# Zoloft (sertraline)

Generic name: Sertraline Available strengths: 25 mg, 50 mg, 100 mg tablets; 20 mg/mL oral concentrate Available in generic: Yes Drug class: Selective serotonin reuptake inhibitor antidepressant

#### **General Information**

**Zoloft (sertraline)** was approved by the U.S. Food and Drug Administration (FDA) for treatment of major depressive disorder, panic disorder, obsessive-compulsive disorder, social anxiety disorder, premenstrual dysphoric disorder, and posttraumatic stress disorder. The use of a medication for its approved indications is called its *labeled use*. In clinical practice, however, physicians often prescribe medications for *unlabeled* ("off-label") uses when published clinical studies, case reports, or their own clinical experiences support the efficacy and safety of those treatments. Zoloft may be used to treat other psychiatric disorders, including generalized anxiety disorder.

Zoloft is a **serotonin**-specific medication that works by blocking the reuptake of the neurotransmitter serotonin back into brain cells, thereby increasing its levels in the brain. Depression and other mental disorders may be caused by abnormally low levels of serotonin. This abnormality may in turn produce changes in affected areas of the brain, resulting in psychiatric symptoms such as depression or anxiety. The presumed action of Zoloft and other selective serotonin reuptake inhibitors (SSRIs) is to increase serotonin levels, which may help to restore those areas of the brain to normal functioning.

## **Dosing Information**

For depression, the usual starting dose of Zoloft is 50 mg, once a day, which is best taken in the morning. Seniors and people with chronic or severe medical illnesses may require a lower starting dose of 25 mg, taken once a day. For patients with an anxiety disorder, such as panic disorder, the usual starting daily dose is also 25 mg. If no improvement is seen after 3–4 weeks, the dosage of Zoloft may be increased in increments of 50 mg/day to a maximum of 200 mg/day. Treatment of other psychiatric disorders usually requires higher dosages than those used in treating depression. For patients who cannot take a tablet, Zoloft also comes in a liquid form.

For most people, it may take as long as 3–4 weeks to experience the optimal effects of the medication. The duration of medication treatment depends on the individual's personal psychiatric history and family history.

For instance, the length of medication treatment will be longer for those who have had two or more previous episodes of major depressive disorder. For most people, the medication may be tapered 6 months after their depression responds to treatment. However, a small percentage of patients will continue to have depressive symptoms after their antidepressant is reduced or stopped. These individuals may benefit from continuing to take Zoloft for 1 year or longer.

#### **Common Side Effects**

The most frequently reported side effects with Zoloft are gastrointestinal disturbance, principally nausea, vomiting, indigestion, diarrhea, or loose stools. Nervousness, jitteriness, and trouble sleeping are other commonly reported side effects. Occasionally, individuals may experience headaches, sleepiness, and excessive sweating.

Zoloft may induce sexual dysfunction in both men and women. The sexual side effects reported are delayed orgasm in women and retarded ejaculation in men. Some people may experience decreased desire or lack of interest in sexual activity. However, the adverse effects on sexual function with Zoloft are generally less frequent than with Prozac or Paxil.

Patients should discuss these side effects with their physician, especially if they continue to be bothersome 3–4 weeks after the medication is started. If a rash or any other severe symptoms develop, patients should contact their physician immediately.

#### **Adverse Reactions and Precautions**

Zoloft may cause drowsiness in some people. Patients should not drive or operate machinery until they are certain that their alertness or coordination is not affected by the medication. Patients with a known allergy to Zoloft or who have experienced a severe reaction after taking it should not take Zoloft.

## Use in Pregnancy and Breastfeeding: Pregnancy Category C

Zoloft has not been tested in women to determine its safety in pregnancy. The effects of the medication on the developing fetus in pregnant women are unknown. However, newborn babies exposed to antidepressants such as SSRIs late in the third trimester developed complications requiring prolonged hospitalization, respiratory support, and tube feeding. Women who are pregnant or may become pregnant should discuss this with their physician. Some women may experience a recurrence of their depression when they stop their antidepressant. In these circumstances it may be necessary to restart the medication or seek an alternative medication or treatment.

Nursing mothers should not take Zoloft, because small amounts will pass into breast milk and be ingested by the baby. If stopping the antidepressant is not an alternative, breastfeeding should not be started or should be discontinued.

## **Possible Drug Interactions**

The combined use of Zoloft with certain other medications may result in adverse drug interactions, because one medication may alter the blood levels of the other. The clinically significant drug interactions reported with Zoloft are summarized in the table on the next page.

