



Venlafaxine hydrochloride (marketed as Effexor)

This is a summary of the most important information about Effexor. For details, talk to your healthcare professional.

FDA ALERT [07/2006] – Possible Life-Threatening Serotonin Syndrome When Used With Triptan Medicines

A life-threatening condition called serotonin syndrome can happen when medicines called serotonin and norepinephrine reuptake inhibitors (SNRIs), such as Effexor, and medicines used to treat migraine headaches known as 5-hydroxytryptamine receptor agonists (triptans), are used together. Signs and symptoms of serotonin syndrome include the following:

- restlessness
- hallucinations
- loss of coordination
- fast heart beat
- increased body temperature
- fast changes in blood pressure
- overactive reflexes
- diarrhea
- coma
- nausea
- vomiting

Serotonin syndrome may be more likely to occur when starting or increasing the dose of an SNRI or a triptan. This information comes from reports sent to FDA and knowledge of how these medicines work. If you take migraine headache medicines, ask your healthcare professional if your medicine is a triptan.

Before you take Effexor and a triptan together, talk to your healthcare professional. If you must take these medicines together, be aware of the possibility of serotonin syndrome, and get medical care right away if you think serotonin syndrome is happening to you.

This information reflects FDA's current analysis of data available to FDA concerning this drug. FDA intends to update this sheet when additional information or analyses become available.

What Is Effexor?

Effexor is in a class of medicines called serotonin and norepinephrine reuptake inhibitors (SNRIs).

Effexor is used to treat depression.

Effexor XR is used to treat:

- Depression
- Generalized anxiety disorder (GAD)
- Social anxiety disorder (SAD)

Who Should Not Take Effexor?

Never take Effexor if you are taking another drug used to treat depression, called a Monoamine Oxidase Inhibitor (MAOI), or if you have stopped taking an MAOI in the last 14 days. Taking Effexor close in time to an MAOI can result in serious, sometimes fatal, reactions, including:

- **High body temperature**
- **Coma**
- **Seizures (convulsions)**

MAOI drugs include Nardil (phenelzine sulfate), Parnate (tranylcypromine sulfate), Marplan (isocarboxazid), and other brands.

What Are The Risks?

- **Possible life-threatening serotonin syndrome when used with triptan medicines:** See FDA Alert [07/2006] above.
- **Suicidal thoughts or actions:** Persons taking Effexor may be more likely to think about killing themselves or actually try to do so, especially when Effexor is first started or the dose is changed. People close to persons taking Effexor can help by paying attention to changes in user's moods or actions. Contact your healthcare professional right away if someone using Effexor talks about or shows signs of killing him or herself. If you are taking Effexor yourself and you start thinking about killing





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yourself, tell your healthcare professional about this side effect right away.

- **Stopping Effexor:** Do not stop taking Effexor suddenly because you could get side effects. Your healthcare professional will slowly decrease your dose.
- **High blood pressure and heart problems:** You may get high blood pressure or a faster heartbeat.
- **Bleeding problems:** Effexor may cause bleeding problems.
- **Mania:** You may become unusually hyperactive, excitable or elated.
- **Seizures:** You may experience a seizure (convulsion), even if you are not taking Effexor close in time with a MAOI.
- **Pregnancy:** Tell your healthcare professional if you are or may be pregnant because babies delivered to mothers taking Effexor late in pregnancy have developed problems, such as difficulty breathing and feeding.
- **Weight loss:** Effexor can cause weight loss.
- **Sexual problems:** You may have problems with impotence (erectile dysfunction), abnormal ejaculation, difficulty reaching orgasm, or decreased libido (sexual desire).
- **Other side effects** include nausea, sleepiness, dry mouth, dizziness, difficulty sleeping and constipation.

- **Tell your healthcare professional** about all your medical conditions, especially if you have liver, kidney, or heart disease, or glaucoma. Tell your healthcare professional if you are breast-feeding or plan to breast-feed your baby.

Are There Any Interactions With Drugs or Foods?

- Effexor may interact with medicines other than the ones already mentioned in this information sheet. These interactions can cause serious side effects. Tell your healthcare professional about all medicines, vitamins, and herbal supplements you take.
- If you plan to drink alcohol, talk to your healthcare professional.

How Do I Take Effexor?

- Effexor is taken by mouth, with food, exactly as prescribed by your healthcare professional.
- Swallow Effexor XR capsules whole. Do not crush or chew them. You may open the capsule, sprinkle the contents on a spoonful of applesauce, and take right away without chewing. Then follow with a glass of water.

Is There Anything Else I Need To Know?

You can get more information about antidepressants at:

<http://www.fda.gov/cder/drug/antidepressants/default.htm>

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