

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

What should I tell my healthcare provider before taking sertraline hydrochloride oral solution?

Before starting sertraline hydrochloride oral solution, tell your healthcare provider:

- **if you have:**
 - o liver problems
 - o heart problems
 - o bipolar disorder or mania
 - o kidney problems
 - o or have had seizures or convulsions
 - o low sodium levels in your blood
 - o a history of a stroke
 - o high blood pressure
 - o or have had bleeding problems
- **are pregnant or plan to become pregnant.** Your baby may have withdrawal symptoms after birth or may be at increased risk for a serious lung problem at birth. Talk to your healthcare provider about the benefits and risks of taking sertraline hydrochloride oral solution during pregnancy.
 - o There is a pregnancy registry for females who are exposed to sertraline hydrochloride oral solution during pregnancy. The purpose of the registry is to collect information about the health of females exposed to sertraline hydrochloride oral solution and their baby. If you or your child become pregnant during treatment with sertraline hydrochloride oral solution, talk to your healthcare provider about registering with the National Pregnancy Registry for Antidepressants. You can register by calling 1-866-961-2388 or by visiting online at <https://womensmentalhealth.org/research/pregnancyregistry/antidepressants/>.
- **are breastfeeding or plan to breastfeed.** A small amount of sertraline hydrochloride oral solution may pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby while taking sertraline hydrochloride oral solution.

Tell your healthcare provider about all the medicines that you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Especially tell your healthcare provider if you or your child take:

- medicines used to treat migraine headaches called triptans
- tricyclic antidepressants
- lithium
- tramadol, fentanyl, meperidine, methadone, or other opioids
- tryptophan
- buspirone
- amphetamines
- phenytoin
- St. John’s Wort
- medicines that can affect blood clotting such as aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs), other antiplatelet medicines, warfarin, and other anticoagulants
- diuretics
- medicines used to treat mood, anxiety, psychotic, or thought disorders, including selective serotonin reuptake (SSRIs) and serotonin norepinephrine reuptake inhibitors (SNRIs)

Sertraline hydrochloride oral solution 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 sertraline hydrochloride oral solution with your other medicines. **Do not** start or stop any medicine while taking sertraline hydrochloride oral solution without talking to your healthcare provider first.

How should I take sertraline hydrochloride oral solution?

- Take sertraline hydrochloride oral solution exactly as prescribed. Your healthcare provider may need to change the dose of sertraline hydrochloride oral solution until it is the right dose for you.
- Sertraline hydrochloride oral solution may look cloudy or hazy after mixing, this is normal.
- Sertraline hydrochloride oral solution must be diluted before use:
 - o **Do not** mix sertraline hydrochloride oral solution until you are ready to take it.
 - o When diluting sertraline hydrochloride oral solution, use **only** water, ginger ale, lemon/lime soda, lemonade, or orange juice.
- If you miss a dose of sertraline hydrochloride oral solution, 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 sertraline hydrochloride oral solution at the same time.

If you take too much sertraline hydrochloride oral solution, call your healthcare provider or poison control center right away, or go to the nearest hospital emergency room right away.

What should I avoid while taking sertraline hydrochloride oral solution?

Sertraline hydrochloride oral solution 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 sertraline hydrochloride oral solution affects you. **Do not** drink alcohol while you take sertraline hydrochloride oral solution.

What are the possible side effects of sertraline hydrochloride oral solution?

Sertraline hydrochloride oral solution may cause serious side effects, including:

- **See “What is the most important information I should know about sertraline hydrochloride oral solution?”**

The most common side effects in adults who take sertraline hydrochloride oral solution include:

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

The most common side effects in children and adolescents who take include abnormal increase in muscle movement or agitation, nose bleeds, urinary incontinence, aggressive reaction, possible slowed growth rate, and weight change. Your child’s height and weight should be monitored during treatment with sertraline hydrochloride oral solution.

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 sertraline hydrochloride oral solution. 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 sertraline hydrochloride oral solution?

- Store sertraline hydrochloride oral solution at room temperature, 68° to 77°F (20° to 25°C).
- Keep sertraline hydrochloride oral solution bottle closed tightly.

Keep sertraline hydrochloride oral solution and all medicines out of the reach of children.

General information about the safe and effective use of sertraline hydrochloride oral solution

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

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

For more information, call Rising Pharma Holdings, Inc. at 1-844-874-7464.

What are the ingredients in sertraline hydrochloride oral solution?

Active ingredient: sertraline hydrochloride

Inactive ingredients: alcohol (12%), natural peppermint flavor, propylene glycol and purified water.

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

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