



Patient Information Sheet

Paroxetine hydrochloride (marketed as Paxil)

This is a summary of the most important information about Paxil. 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 selective serotonin reuptake inhibitors (SSRIs), such as Paxil, 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 SSRI 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 Paxil 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.

FDA ALERT [07/2006] – Infant Persistent Pulmonary Hypertension

The results of a study that looked at the use of antidepressant medicines during pregnancy in mothers of babies born with a serious condition called persistent pulmonary hypertension of the newborn (PPHN) were recently published in a medical journal.

Babies born with PPHN have abnormal blood flow through the heart and lungs and do not get enough oxygen to their bodies. Babies with PPHN can be very sick and may die.

The study results showed that:

- babies born to mothers who took selective serotonin reuptake inhibitors (SSRIs), the family of medicines Paxil belongs to,
- 20 weeks or later in their pregnancies,
- had a higher chance (were 6 times as likely) to have persistent pulmonary hypertension (PPHN),
- than babies born to mothers who did not take antidepressants during pregnancy.

The FDA plans to further look at the role of SSRIs in babies with PPHN.

Talk to your doctor if you are taking Paxil and are pregnant or are planning to have a baby. You and your doctor will need to talk about the best way to treat your depression during pregnancy.

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What Is Paxil?

Paxil is in a class of medicines called selective serotonin reuptake inhibitors (SSRIs).

Paxil tablets and oral suspension are used to treat:

- Depression
- Panic disorder
- Social anxiety disorder (SAD)
- Obsessive-compulsive disorder (OCD)
- Posttraumatic stress disorder (PTSD)
- Generalized anxiety disorder (GAD)

Paxil CR is used to treat:

- Depression
- Panic disorder
- Social anxiety disorder (SAD)
- Premenstrual dysphoric disorder (PMDD)

Who Should Not Take Paxil?

- Never take Paxil 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 Paxil 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 Paxil if you are taking Mellaril (thioridazine), used to treat schizophrenia, because it can result in serious heart beat problems.

What Are The Risks?

The following are the major potential risks and side effects of Paxil therapy. However, this list is not complete.

- **Possible life-threatening serotonin syndrome when used with triptan medicines:** See FDA Alert [07/2006] above.
- **Infant persistent pulmonary hypertension:** See FDA Alert [07/2006] above.
- **Suicidal thoughts or actions:** Persons taking Paxil may be more likely to think about killing themselves or actually try to do so, especially when Paxil is first started or the dose is changed. People close to persons taking Paxil can help by paying attention to changes in user's moods or actions. Contact your healthcare professional right away if someone using Paxil talks about or shows signs of killing him or herself. If you are taking Paxil yourself and you start thinking about killing yourself, tell your healthcare professional about this side effect right away.
- **Stopping Paxil:** Do not stop taking Paxil suddenly because you could get side effects. Your healthcare professional will slowly decrease your dose.
- **Bleeding problems:** Paxil may cause bleeding problems, especially if taken with aspirin, NSAIDs (nonsteroidal anti-inflammatory drugs, such as ibuprofen or naproxen), or other drugs that affect bleeding.
- **Mania:** You may become hyperactive, excitable or elated.
- **Seizures:** You may experience a seizure (convulsion) even if you are not taking Paxil close in time with a MAOI.





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- **Pregnancy:** Tell your healthcare professional if you are or may be pregnant (see **FDA Alert [07/2006] above**). In addition to the issue described in the alert, babies delivered to mothers taking Paxil late in pregnancy have developed problems, such as difficulty breathing and feeding. Babies delivered to mothers taking Paxil early in pregnancy are sometimes born with heart problems.
- **Sexual problems:** You may have problems with impotence (erectile dysfunction), abnormal ejaculation, difficulty reaching orgasm, or decreased libido (sexual desire).
- **Other side effects** include weakness, dry mouth, constipation, yawning, infection, diarrhea, sweating, dizziness, tremor, nervousness, nausea, difficulty sleeping, decreased appetite, and sleepiness.
- **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?

- Paxil 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 Paxil?

- Paxil is taken by mouth, with or without food, once a day.
- Swallow Paxil tablets whole. Do not crush or chew them.

Is There Anything Else I Need to Know?

You can get more information about antidepressants at:

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

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