Coumadin (warfarin)	Zoloft may increase the anticoagulant action of Coumadin and increase risk of bleeding.
Tricyclic antidepressants (TCAs)	Zoloft may increase the levels of TCAs, primarily desipramine (Norpramin) and imipramine (Tofranil), and the potential for toxicity.
Tagamet (cimetidine)	Tagamet may increase the level of Zoloft and increase the potential for side effects.

Other medications, including herbal supplements (such as St. John's wort), that boost serotonin may result in excessive levels of that neurotransmitter when combined with Zoloft and produce a toxic syndrome known as **serotonin syndrome**. The early signs of serotonin syndrome are restlessness, confusion, tremors, flushing, and involuntary muscle jerks. If the medications are not stopped, the individual may develop more life-threatening complications resulting in muscle disorders, high fever, respiratory problems, clotting problems, and destruction of red blood cells that may lead to acute renal failure. Patients taking Zoloft should be alert to the possible signs of serotonin syndrome, which require immediate medical attention and discontinuation of the serotonin-boosting medications.

Antidepressants known as **monoamine oxidase inhibitors** (MAOIs) should not be taken together with Zoloft, because the combination may potentially produce a toxic reaction that includes elevated temperature, high blood pressure, and extreme excitation and agitation. Patients should consult their physician or pharmacist before taking any new medications, including over-the-counter medications and herbal supplements, with Zoloft.

Patients taking Zoloft should avoid alcohol or should consume it in moderation because the combination may worsen depression.

#### Overdose

Like other SSRIs, Zoloft is much safer in overdose than the older TCAs and some of the newer antidepressants. There are no reports of fatality after overdose with Zoloft alone. However, fatal outcomes have been reported when Zoloft was taken in combination with other medications.

Any suspected overdose should be treated as an emergency. The person should be taken to the emergency room for observation and treatment. The prescription bottle of medication (and any other medication suspected in the overdose) should be brought as well, because the information on the prescription label can be helpful to the treating physician in determining the number of pills ingested.

#### **Special Considerations**

Most cases of major depression can be treated successfully, usually with medication, psychotherapy, or both. The combination of psychotherapy and antidepressants is very effective in treating moderate to severe depression. The medications improve mood, sleep, energy, and appetite while therapy strengthens coping skills, deals with possible underlying issues, and improves thought patterns and behavior.

In general, antidepressants alone help about 60%–70% of those taking them. Although a few individuals may experience some improvement from antidepressants by the end of the first week, most people do not see significant benefits from their antidepressants until after 3–4 weeks, and it can sometimes take as long as 8 weeks for the medication to produce its full effects. Thus it is critical that patients continue to take their antidepressant long enough for the medication to be beneficial and that patients not get discouraged and stop their medication prematurely if they do not feel better immediately.

In short-term studies, antidepressants were found to increase the risk of suicidal thinking and behavior in children and adolescents with major depression and other psychiatric disorders. The FDA requires the prescriber to warn of this risk in children and adolescents when starting antidepressant therapy. According to the FDA findings, the risk of suicidal thoughts and behaviors associated with antidepressants is age-related. This phenomenon tends to occur in the younger population and is most likely to occur early in the course of treatment. In adults over 24 years of age, there did not appear to be an increased risk of suicidality with anti-depressants compared with placebo. In patients over age 65, the findings showed that antidepressants had a "protective effect" against suicidal thoughts and behavior. Other studies have found that when more people in a community are taking antidepressants, the suicide rate is lower.

The risk of suicide is inherent in depression and may persist until the individual responds to treatment. After starting or changing antidepressant therapy, the person, especially a child or adolescent, should be closely observed for worsening signs of depression, and the family or caregiver should communicate any concerns to the physician.

- **Warning:** Always let your physician or a family member know if you have suicidal thoughts. Notify your psychiatrist or your family physician whenever your depressive symptoms worsen or whenever you feel unable to control suicidal urges or thoughts.
- Do not discontinue Zoloft abruptly. Your dosage should be tapered gradually to prevent discontinuation symptoms.
- If you miss a dose, take it as soon as possible, within 2–3 hours of the scheduled dose. If it is close to the next scheduled dose, skip the missed dose and continue on your regular dosing schedule. Do not take double doses.
- Zoloft may be taken with or without food.
- Store the medication in its originally labeled, light-resistant container, away from heat and moisture. Heat and moisture may precipitate breakdown of your medication, and the medication may lose its therapeutic effects.
- Keep your medication out of reach of children.

#### If you have any questions about your medication, consult your physician or pharmacist.

#### **Notes**

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