

# Brightside Specialty Pharmacy

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## Patient Education for SERTRALINE HCL 100 MG TABLET



Excreted in breast milk With MAOIs, serious interaction; Risk of HTN, hyperpyrexia or death Avoid taking with other CNS depressant drugs or alcohol May cause drowsiness or dizziness Use caution driving. Worsening depression/thoughts of suicide should be reported ASAP Dispense & explain patient package insert and medication guide. Discuss gradual dose reduction with MD before stopping medication May cause problems in newborns. Use with caution in 3rd trimester

Check with doctor if you are breast feeding Inform doctor about all the medicines you use Avoid alcohol/other drugs that make you sleepy May make you drowsy or dizzy. Drive with caution Immediately report to MD any thoughts of suicide. Important to read patient package insert& med guide MD may need to reduce the dose before you stop it. Discuss risk vs benefits of use during pregnancy.

### Education Section

#### IMPORTANT:

HOW TO USE THIS INFORMATION: This is a summary and

does NOT have all possible information about this product. This information does not assure that this product is safe, effective, or appropriate for you. This information is not individual medical advice and does not substitute for the advice of your health care professional. Always ask your health care professional for complete information about this product and your specific health needs.

SERTRALINE - ORAL

(SER-truh-leen)

#### COMMON BRAND NAME(S):

Zoloft

#### WARNING:

Antidepressant medications are used to treat a variety

of conditions, including depression and other mental/mood disorders. These medications can help prevent suicidal thoughts/attempts and provide other important benefits. However, a small number of people (especially people younger than 25) who take antidepressants for any condition may experience worsening depression, other mental/mood symptoms, or suicidal thoughts/attempts. It is very important to talk with the doctor about the risks and benefits of antidepressant medication (especially for people younger than 25), even if treatment is not for a mental/mood condition.

Tell the doctor right away if you notice worsening depression/other psychiatric conditions, unusual behavior changes (including possible suicidal thoughts/attempts), or other mental/mood changes (including new/worsening anxiety, panic attacks, trouble sleeping, irritability, hostile/angry feelings, impulsive actions, severe restlessness, very rapid speech). Be especially watchful for these symptoms when a new antidepressant is started or when the dose is changed.

#### USES:

Sertraline is used to treat depression, panic attacks,

obsessive compulsive disorder, post-traumatic stress disorder,

social anxiety disorder (social phobia), and a severe form of premenstrual syndrome (premenstrual dysphoric disorder).

This medication may improve your mood, sleep, appetite, and energy level and may help restore your interest in daily living. It may decrease fear, anxiety, unwanted thoughts, and the number of panic attacks. It may also reduce the urge to perform repeated tasks (compulsions such as hand-washing, counting, and checking) that interfere with daily living. Sertraline is known as a selective serotonin reuptake inhibitor (SSRI). It works by helping to restore the balance of a certain natural substance (serotonin) in the brain.

#### OTHER USES:

This section contains uses of this drug that are not

listed in the approved professional labeling for the drug but that may be prescribed by your health care professional. Use this drug for a condition that is listed in this section only if it has been so prescribed by your health care professional.

This drug may also be used for binge eating disorder (BED).

#### HOW TO USE:

Read the Medication Guide and, if available, the

Patient Information Leaflet provided by your pharmacist before you start using sertraline and each time you get a refill. If you have any questions, ask your doctor or pharmacist.

Take this medication by mouth as directed by your doctor, usually once daily either in the morning or evening. The tablet or liquid form of this medication may be taken with or without food.

The 25 milligrams, 50 milligrams, and 100 milligrams capsule is usually taken with food. The 150 milligrams and 200 milligrams capsule may be taken with or without food. Swallow the capsules whole. Do not crush or chew the capsules. If you have any questions about how to take the capsule form of this medication, ask your doctor or pharmacist.

The liquid form of this medication must be mixed with another liquid before use. Just before taking, carefully measure the dose using the medicine dropper provided. Do not use a household spoon because you may not get the correct dose. Mix the dose with a half cup (4 ounces/120 milliliters) of water, ginger ale,

lemon-lime soda, lemonade, or orange juice. Do not use other liquids to mix this drug. The mixture may appear cloudy, which is normal and harmless. Drink all of the mixture right away. Do not prepare a supply in advance.

