

Medication Guide
ZOLOFT (ZOH-loft)
(sertraline hydrochloride)
(Tablets and Oral Concentrate (solution))

Read the Medication Guide that comes with ZOLOFT before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or treatment. Talk with your healthcare provider if there is something you do not understand or want to learn more about.

What is the most important information I should know about ZOLOFT?

ZOLOFT and other antidepressant medicines may cause serious side effects, including:

1. Suicidal thoughts or actions:

- **ZOLOFT and other antidepressant medicines may increase suicidal thoughts or actions** in some children, teenagers, or young adults within the **first few months of treatment or when the dose is changed**.
- 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.
 - Pay particular attention to such changes when ZOLOFT is started or when the dose is changed.

Keep all follow-up visits with your healthcare provider and call between visits if you are worried about symptoms.

Call your healthcare provider right away if you have any of the following symptoms, or call 911 if an emergency, especially if they are new, worse, or worry you:

- attempts to commit suicide
- acting on dangerous impulses
- acting aggressive or violent
- thoughts about suicide or dying
- new or worse depression
- new or worse anxiety or panic attacks
- feeling agitated, restless, angry or irritable
- trouble sleeping
- an increase in activity or talking more than what is normal for you
- other unusual changes in behavior or mood

Call your healthcare provider right away if you have any of the following symptoms, or call 911 if an emergency. ZOLOFT may be associated with these serious side effects:

2. Serotonin Syndrome or Neuroleptic Malignant Syndrome-like reactions. This condition can be life-threatening and may include:

- 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 rigidity

3. Severe allergic reactions:

- trouble breathing
- swelling of the face, tongue, eyes or mouth
- rash, itchy welts (hives) or blisters, alone or with fever or joint pain

4. Abnormal bleeding: ZOLOFT and other antidepressant medicines may increase your risk of bleeding or bruising, especially if you take the blood thinner warfarin (Coumadin[®], Jantoven[®]), a non-steroidal anti-inflammatory drug (NSAIDs, like ibuprofen or naproxen), or aspirin.

5. Seizures or convulsions

6. Manic episodes:

- greatly increased energy

- severe trouble sleeping
- racing thoughts
- reckless behavior
- unusually grand ideas
- excessive happiness or irritability
- talking more or faster than usual

7. Changes in appetite or weight. Children and adolescents should have height and weight monitored during treatment.

8. Low salt (sodium) levels in the blood. Elderly people may be at greater risk for this. Symptoms may include:

- headache
- weakness or feeling unsteady
- confusion, problems concentrating or thinking or memory problems

Do not stop ZOLOFT without first talking to your healthcare provider. Stopping ZOLOFT too quickly may cause serious symptoms including:

- anxiety, irritability, high or low mood, feeling restless or changes in sleep habits
- headache, sweating, nausea, dizziness
- electric shock-like sensations, shaking, confusion

What is ZOLOFT?

ZOLOFT is a prescription medicine used to treat depression. It is important to talk with your healthcare provider about the risks of treating depression and also the risks of not treating it. You should discuss all treatment choices with your healthcare provider. ZOLOFT is also used to treat:

- Major Depressive Disorder (MDD)
- Obsessive Compulsive Disorder (OCD)
- Panic Disorder
- Posttraumatic Stress Disorder (PTSD)
- Social Anxiety Disorder
- Premenstrual Dysphoric Disorder (PMDD)

Talk to your healthcare provider if you do not think that your condition is getting better with ZOLOFT treatment.

Who should not take ZOLOFT?

Do not take ZOLOFT if you:

- are allergic to sertraline or any of the ingredients in ZOLOFT. See the end of this Medication Guide for a complete list of ingredients in ZOLOFT.
- **take the antipsychotic medicine pimozide (Orap[®]) because this can cause serious heart problems.**
- take Antabuse[®] (disulfiram) (if you are taking the liquid form of ZOLOFT) due to the alcohol content.
- take a Monoamine Oxidase Inhibitor (MAOI). Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI, including the antibiotic linezolid.
 - Do not take an MAOI within 2 weeks of stopping ZOLOFT.
 - Do not start ZOLOFT if you stopped taking an MAOI in the last 2 weeks.

People who take ZOLOFT close in time to an MAOI may have serious or even life-threatening side effects. Get medical help right away if you have any of these symptoms:

- high fever
- uncontrolled muscle spasms

- stiff muscles
- rapid changes in heart rate or blood pressure
- confusion
- loss of consciousness (pass out)

What should I tell my healthcare provider before taking ZOLOFT? Ask if you are not sure.

