Sertraline

Brand Names: US
Zoloft

Brand Names: Canada
Zoloft

Warning

- Drugs like this one have raised the chance of suicidal thoughts or actions in children and young adults. The risk may be greater in people who have had these thoughts or actions in the past. All people who take this drug need to be watched closely. Call the doctor right away if signs like low mood (depression), nervousness, restlessness, grouchiness, panic attacks, or changes in mood or actions are new or worse. Call the doctor right away if any thoughts or actions of suicide occur.

What is this drug used for?

- It is used to treat low mood (depression).
- It is used to treat obsessive-compulsive problems.
- It is used to treat panic attacks.
- It is used to treat post-traumatic stress.
- It is used to treat mood problems caused by monthly periods.
- It is used to treat social anxiety problems.
- It may be given to your child for other reasons. Talk with the doctor.

What do I need to tell the doctor BEFORE my child takes this drug?

All products:
• If your child has an allergy to this drug or any part of this drug.
• If your child is allergic to any drugs like this one or any other drugs, foods, or other substances. Tell the doctor about the allergy and what signs your child had, like rash; hives; itching; shortness of breath; wheezing; cough; swelling of face, lips, tongue, or throat; or any other signs.
• If your child has liver disease.
• If your child is taking any of these drugs: Linezolid or methylene blue.
• If your child is taking pimozide.
• If your child has taken certain drugs used for low mood (depression) like isocarboxazid, phenelzine, or tranylcypromine or drugs used for certain other health problems in the last 14 days. Taking this drug within 14 days of those drugs can cause very bad high blood pressure.
• If your child is taking any drugs that can cause a certain type of heartbeat that is not normal (prolonged QT interval). There are many drugs that can do this. Ask the doctor or pharmacist if you are not sure.

Liquid:

• If your child has a latex allergy. The dropper has rubber.
• If your child is taking disulfiram.
• If your child is pregnant or may be pregnant. Do not give this form of this drug to your child if she is pregnant.

This is not a list of all drugs or health problems that interact with this drug.

Tell the doctor and pharmacist about all of your child’s drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for your child to take this drug with all of his/her drugs and health problems. Do not start, stop, or change the dose of any drug your child takes without checking with the doctor.

What are some things I need to know or do while my child takes this drug?

All products:
Tell all of your child’s health care providers that your child is taking this drug. This includes your child’s doctors, nurses, pharmacists, and dentists.

Have your child avoid tasks or actions that call for alertness until you see how this drug affects your child. These are things like riding a bike, playing sports, or using items such as scissors, lawnmowers, electric scooters, toy cars, or motorized vehicles.

Do not stop giving this drug to your child all of a sudden without calling the doctor. Your child may have a greater risk of side effects. If your child needs to stop this drug, you will want to slowly stop it as told by the doctor.

Alcohol may interact with this drug. Be sure your child does not drink alcohol.

Talk with the doctor before giving your child other drugs and natural products that may slow your child’s actions.

In depression, sleep and appetite may get better soon after starting this drug. Other low mood signs may take up to 4 weeks to get better.

This drug may raise the chance of a broken bone. Talk with the doctor.

This drug may raise the chance of bleeding. Sometimes, bleeding can be life-threatening. Talk with the doctor.

This drug can cause low sodium levels. Very low sodium levels can be life-threatening, leading to seizures, passing out, trouble breathing, or death. Talk with the doctor.

This drug may affect certain lab tests. Tell all of your child’s health care providers and lab workers that your child takes this drug.

This drug may affect how much of some other drugs are in the body. If your child is taking other drugs, talk with the doctor. Your child may need to have blood work checked more closely while taking this drug with other drugs.

This drug is not approved for use in all children. Talk with the doctor to be sure that this drug is right for your child.

Use with care in children. Talk with the doctor.

This drug may affect growth in children and teens in some cases. They may need regular growth checks. Talk with the doctor.
If your child is pregnant:

- Taking this drug late in pregnancy may raise the chance of breathing or feeding problems, low body temperature, or withdrawal symptoms in the newborn. Talk with the doctor.

If your child is breast-feeding a baby:

- Tell the doctor if your child is breast-feeding a baby. You will need to talk about any risks to the baby.

Tablets and capsules:

- Tell the doctor if your child is pregnant or becomes pregnant. You will need to talk about the benefits and risks of your child using this drug while pregnant.

What are some side effects that I need to call my child’s doctor about right away?

**WARNING/CAUTION:** Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your child’s doctor or get medical help right away if your child has any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.

- Signs of low sodium levels like headache, trouble focusing, memory problems, feeling confused, weakness, seizures, or change in balance.

- Signs of bleeding like throwing up blood or throw up that looks like coffee grounds; coughing up blood; blood in the urine; black, red, or tarry stools; bleeding from the gums; vaginal bleeding that is not normal; bruises without a reason or that get bigger; or any bleeding that is very bad or that you cannot stop.