If you are taking this medication for premenstrual problems, your doctor may direct you to take this drug every day of the month or for only the 2 weeks before your period until the start of your period.

The dosage is based on your medical condition and response to treatment. To reduce your risk of side effects, your doctor may direct you to start this medication at a low dose and gradually increase your dose. Follow your doctor's instructions carefully. Take this medication regularly to get the most benefit from it. To help you remember, take it at the same time each day.

Keep taking this medication even if you feel well. Do not stop taking this medication without consulting your doctor. Some conditions may become worse when this drug is suddenly stopped. Also, you may experience symptoms such as mood swings, headache, tiredness, sleep changes, and brief feelings similar to electric shock. To prevent these symptoms while you are stopping treatment with this drug, your doctor may reduce your dose gradually. Report any new or worsening symptoms right away.

Tell your doctor if your condition lasts or gets worse.

#### **SIDE EFFECTS:**

See also Warning section.

Nausea, dizziness, drowsiness, dry mouth, loss of appetite, increased sweating, diarrhea, upset stomach, or trouble sleeping may occur. If any of these effects last or get worse, tell your doctor or pharmacist promptly.

Remember that this medication has been prescribed because your doctor has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Tell your doctor right away if you have any serious side effects, including: easy bleeding/bruising, decreased interest in sex, changes in sexual ability, muscle cramps/weakness, shaking (tremor), unusual weight loss.

Get medical help right away if you have any very serious side effects, including: fast/irregular heartbeat, fainting, black stools, vomit that looks like coffee grounds, eye pain/swelling/redness, widened pupils, vision changes (such as seeing rainbows around lights at night, blurred vision).

This medication may increase serotonin and rarely cause a very serious condition called serotonin syndrome/toxicity. The risk increases if you are also taking other drugs that increase serotonin, so tell your doctor or pharmacist of all the drugs you take (see Drug Interactions section). Get medical help right away if you develop some of the following symptoms: fast heartbeat, hallucinations, loss of coordination, severe dizziness, severe nausea/vomiting/diarrhea, twitching muscles, unexplained fever, unusual agitation/restlessness.

Rarely, males may have a painful or prolonged erection lasting 4 or more hours. If this occurs, stop using this drug and get medical help right away, or permanent problems could occur.

A very serious allergic reaction to this drug is rare.

However, get medical help right away if you notice any symptoms

of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

In the US -

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

#### **PRECAUTIONS:**

Before taking sertraline, tell your doctor or

pharmacist if you are allergic to it; or if you have any other allergies. This product may contain inactive ingredients (such as latex found in the medicine dropper, tartrazine found in some brands), which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: personal or family history of bipolar/manic-depressive disorder, bleeding problems, liver disease, seizure disorder, thyroid disease, personal or family history of glaucoma (angle-closure type).

Sertraline may cause a condition that affects the heart rhythm (QT prolongation). QT prolongation can rarely cause serious (rarely fatal) fast/irregular heartbeat and other symptoms (such as severe dizziness, fainting) that need medical attention right away.

The risk of QT prolongation may be increased if you have certain medical conditions or are taking other drugs that may cause QT prolongation. Before using sertraline, tell your doctor or pharmacist of all the drugs you take and if you have any of the following conditions: certain heart problems (heart failure, slow heartbeat, QT prolongation in the EKG), family history of certain heart problems (QT prolongation in the EKG, sudden cardiac death).

Low levels of potassium or magnesium in the blood may also increase your risk of QT prolongation. This risk may increase if you use certain drugs (such as diuretics/"water pills") or if you have conditions such as severe sweating, diarrhea, or vomiting. Talk to your doctor about using sertraline safely.

This drug may make you dizzy or drowsy. Alcohol or marijuana (cannabis) can make you more dizzy or drowsy. Do not drive, use machinery, or do anything that needs alertness until you can do it safely. Avoid alcoholic beverages. Talk to your doctor if you are using marijuana (cannabis).

