, and thoughts of death (suicidal thinking).

GAD occurs when a person experiences excessive anxiety or worry for at least six months along with restlessness, fatigue, difficulty concentrating, irritability, muscle tension or sleep disturbance.

Panic Disorder occurs when a person experiences unexpected and repeated episodes of intense fear along with physical symptoms including chest pain, shortness of breath, heart palpitations, sweating, dizziness, and nausea.

Social Anxiety Disorder is an anxiety disorder in which a person experiences extreme fear in situations where they have to meet new people. The person may have physical symptoms in social situations (e.g. blushing, sweating, shaking, dry mouth, palpitations) and commonly tries to avoid them.

What is the most important information I should know about Effexor®?

After starting venlafaxine, symptoms gradually decrease over a period of weeks. Sleep and other physical symptoms may improve before there is noticeable improvement in mood or interest in activities. Once symptoms are under control, MDD usually requires long-term treatment to help prevent the return of depressive symptoms. Only your healthcare provider can determine the length of generic name treatment that is right for you.

Do not stop taking venlafaxine or change your dose without talking to with your healthcare provider first.

Stopping venlafaxine abruptly may result in one or more of the following withdrawal symptoms: irritability, nausea, dizziness, vomiting, nightmares, headache and paresthesias (prickling, tingling sensation on the skin).

Because depression is also a part of Bipolar illness, people who take antidepressants may be at risk for "switching" from depression into mania. Symptoms of mania include "high" or irritable mood, very high self esteem, decreased need for sleep, pressure to keep

talking, racing thoughts, being easily distracted, frequently involved in activities with a large risk for bad consequences (for example, excessive buying sprees).

Are there specific concerns about Effexor® and pregnancy?

If you are planning on becoming pregnant, notify your healthcare provider so that he/she can best manage your medications. People living with MDD who wish to become pregnant face important decisions, each with risks and benefits. Untreated depression or depression relapse may have negative consequences for both the fetus and the mother. Women who discontinue antidepressant therapy are up to five times more likely to have a depression relapse than those who continued their antidepressant. There are many dimensions to these choices, so be sure to confer with your doctor and caregivers.

Regarding breast-feeding, caution is advised since venlafaxine does pass into breast milk.

What should I discuss with my healthcare provider before taking Effexor®?

- The most bothersome symptoms of your condition
- If you have thoughts of suicide
- Medications you have taken in the past for your condition, whether they were effective or caused any adverse effects
- Any medical problems that you may have, especially high blood pressure
- All other medications you are currently taking and any medication allergies you have
- If you are pregnant, plan to become pregnant, or are breast-feeding
- If you drink alcohol or use drugs

How should I take Effexor®?

Venlafaxine may be taken with food to minimize stomach upset

Venlafaxine immediate release tablets are usually taken two times per day.

Venlafaxine extended release capsules are usually taken once daily at the same time each day. Swallow the capsule whole with plenty of fluids. Do not divide, cut, chew, crush, or place the capsules in water. Alternatively, the dose may be administered by carefully opening the capsule and sprinkling the entire contents on a spoonful of applesauce. This drug/food mixture should be swallowed immediately without chewing and followed with a glass of water to ensure complete swallowing of the pellets

While the total daily dose usually ranges from 37.5 mg to 225 mg, your healthcare provider will determine the dose that is right for you based upon your response

What happens if I miss a dose of Effexor®?

If you miss a dose of venlafaxine, take it as soon as you remember unless it is close to when your next dose is due. If you missed a dose of medication and it is close to the time of your next dose, skip the missed dose and take your next dose at the regularly scheduled time. Do not double your next dose or take more than your prescribed dose.

What should I avoid while taking Effexor®?

Avoid drinking alcohol or using illegal drugs while you are taking antidepressant medications because the beneficial effects of the medication may be decreased and adverse effects may be increased (e.g. sedation).

What happens if I overdose with Effexor®?

If an overdose occurs, whether intentional or accidental, immediate medical attention may be necessary. Call your doctor or emergency medical service (911). You may also contact the poison control center (1-800-222-1222).

Symptoms of overdose include drowsiness, nausea, vomiting, abdominal pain, tremor, slow heart rate, and seizures. A specific antidote does not exist.

What are the possible side effects of Effexor®?

Side effects with venlafaxine are generally mild and are similar to those reported with other antidepressants. The most commonly reported side effects are increased sweating, sleepiness, insomnia, nausea, diarrhea, tremor, dry mouth, loss of strength, headache, weight loss or gain, dizziness, and restlessness. If you experience side effects after starting venlafaxine they will often improve over the first week or two as you continue to take the medication. Sexual side effects such as problems with ejaculation may also occur, and often do not diminish over time. Venlafaxine has been associated with an increase in blood pressure as well. Patients taking venlafaxine should have their blood pressure checked regularly and patient with preexisting high blood pressure should have the blood pressure under control before starting venlafaxine.

Are there any risks for taking Effexor® for long periods of time?

To date, there are no known problems associated with long term use of venlafaxine. It is a safe and effective medication when used as directed.

What other drugs may interact with Effexor®?

Venlafaxine should not be taken with or within two weeks of taking monoamine oxidase inhibitors (MAOIs). These include phenelzine (Nardil®), tranylcypromine (Parnate®), isocarboxazid (Marplan®) and selegeline (Emsam®).

Although rare, there is an increased risk of serotonin syndrome when venlafaxine is used with other medications that increase serotonin such as other antidepressants, migraine medications called “triptans” (e.g. Imitrex®) and the analgesic tramadol (Ultram®).

Always let your doctor know what other prescription, over-the-counter, and herbal medications you are taking.

How long does it take for Effexor® to work?

While symptoms of depressed mood and lack of interest in activities may need up to 4-6 weeks to improve; disturbances in sleep, energy, or appetite may show some improvement within the first 1-2 weeks. Improvement in these physical symptoms can be an important early signal that the medication is working.

Like other medications used for anxiety disorders (e.g. panic disorder, GAD and social anxiety disorder) venlafaxine may take several weeks before it is fully effective. It is important to give the medication sufficient time before judging whether or not it will work for a given person.

*Updated by
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(March 2007)*



NAMI wishes to thank the College of Psychiatric and Neurological Pharmacists for producing this fact sheet.

Reviewed by Dr. Ken Duckworth, NAMI Medical Director

For further information please contact the pharmaceutical company listed below.

Wyeth	500 Arcola Rd. Collegeville, PA 19426	610-902-1200	www.wyeth.com
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Free or low-cost medications provided by pharmaceutical companies

Some pharmaceutical companies offer medication assistance programs to low-income individuals and families. These programs typically require a doctor's consent and proof of financial status. They may also require that you have either no health insurance, or no prescription drug benefit through your health insurance. Please contact the pharmaceutical company directly for specific eligibility requirements and application information.

Effexor Rx Assistance Program: 1- 800-568-9938