- Seizures.

- Chest pain or pressure.
• Not able to control bladder.
• Very bad headache.
• A big weight gain or loss.
• For females, menstrual changes. These include lots of bleeding, spotting, or bleeding between cycles
• A very bad and sometimes deadly health problem called serotonin syndrome may happen. The risk may be greater if your child takes this drug with drugs for depression, migraines, or certain other drugs. Call your child’s doctor right away if your child has agitation; change in balance; confusion; hallucinations; fever; a fast or abnormal heartbeat; flushing; muscle twitching or stiffness; seizures; shivering or shaking; sweating a lot; very bad diarrhea, upset stomach, or throwing up; or very bad headache.
• Some people may have a higher chance of eye problems with this drug. The doctor may want your child to have an eye exam to see if your child has a higher chance of these eye problems. Call the doctor right away if your child has eye pain, change in eyesight, or swelling or redness in or around the eye.
• A type of abnormal heartbeat (prolonged QT interval) has happened with this drug. Sometimes, this has led to another type of unsafe abnormal heartbeat (torsades de pointes). Call your child’s doctor right away if your child has a fast or abnormal heartbeat, or if your child passes out.
• A very bad skin reaction (Stevens-Johnson syndrome/toxic epidermal necrolysis) may happen. It can cause very bad health problems that may not go away, and sometimes death. Get medical help right away if your child has signs like red, swollen, blistered, or peeling skin (with or without fever); red or irritated eyes; or sores in the mouth, throat, nose, or eyes.
• Very bad and sometimes deadly liver problems have happened with this drug. Call your child’s doctor right away if your child has signs of liver problems like dark urine, feeling tired, not hungry, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.

**If your child is or may be sexually active:**

• Sex problems like lowered interest in sex or ejaculation problems.

**What are some other side effects of this drug?**
All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your child’s doctor or get medical help if any of these side effects or any other side effects bother your child or do not go away:

- Dizziness.
- Feeling sleepy.
- Feeling tired or weak.
- Upset stomach.
- Diarrhea.
- Feeling nervous and excitable.
- Dry mouth.
- Constipation.
- Not able to sleep.
- Sweating a lot.
- Shakiness.
- Not hungry.
- Belly pain.

These are not all of the side effects that may occur. If you have questions about side effects, call your child’s doctor. Call your child’s doctor for medical advice about side effects.

You may report side effects to your national health agency.

**How is this drug best given?**

Give this drug as ordered by your child’s doctor. Read all information given to you. Follow all instructions closely.

**Tablets:**

- Give this drug with or without food.

**Capsules:**
• Give this drug with food.

**Liquid:**

• Only use the measuring device that comes with this liquid drug.
• Mix liquid with $\frac{1}{2}$ cup of water, ginger ale, lemon-lime soda, lemonade, or orange juice.
• After mixing, give the dose right away. Do not store for future use.
• This drug may look hazy after mixing. This is normal.

**All products:**

• To gain the most benefit, do not miss giving your child doses.
• Keep giving this drug to your child as you have been told by your child’s doctor or other health care provider, even if your child feels well.

**What do I do if my child misses a dose?**

• Give a missed dose as soon as you think about it.
• If it is close to the time for your child’s next dose, skip the missed dose and go back to your child’s normal time.
• Do not give 2 doses at the same time or extra doses.

**How do I store and/or throw out this drug?**

• Store at room temperature.
• Keep lid tightly closed.
• Store in a dry place. Do not store in a bathroom.
• Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
• Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.
General drug facts

- If your child’s symptoms or health problems do not get better or if they become worse, call your child’s doctor.

- Do not share your child’s drug with others and do not give anyone else’s drug to your child.

- Keep a list of all your child’s drugs (prescription, natural products, vitamins, OTC) with you. Give this list to your child’s doctor.

- Talk with your child’s doctor before giving your child any new drug, including prescription or OTC, natural products, or vitamins.

- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your child’s doctor, nurse, pharmacist, or other health care provider.

- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

Consumer Information Use and Disclaimer

This information should not be used to decide whether or not to take this medicine or any other medicine. Only the healthcare provider has the knowledge and training to decide which medicines are right for a specific patient. This information does not endorse any medicine as safe, effective, or approved for treating any patient or health condition. This is only a brief summary of general information about this medicine. It does NOT include all information about the possible uses, directions, warnings, precautions, interactions, adverse effects, or risks that may apply to this medicine. This information is not specific medical advice and does not replace information you receive from the healthcare provider. You must talk with the healthcare provider for complete information about the risks and benefits of using this medicine.

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If you have any questions or concerns, talk with a member of your healthcare team. You can reach them Monday through Friday from 9:00 AM to 5:00 PM at ____________________. After 5:00 PM, during the weekend, and on holidays, please call____________________. If there’s no number listed, or you’re not sure, call 212-639-2000.

Sertraline

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