



Patient Information Sheet

Duloxetine hydrochloride (marketed as Cymbalta)

This is a summary of the most important information about Cymbalta. 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 Cymbalta, 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 SSNI 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 Cymbalta 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 Cymbalta?

Cymbalta is in a class of medicines called serotonin and norepinephrine reuptake inhibitors (SNRIs). Cymbalta is used to treat depression.

Who Should Not Take Cymbalta?

- **Never take Cymbalta 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 Cymbalta 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.

- Never take Cymbalta if you have uncontrolled narrow-angle glaucoma (disease causing increased pressure in the eye).
- Do not take Cymbalta if you have serious kidney or liver disease or drink alcohol excessively.

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 Cymbalta may be more likely to think about killing themselves or actually try to do so, especially when Cymbalta is first started or the dose is changed. People close to persons taking Cymbalta can help by paying attention to changes in user's moods or actions. Contact your healthcare professional right away if someone using Cymbalta talks about or shows





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signs of killing him or herself. If you are taking Cymbalta yourself and you start thinking about killing yourself, tell your healthcare professional about this side effect right away.

- **Stopping Cymbalta:** Do not stop taking Cymbalta suddenly because you could get side effects. Your healthcare professional will slowly decrease your dose.
- **Possible liver damage:** Cymbalta may cause liver damage. **Do not drink alcohol** while taking Cymbalta because this can make liver damage worse.
- **Blood pressure:** Your blood pressure may increase.
- **Mania:** You may become unusually hyperactive, excitable or elated.
- **Seizures:** You may experience a seizure (convulsion), even if you are not taking Cymbalta close in time with a MAOI.
- **Pregnancy:** Tell your healthcare professional if you are or may be pregnant because babies delivered to mothers taking Cymbalta late in pregnancy have developed problems, such as difficulty breathing and feeding.
- **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, dry mouth, constipation, decreased appetite, fatigue, sleepiness, and increased sweating.
- **Tell your healthcare professional** about all your medical conditions, especially if you have

liver or kidney 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?

- Cymbalta may interact with medicines other than the ones already mentioned in this information sheet, causing serious side effects. Tell your healthcare professional about all medicines, vitamins, and herbal supplements you take, especially those used to treat anxiety, mental illness, depression, infections, or heart problems.
- **Do not drink alcohol** while taking Cymbalta.

How Do I Take Cymbalta?

- Cymbalta is taken by mouth, with or without food, exactly as prescribed by your healthcare professional.
- Swallow Cymbalta capsules whole. Do not crush or chew them. Do **not** open the capsule and mix the contents with liquid or food.

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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