

Paxil (paroxetine hydrochloride)

FDA Alerts

[12/2005] Increase in the Risk of Birth Defects

Early results of new studies show that paroxetine increases the risk of birth defects, particularly heart defects, when women take it during the first three months of pregnancy. Paroxetine should usually not be taken during pregnancy, but for some women who have already been taking paroxetine, the benefits of continuing paroxetine may be greater than the potential risk to the baby. Women taking paroxetine who are pregnant, think they may be pregnant, or plan to become pregnant should talk to their physicians about the potential risks of taking paroxetine during pregnancy.

The early results of two studies showed that women who took paroxetine (Paxil) during the first three months of pregnancy were about one and a half to two times as likely to have a baby with a heart defect as women who received other antidepressants, and women in the general population. Most of the heart defects in these studies were not life-threatening, and happened mainly in the inside walls of the heart muscle where repairs can be done if needed (atrial and ventricular septal defects). Sometimes these septal defects resolve without treatment. In one of the studies, the risk of heart defects in babies whose mothers had taken paroxetine early in pregnancy was 2%, compared to a 1% risk in the whole population. In the other study, the risk of heart defects in babies whose mothers had taken paroxetine in the first three months of pregnancy was 1.5%, compared to 1% in babies whose mothers had taken other antidepressants in the first three months of pregnancy. This study also showed that women who took paroxetine in the first three months of pregnancy were about twice as likely to have a baby with any birth defect as women who took other antidepressants.

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) was 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 PPHN than babies born to mothers who did not take antidepressants during pregnancy (6-12 per 1000 births versus 1-2 per 1000 births).

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.

This information reflects the FDA's current analysis of data available to FDA concerning this drug

FDA ALERT [07/2006] – Potentially 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 “triptans” (e.g. sumatriptan/ Imitrex[®]) are used together. Signs and symptoms of serotonin syndrome may include: restlessness, hallucinations, loss of coordination, fast heart beat, increased body temperature, fast changes in blood pressure, overactive reflexes, diarrhea, nausea, vomiting and coma.

Serotonin syndrome may be more likely to occur when starting or increasing the dose of an SSRI or 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 the FDA's current analysis of data available to FDA concerning this drug

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 PAXIL 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. PAXIL is not approved for use in pediatric patients.

Brand and Generic Names:

- Brand names = Paxil[®], Paxil CR[®], Pexeva[®]

Tablets (immediate release): 10 mg, 20 mg, 30mg, 40 mg

Tablets (controlled release): 12.5 mg, 25 mg, 37.5 mg

Liquid: 10 mg / 5 ml oral solution (orange flavor)

- Generic names = paroxetine hydrochloride, paroxetine mesylate

What is Paxil[®] and what does it treat?

Paroxetine is an antidepressant medication that works in the brain. It is approved for the treatment of Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD), social anxiety disorder (social phobia), panic disorder, Obsessive Compulsive Disorder (OCD), Posttraumatic Stress Disorder (PTSD), and Premenstrual Dysphoric Disorder (PMDD).

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.

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

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.

OCD occurs when a person experiences the following symptoms at the same time: obsessions (unwanted, recurrent and disturbing thoughts) and compulsions (repetitive, ritualized behaviors that the person feels driven to perform in order to lessen the anxiety produced by the obsessions).

PTSD occurs when a person experiences a traumatic event (e.g. assault, combat experience) and then later experiences flashbacks, nightmares, feels on edge and avoids situations that remind them of the event.

PMDD occurs when a woman experiences symptoms including irritability, mood changes, bloating, tension, breast tenderness and sadness in association with the menstrual cycle.

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

After starting paroxetine, 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 paroxetine or change your dose without talking to with your healthcare provider first.

Stopping paroxetine 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 Paxil® 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. This is a complex decision as untreated MDD or depression relapse may have negative consequences for

both the fetus and the mother. There are many dimensions to these choices, so be sure to confer with your doctor and caregivers.

For mothers who have taken SSRIs during their pregnancy, there appears to be less than a 1% chance of infants developing persistent pulmonary hypertension. This is a potentially fatal condition that is associated with use of the antidepressant in the second half of pregnancy. However, women who discontinued antidepressant therapy were five times more likely to have a depression relapse than those who continued their antidepressant. Paroxetine has been shown to increase risk of cardiac defects over that of other antidepressants (1.5% vs. 1%) and has been associated with an increased risk of birth defects when compared to the general population (2% vs. 1%).

Untreated depression or depression relapse may have negative consequences for both the fetus and the mother. If you are pregnant, please discuss the risks and benefits of this medication use with your healthcare provider.

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

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

- 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
- 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 Paxil®?

Paroxetine is usually taken once daily with or without food. It may be taken with food to minimize stomach upset..

While the dose of paroxetine usually ranges from 10 mg to 40 mg (50 mg for controlled release), your healthcare provider will determine the dose that is right for you based upon your response.

When used for PMDD, paroxetine may be taken continuously (every day) or intermittently (usually starting 14 days prior to the anticipated onset of menstruation through the first full day of menses and repeating with each cycle). Your healthcare provider will determine the regimen that is right for you.

What happens if I miss a dose of Paxil®?

If you miss a dose of paroxetine, 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 Paxil®?

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 Paxil®?

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 Paxil®?

Side effects with paroxetine are generally mild and are similar to those reported with other SSRI 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 paroxetine 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.

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

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

What other drugs may interact with Paxil®?

Paroxetine 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 paroxetine 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 Paxil® to work?

While 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) paroxetine 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.

GlaxoSmithKline	One Franklin Plaza P.O Box 7929 Philadelphia, PA 19101	888-825-5249	www.gsk.com
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Paxil Rx Assistance Program: 1-866-728-4368