Medication Guide

Sertraline Hydrochloride Tablets USP
(ser' tra leen hye'' droe klor' ide)

What is the most important information I should know about sertraline hydrochloride tablets?

Sertraline hydrochloride tablets and other antidepressant medicines may cause serious side effects. Call your healthcare provider right away if you have any of the following symptoms, or call 911 if there is an emergency.

1. **Suicidal thoughts or actions:**
   - **Sertraline hydrochloride tablets and other antidepressant medicines may increase suicidal thoughts or actions** in some people 24 years of age and younger, especially 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 sertraline hydrochloride tablets 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

2. **Serotonin Syndrome.** This condition can be life-threatening and symptoms may include:
   - agitation, hallucinations, coma, or other changes in mental status
   - racing heartbeat, high or low blood pressure
   - coordination problems or muscle twitching (overactive reflexes)
   - nausea, vomiting, or diarrhea
   - sweating or fever
   - muscle rigidity

3. **Increased chance of bleeding**: Sertraline hydrochloride tablets 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.

4. **Manic episodes.** Symptoms may include:

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

5. Seizures or convulsions.

6. Glaucoma (angle-closure glaucoma). Many antidepressant medicines including sertraline hydrochloride tablets may cause a certain type of eye problem called angle-closure glaucoma. Call your healthcare provider if you have eye pain, changes in your vision, or swelling or redness in or around the eye. Only some people are at risk for these problems. You may want to undergo an eye examination to see if you are at risk and receive preventative treatment if you are.

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 sertraline hydrochloride tablets without first talking to your healthcare provider. Stopping sertraline hydrochloride tablets 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 are sertraline hydrochloride tablets?

Sertraline hydrochloride tablets are a prescription medicine used to treat:
- Major Depressive Disorder (MDD)
- Panic Disorder
- Social Anxiety Disorder
- Obsessive Compulsive Disorder (OCD)
- Posttraumatic Stress Disorder (PTSD)
- Premenstrual Dysphoric Disorder (PMDD)

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.

Sertraline hydrochloride tablets are safe and effective in treating children with OCD age 6 to 17 years.

It is not known if sertraline hydrochloride tablets are is safe and effective for use in children under 6 years of age with OCD or children with other behavior health conditions.

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

Who should not take sertraline hydrochloride tablets?

Do not take sertraline hydrochloride tablets if you:

- 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.
- have taken an MAOI within 2 weeks of stopping sertraline hydrochloride tablets unless directed to do so by your healthcare provider.
- have stopped taking an MAOI in the last 2 weeks unless directed to do so by your healthcare provider.
- take any other medicines that contain sertraline (such as sertraline HCl or sertraline hydrochloride).
- take the antipsychotic medicine pimozide (Orap®) because this can cause serious heart problems.
- are allergic to sertraline or any of the ingredients in sertraline hydrochloride tablets. See the end of this Medication Guide for a complete list of ingredients in sertraline hydrochloride tablets.
- take Antabuse® (disulfiram) (if you are taking the liquid form of sertraline hydrochloride tablets) due to the alcohol content.

People who take sertraline hydrochloride tablets 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 sertraline hydrochloride tablets?

Before starting sertraline hydrochloride tablets, tell your healthcare provider:

- **if you have:**
- liver problems
- heart problems
- bipolar disorder or mania
- kidney problems
- or have had seizures or convulsions
- low sodium levels in your blood
- a history of a stroke
- high blood pressure
- 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 tablets during pregnancy.
- **are breastfeeding or plan to breastfeed**. A small amount of sertraline hydrochloride tablets may pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby while taking sertraline hydrochloride tablets.

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

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

How should I take sertraline hydrochloride tablets?

- Take sertraline hydrochloride tablets exactly as prescribed. Your healthcare provider may need to change the dose of sertraline hydrochloride tablets until it is the right dose for you.
- Sertraline hydrochloride tablets may be taken with or without food.
- If you miss a dose of sertraline hydrochloride tablets, 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 tablets at the same time.

If you take too much sertraline hydrochloride, 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 tablets?

Sertraline hydrochloride tablets 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 tablets affect you. **Do not** drink alcohol while you take sertraline hydrochloride tablets.

What are the possible side effects of sertraline hydrochloride tablets?

Sertraline hydrochloride tablets may cause serious side effects, including:

- **See "What is the most important information I should know about sertraline hydrochloride tablets?"**

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

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

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 tablets.

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 tablets. 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 tablets?

Store sertraline hydrochloride tablets at room temperature, 20° to 25°C (68° to 77°F).

Keep sertraline hydrochloride tablets bottle closed tightly.

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

General information about the safe and effective use of sertraline hydrochloride tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use sertraline hydrochloride tablets for a condition for which it was not prescribed. Do not give sertraline hydrochloride tablets 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 tablets. If you would like more information, talk with your healthcare provider. You may ask your healthcare provider or pharmacist for information about sertraline hydrochloride tablets that is written for healthcare professionals.

For more information about sertraline hydrochloride tablets call Aurobindo Pharma USA, Inc. at 1-866-850-2876.

What are the ingredients in sertraline hydrochloride tablets?

Active ingredient: sertraline hydrochloride

Inactive ingredients:

Tablets: microcrystalline cellulose, sodium starch glycolate, hydroxypropyl cellulose, dibasic calcium phosphate dihydrate, magnesium stearate, hypromellose, titanium dioxide, polyethylene glycol, and polysorbate 80. Besides, 25 mg contains D&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, FD&C red #40 aluminum lake; 50 mg contains FD&C blue #2 aluminum lake; and 100 mg contains iron oxide yellow.

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

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