

PATIENT SUMMARY OF INFORMATION ABOUT



This summary contains important information about ZOLOFT.

It is not meant to take the place of your doctor's instructions. Read this information carefully before you start taking ZOLOFT. Ask your doctor or pharmacist if you do not understand any of this information or if you want to know more about ZOLOFT.

What Conditions Does ZOLOFT Treat?

ZOLOFT is a prescription medicine used to treat depression, panic disorder, obsessive-compulsive disorder (also called OCD) and posttraumatic stress disorder (also called PTSD) in adults. ZOLOFT is also used to treat OCD in children (ages 6-12) and adolescents (ages 12-17).

Depression

Symptoms of depression vary from person to person. You may have depression if you have five or more of the following symptoms and you have these symptoms almost all of the time during the same two-week period or longer. At least one of the symptoms must be a "sad" feeling that will not go away or a loss of interest or pleasure in most activities. Other symptoms are:

- changes in sleeping patterns
- restlessness or slowed movements
- fatigue or lack of energy
- changes in appetite or weight
- feeling worthless or guilty for no real reason
- trouble concentrating or making decisions
- repeated thoughts of death or suicide

In depression, these symptoms interfere with your day-to-day activities.

Panic Disorder

People with panic disorder have repeated, unexpected panic attacks. A **panic attack** is an unexpected attack of fear, anxiety or discomfort with at least four or more of the following symptoms that develop suddenly and usually reach a peak within 10 minutes:

- fast heart rate or pounding heart
- chest pain or discomfort
- sweating
- trembling or shaking
- shortness of breath or a feeling of smothering
- choking feeling
- nausea or upset stomach
- dizziness or feeling faint
- numbness or tingling
- chills or hot flashes
- feeling out of touch with reality
- fear of losing control
- fear of dying

In panic disorder, the panic attack(s) are followed by one month or longer of concern about having more attacks, or concern about what effect the panic attack(s) may have, or having a change in behavior.

Obsessive-Compulsive Disorder (OCD)

In OCD, a person may have two types of symptoms called obsessions or compulsions.

Obsessions: These are unwanted thoughts that stay in a person's mind. Even though the person knows these thoughts do not make sense, they cannot get rid of them. These thoughts can be frightening and embarrassing.

Compulsions: These are actions or thoughts that a person does over and over again to get rid of their unwanted thoughts. They believe this will help prevent something terrible from happening. These repeated actions may take hours to perform and can interfere with daily life.

Posttraumatic Stress Disorder (PTSD)

People with PTSD suffer from symptoms because they suffered, witnessed or learned of a life-threatening event or other serious event and felt intense fear, helplessness or horror because of the event.

A person with PTSD must have one or more symptoms from each of the following categories for at least a month and these symptoms must seriously interfere with being able to lead a normal life.

- Reliving the event through upsetting thoughts, nightmares or flashbacks, or having very strong mental and physical reactions if something reminds the person of the event.
- Avoiding activities, thoughts, feelings or conversations that remind the person of the event; feeling numb to one's surroundings; or being unable to remember details of the event. Having a loss of interest in important activities, feeling all alone, being unable to have normal emotions or feeling that there is nothing to look forward to in the future may also be experienced.
- Feeling that one can never relax and must be on guard all the time to protect oneself, trouble sleeping, feeling irritable, overreacting when startled, angry outbursts or trouble concentrating.

ZOLOFT is approved to treat PTSD in both men and women. More women than men experience PTSD. There were three times more women than men in ZOLOFT PTSD clinical studies, and in these studies women responded better to ZOLOFT than men. What this means to the treatment of a patient is unknown. Only a doctor can determine if ZOLOFT is right for a patient.

How ZOLOFT Works

Everyone has a normal substance in the brain called serotonin. It is thought that not having enough serotonin may contribute to depression, panic disorder, OCD and PTSD. How ZOLOFT works for all of these conditions is not known. What is known is that ZOLOFT may help correct the chemical imbalance of serotonin in the brain. This helps relieve your symptoms. It may take several weeks for your symptoms to get better.

ZOLOFT Is Not For Everyone

While you are taking ZOLOFT, you should never take a monoamine oxidase inhibitor (MAOI) medicine. MAOI medicines are used to treat depression and other conditions. If you have been taking an MAOI, you must stop the MAOI *at least 14 days* before you start taking ZOLOFT. In addition, you must wait *at least 14 days* after stopping ZOLOFT before you can safely start taking an MAOI medicine. A very serious reaction or even death could occur if ZOLOFT is taken at the same time as an MAOI medicine. Be sure to ask your doctor or pharmacist if any medicine you are taking is an MAOI.

