

Are allergic to sertraline or any of the inactive ingredients in ZOLOFT

Take Antabuse® (disulfiram) (if you are taking the liquid form of ZOLOFT) due to the alcohol content of the liquid form of ZOLOFT

Call a doctor right away if you or a person you know who is taking ZOLOFT has any of the following symptoms, especially if they are new, worse, or worry you:

- Attempts to commit suicide
- Acting aggressive or violent
- New or worse depression
- Feeling agitated, restless, angry, or irritable
- An increase in activity or talking more than what is normal for you
- Acting on dangerous impulses
- Thoughts about suicide or dying
- New or worse anxiety or panic attacks
- Trouble sleeping
- Other unusual changes in behavior or mood

*RUNNING THIRTY FEET-STRAIGHT AT SOMEONE
HOLDING A HANDGUN-ACKNOWLEDGED VERBALLY*

Depression or other serious mental illnesses are the most important causes of suicidal thoughts or actions. Watch for these changes and call your healthcare provider right away if you notice new or sudden changes in mood, behavior, actions, thoughts, or feelings, especially if severe. Keep all follow-up visits with your healthcare provider and call between visits if you are worried about symptoms.

Before taking ZOLOFT, tell your doctor and pharmacist about all prescription and over-the-counter medications and supplements you take or plan to take including: those to treat migraines, psychiatric disorders (including other antidepressants or amphetamines) to avoid a potentially life-threatening condition called serotonin syndrome; aspirin, other NSAID pain relievers, or other blood thinners because they may increase the risk of bleeding.

Tell your doctor immediately if you

- Become severely ill and have some or all of these symptoms: agitation, hallucinations, coma, or other changes in mental status; coordination problems or muscle twitching (overactive reflexes); racing heartbeat, high or low blood pressure; sweating or fever; nausea, vomiting, or diarrhea; muscle tightness, as these may be the symptoms of a life-threatening condition called Serotonin Syndrome
- Have a rash, hives, swelling, or trouble breathing as these may be the symptoms of an allergic reaction
- Have seizures or convulsions
- Have any increased or unusual bruising or bleeding, especially if you take the blood thinner warfarin (Coumadin®, Jantoven®), a non-steroidal anti-inflammatory drug (NSAID), or aspirin
- Have a headache; weakness or feeling unsteady; confusion, problems concentrating, thinking, or remembering, as these may be the symptoms of low salt (sodium) levels in the blood (hyponatremia). Elderly people may be at greater risk for this
- Do not stop ZOLOFT without first talking to your healthcare provider.** Stopping ZOLOFT may cause serious symptoms, including anxiety, irritability, high or low mood, feeling restless or sleepy; headache, sweating, nausea, dizziness; electric shock-like sensations, shaking, and confusion.

Some people are at risk for visual problems such as eye pain, changes in vision, or swelling or redness around the eye. You may want to undergo an eye examination to see if you are at risk and get preventative treatment if you are.

ZOLOFT can cause sleepiness or may affect your ability to make decisions, think clearly, or react quickly. You should not drive, operate heavy machinery, or do other dangerous activities until you know how ZOLOFT affects you.

Drinking alcohol while taking ZOLOFT is not recommended.

Women who are pregnant, plan to become pregnant, or who are breastfeeding should not take ZOLOFT without consulting their physician.

The most common side effects in adults treated with ZOLOFT include:

- Nausea, loss of appetite, diarrhea, or indigestion
- Increased sweating
- Tremor or shaking
- Agitation
- Change in sleep habits including increased sleepiness or insomnia
- Sexual problems including decreased libido and ejaculation failure
- Feeling tired or fatigued
- Anxiety

In children and adolescents treated with ZOLOFT, adverse reactions were generally similar to those seen in adults with the following additional side effects: abnormal increase in muscle movement or agitation, nose bleeds, urinary incontinence, aggressive reaction, possible slowed growth rate, and weight change.

INDICATIONS

ZOLOFT is a prescription medication for the treatment, in adults, of Major Depressive Disorder (MDD), Obsessive-Compulsive Disorder (OCD), Panic Disorder, Posttraumatic Stress Disorder (PTSD), Premenstrual Dysphoric Disorder (PMDD), and Social Anxiety Disorder. It is also approved to treat Obsessive Compulsive Disorder (OCD) in children and adolescents aged 6-17 years.

Product names referenced herein are trademarks of their respective owners.

Please see **Full Prescribing Information, including BOXED WARNING and Medication Guide.**