Before starting ZOLOFT, tell your healthcare provider if you:

- Are taking certain drugs such as:
 - Medicines used to treat migraine headaches such as:
 - triptans
 - Medicines used to treat mood, anxiety, psychotic or thought disorders, such as:
 - tricyclic antidepressants
 - lithium
 - diazepam
 - SSRIs
 - SNRIs
 - antipsychotic drugs
 - valproate
 - Medicines used to treat seizures such as:
 - phenytoin
 - Medicines used to treat pain such as:
 - tramadol
 - Medicines used to thin your blood such as:
 - warfarin
 - Medicines used to control your heartbeat such as :
 - propafenone
 - flecainide
 - digitoxin
 - Medicines used to treat type II diabetes such as:
 - tolbutamide
 - Cimetidine used to treat heartburn
 - Over-the-counter medicines or supplements such as:
 - Aspirin or other NSAIDs
 - tryptophan
 - St. John's Wort
- have liver problems
- have kidney problems.
- have heart problems
- have or had seizures or convulsions
- have bipolar disorder or mania
- have low sodium levels in your blood
- have a history of a stroke
- have high blood pressure
- have or had bleeding problems
- are pregnant or plan to become pregnant. It is not known if ZOLOFT will harm your unborn baby. Talk to your healthcare provider about the benefits and risks of treating depression during pregnancy.
- are breast-feeding or plan to breast-feed. Some ZOLOFT may pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby while taking ZOLOFT.

Tell your healthcare provider about all the medicines that you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. ZOLOFT and some medicines may interact with each other, may not work as well, or may cause serious side effects.

Your healthcare provider or pharmacist can tell you if it is safe to take ZOLOFT with your other medicines. Do not start or stop any medicine while taking ZOLOFT without talking to your healthcare provider first.

If you take ZOLOFT, you should not take any other medicines that contain sertraline (sertraline HCl, sertraline hydrochloride, etc.).

How should I take ZOLOFT?

- Take ZOLOFT exactly as prescribed. Your healthcare provider may need to change the dose of ZOLOFT until it is the right dose for you.
- ZOLOFT Tablets may be taken with or without food.
- ZOLOFT Oral Concentrate must be diluted before use:
 - Follow the instructions carefully
 - When diluting ZOLOFT Oral Concentrate, use ONLY water, ginger ale, lemon/lime soda, lemonade, or orange juice.
 - If you are sensitive to latex, be careful when using the dropper to dispense the Oral Concentrate.
- If you miss a dose of ZOLOFT, take the missed dose as soon as you remember. If it is almost time for the next dose, skip the missed dose and take your next dose at the regular time. Do not take two doses of ZOLOFT at the same time.
- If you take too much ZOLOFT, call your healthcare provider or poison control center right away, or get emergency treatment.

What should I avoid while taking ZOLOFT?

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. Do not drink alcohol while using ZOLOFT.

What are the possible side effects of ZOLOFT?

ZOLOFT may cause serious side effects, including:

- See “What is the most important information I should know about ZOLOFT?”
- **Feeling anxious or trouble sleeping**

Common possible side effects in people who take ZOLOFT include:

- nausea, loss of appetite, diarrhea or indigestion
- change in sleep habits including increased sleepiness or insomnia
- increased sweating
- sexual problems including decreased libido and ejaculation failure
- tremor or shaking
- feeling tired or fatigued
- agitation

Other side effects in children and adolescents include:

- abnormal increase in muscle movement or agitation
- nose bleed
- urinating more often

- urinary incontinence
- aggressive reaction
- heavy menstrual periods
- possible slowed growth rate and weight change. Your child's height and weight should be monitored during treatment with ZOLOFT.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of ZOLOFT. For more information, ask your healthcare provider or pharmacist.

CALL YOUR DOCTOR FOR MEDICAL ADVICE ABOUT SIDE EFFECTS. YOU MAY REPORT SIDE EFFECTS TO THE FDA AT 1-800-FDA-1088.

How should I store ZOLOFT?

- Store ZOLOFT at room temperature, between 59°F and 86°F (15°C to 30°C).
- Keep ZOLOFT bottle closed tightly.

Keep ZOLOFT and all medicines out of the reach of children.

General information about ZOLOFT

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ZOLOFT for a condition for which it was not prescribed. Do not give ZOLOFT to other people, even if they have the same condition. It may harm them.

This Medication Guide summarizes the most important information about ZOLOFT. If you would like more information, talk with your healthcare provider. You may ask your healthcare provider or pharmacist for information about ZOLOFT that is written for healthcare professionals.

For more information about ZOLOFT call 1-800-438-1985 or go to www.pfizer.com

What are the ingredients in ZOLOFT?

Active ingredient: sertraline hydrochloride

Inactive ingredients

- **Tablets:** dibasic calcium phosphate dihydrate, D&C Yellow #10 aluminum lake (in 25 mg tablet), FD&C Blue #1 aluminum lake (in 25 mg tablet), FD&C Red #40 aluminum lake (in 25 mg tablet), FD&C Blue #2 aluminum lake (in 50 mg tablet), hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, sodium starch glycolate, synthetic yellow iron oxide (in 100 mg tablet), and titanium dioxide
- **Oral concentration:** glycerin, alcohol (12%), menthol, butylated hydroxytoluene (BHT)

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This Medication Guide has been approved by the U.S. Food and Drug Administration.