The liquid form of ZOLOFT contains alcohol and should not be taken if you are taking Antabuse (disulfiram).

What To Tell Your Doctor Before You Start ZOLOFT

Only your doctor can decide if ZOLOFT is right for you. Before you start ZOLOFT, be sure to tell your doctor if you:

- are taking or have taken any prescription medicines within the past 14 days
- are taking or have taken any over-the-counter medicines you can buy without a prescription, including natural/herbal remedies, within the past 14 days
- have had any liver problems
- have ever had a seizure
- are pregnant, plan to become pregnant, think you might be pregnant or are breast-feeding
- are allergic to any medicines or latex
- have ever had an allergic reaction to sertraline or any of the other ingredients of ZOLOFT tablets or Oral Concentrate. Ask your doctor or pharmacist for a list of these ingredients if you have any questions.

ZOLOFT And Other Medicines

Some medicines can affect how ZOLOFT works. Check with your doctor or pharmacist before starting any new prescription or non-prescription medicines, including natural/herbal remedies. Do not stop any of your other medicines while you are on ZOLOFT without checking with your doctor.

How To Take ZOLOFT

ZOLOFT comes in three different strengths of tablets (25 mg, 50 mg, 100 mg) as well as a liquid (20 mg/mL). Your doctor will tell you how much to take, and may decide to adjust your dose over time.

If you were prescribed ZOLOFT Oral Concentrate, you must mix it with another liquid before taking it.

- Pour 4 oz. (1/2 cup) of any of the following liquids into a drinking glass: water, ginger ale, lemon/lime soda, lemonade or orange juice. **Do not use any other liquids besides these.**
- Draw up the proper amount of ZOLOFT Oral Concentrate into the special dropper that comes with the medicine.
- Squeeze the ZOLOFT Oral Concentrate out of the dropper into the drinking glass. Stir well. It is normal if a slight haze appears after mixing.
- Drink all the liquid as soon as you have mixed it. Do not mix it in advance.

Since the dropper bulb for the liquid form of ZOLOFT is made from dry natural rubber, make sure to let your doctor know if you have had allergic reactions to latex.

Take ZOLOFT once a day in the morning or evening. You can take ZOLOFT with or without food. Try to take ZOLOFT at the same time every day.

Do not take an extra dose if you are having a bad day. ZOLOFT does not work right away. Do not stop taking ZOLOFT without talking to your doctor first.

Do not run out of ZOLOFT. Make sure you have your refill for ZOLOFT at home before you need it. Continue to take ZOLOFT even when you feel better for as long as your doctor says.

It may take several weeks before you start to feel better. Do not get discouraged. Keep taking ZOLOFT every day for as long as your doctor tells you to take it.

Possible Side Effects

Like all medicines, ZOLOFT may cause side effects in some people. In clinical studies, few people had to stop taking ZOLOFT because of side effects. The most common ones are:

- dry mouth
- diarrhea/loose stools

- upset stomach
- decreased appetite
- feeling unusually tired or sleepy
- trouble sleeping
- sexual problems in men and women
- tremor
- feeling agitated
- indigestion
- increased sweating

Children who take ZOLOFT may also have other side effects such as excessive movement or twitching, fever, not "feeling well," trouble concentrating, not thinking normally, nosebleeds, weight loss, easy bruising, manic or excited behavior, or rapid mood swings.

Until you learn how you are going to respond to ZOLOFT, be careful doing activities when you need to be alert, such as driving a car or operating machinery. Drinking alcohol is not advised while you are being treated with ZOLOFT.

ZOLOFT may cause other less common side effects besides those listed here. For a list of all side effects that have been reported, ask your doctor or pharmacist for the ZOLOFT Professional Package Insert.

What To Do For An Overdose

In case of an overdose, call your doctor or poison control center right away or go to the nearest emergency room.

How To Store ZOLOFT

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

Store ZOLOFT tablets and Oral Concentrate at room temperature (59°-86°F or 15°-30°C).

For More Information About ZOLOFT

This sheet is only a summary. If you have any questions or want more information about ZOLOFT, talk with your doctor or pharmacist. You can also visit www.zoloft.com.

 **U.S. Pharmaceuticals**