

Zoloft (sertraline)

FDA Alerts

FDA ALERT [05/2007] Suicidal Thoughts or Actions in Children and Adults

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 Zoloft® 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. Zoloft® is not approved for use in pediatric patients except for patients with obsessive compulsive disorder (OCD).

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 Zoloft®, 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 Zoloft® 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 [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 Zoloft® 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 Zoloft® 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.

Brand and Generic Names:

- Brand name = Zoloft®

Tablets: 25 mg, 50 mg, 100 mg

Liquid: 20 mg/ml

- Generic name = sertraline

What is Zoloft® and what does it treat?

Sertraline is an antidepressant medication that works in the brain. It is approved for the treatment of Major Depressive Disorder (MDD), Post-traumatic Stress Disorder (PTSD), Premenstrual Dysphoric Disorder (PMDD), as well as Obsessive Compulsive Disorder (OCD) in adults and children.

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).

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.

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).

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

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

Stopping sertraline 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 Zoloft® 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 antidepressants that are similar to sertraline in the second half of pregnancy. However, women who discontinued medication therapy were five times more likely to have a depression relapse than those who continued their antidepressant. 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 sertraline does pass into breast milk.

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

- 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 Zoloft®?

Sertraline is usually taken once daily (at the same time each day). It may be taken with food to minimize stomach upset. If a dose is taken twice a day, take one in the morning and the second dose at noon.

While the dose usually ranges from 50mg to 200 mg, 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.

If you are taking the sertraline oral concentrate, mix your prescribed dose with 4 ounces (oz) of water, ginger ale, lemon-lime soda, lemonade or orange juice. Take it immediately after mixing it with your beverage. Do not mix it with anything other than the liquids listed. Do not mix your dosage in advance. A slight haze may appear after mixing; this is normal.

Note that caution should be exercised with latex sensitivity, as the dropper dispenser provided with sertraline oral concentrate contains dry natural rubber

What happens if I miss a dose of Zoloft®?

If you miss a dose of sertraline, 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 Zoloft®?

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 Zoloft®?

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 Zoloft®?

Side effects with sertraline 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 sertraline 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 Zoloft® for long periods of time?

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

What other drugs may interact with Zoloft®?

Sertraline 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 sertraline 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.

Sertraline Oral Concentrate should **NOT** be taken in combination with disulfiram (Antabuse®) due to the alcohol content of the concentrate.

How long does it take for Zoloft® 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) sertraline 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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(April 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.

Pfizer, Inc.	235 East 42 nd St. New York, NY 10017-5755	800-438-1985	www.pfizer.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.

Zoloft Rx Assistance Program: 1-800-646-4455