The liquid form of this medication contains alcohol. Caution is advised if you have diabetes, alcohol dependence, or liver disease. Some medications (such as metronidazole, disulfiram) can cause a serious reaction when combined with alcohol. Ask your doctor or pharmacist about using this product safely.

Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products).

Older adults may be more sensitive to the side effects of this drug, especially bleeding, loss of coordination, or QT prolongation (see above). Loss of coordination can increase the risk of falling. Older adults may also be more likely to develop a type of salt imbalance (hyponatremia), especially if they are taking "water pills" (diuretics).

Children may be more sensitive to the side effects of the drug, especially loss of appetite and weight loss. Monitor weight and height in children who are taking this drug.

During pregnancy, this medication should be used only when clearly needed. It may harm an unborn baby. Also, babies born to mothers who have used this drug during the last 3 months of pregnancy may rarely develop withdrawal symptoms such as feeding/breathing difficulties, seizures, muscle stiffness, or constant crying. If you notice any of these symptoms in your newborn, tell the doctor promptly.

Since untreated mental/mood problems (such as depression, panic attacks, obsessive compulsive disorder, post-traumatic stress disorder) can be a serious condition, do not stop taking this medication unless directed by your doctor. If you are planning pregnancy, become pregnant, or think you may be pregnant, discuss with your doctor right away the benefits and risks of using this medication during pregnancy.

This drug passes into breast milk. Consult your doctor before breast-feeding.

**DRUG INTERACTIONS:**

See also Precautions section.

Drug interactions may change how your medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval.

Some products that may interact with this drug are: pimozide, other drugs that can cause bleeding/bruising (including antiplatelet drugs such as clopidogrel, NSAIDs such as ibuprofen/naproxen, "blood thinners" such as dabigatran/warfarin).

Taking MAO inhibitors with this medication may cause a serious (possibly fatal) drug interaction. Avoid taking MAO inhibitors (isocarboxazid, linezolid, metaxalone, methylene blue, moclobemide, phenelzine, procarbazine, rasagiline, safinamide, selegiline, tranylcypromine) during treatment with this medication. Most MAO inhibitors should also not be taken for two weeks before and after treatment with this medication. Ask your doctor when to start or stop taking this medication.

The risk of serotonin syndrome/toxicity increases if you are also taking other drugs that increase serotonin. Examples include street drugs such as MDMA/"ecstasy," St. John's wort, certain antidepressants (including other SSRIs such as fluoxetine/paroxetine, SNRIs such as duloxetine/venlafaxine), tryptophan, among others. The risk of serotonin syndrome/toxicity may be more likely when you start or increase the dose of these drugs.

Tell your doctor or pharmacist if you are taking other

products that cause drowsiness such as alcohol, marijuana (cannabis), antihistamines (such as cetirizine, diphenhydramine), drugs for sleep or anxiety (such as alprazolam, diazepam, zolpidem), muscle relaxants, and opioid pain or cough relievers (such as codeine, hydrocodone).

Check the labels on all your medicines (such as allergy or cough-and-cold products) because they may contain ingredients that cause drowsiness. Ask your pharmacist about using those products safely.

Aspirin can increase the risk of bleeding when used with this medication. However, if your doctor has directed you to take low-dose aspirin for heart attack or stroke prevention (usually 81-162 milligrams a day), you should continue taking it unless your doctor instructs you otherwise.

This medication may interfere with certain medical/lab tests (including brain scan for Parkinson's disease), possibly causing false test results. Make sure lab personnel and all your doctors know you use this drug.

**OVERDOSE:**

If someone has overdosed and has serious symptoms such

as passing out or trouble breathing, call 911. Otherwise, call a poison control center right away. US residents can call their local poison control center at 1-800-222-1222. Canada residents can call a provincial poison control center. Symptoms of overdose may include: severe dizziness, fainting.

**NOTES:**

Do not share this medication with others.

Keep all regular medical and psychiatric appointments.

**MISSED DOSE:**

If you miss a dose, take it as soon as you

remember. If it is near the time of the next dose, skip the missed dose. Take your next dose at the regular time. Do not double the dose to catch up.

**STORAGE:**

Store at room temperature away from light and moisture.

Do not store in the bathroom. Keep all medications away from children and pets.

Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company.

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