Medication Guide

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

Read the Medication Guide that comes with sertraline hydrochloride oral solution before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or treatment. Talk with your healthcare provider if there is something you do not understand or want to learn more about.

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

Sertraline hydrochloride oral solution and other antidepressant medicines may cause serious side effects, including:

1. **Suicidal thoughts or actions:**
- **Sertraline hydrochloride oral solution and other antidepressant medicines may increase suicidal thoughts or actions** in some children, teenagers, or young adults 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 oral solution 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

Call your healthcare provider right away if you have any of the following symptoms, or call 911 if an emergency. Sertraline hydrochloride oral solution may be associated with these serious side effects:

2. **Serotonin Syndrome**

This condition can be life-threatening and may include:
- agitation, hallucinations, coma or other changes in mental status

- coordination problems or muscle twitching (overactive reflexes)
- racing heartbeat, high or low blood pressure
- sweating or fever
- nausea, vomiting, or diarrhea
- muscle rigidity

3. Severe allergic reactions:
- trouble breathing
- swelling of the face, tongue, eyes or mouth
- rash, itchy welts (hives) or blisters, alone or with fever or joint pain

4. Abnormal bleeding: Sertraline hydrochloride oral solution 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.

5. Seizures or convulsions

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

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

9. Visual problems
- eye pain
- changes in vision
- 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.

Do not stop sertraline hydrochloride oral solution without first talking to your healthcare provider. Stopping sertraline hydrochloride oral solution 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 is sertraline hydrochloride oral solution ?

Sertraline hydrochloride oral solution is a prescription medicine used to treat depression. 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 oral solution is also used to treat:

- Major Depressive Disorder (MDD)
- Obsessive Compulsive Disorder (OCD)
- Panic Disorder
- Posttraumatic Stress Disorder (PTSD)
- Social Anxiety Disorder
- Premenstrual Dysphoric Disorder (PMDD)

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

Who should not take sertraline hydrochloride oral solution ?

Do not take sertraline hydrochloride oral solution if you:

- are allergic to sertraline or any of the ingredients in sertraline hydrochloride oral solution. See the end of this Medication Guide for a complete list of ingredients in sertraline hydrochloride oral solution.
- **take the antipsychotic medicine pimozide (Orap®) because this can cause serious heart problems.**
- take Antabuse® (disulfiram) (if you are taking the liquid form of sertraline hydrochloride oral solution) due to the alcohol content.
- 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.
- Do not take an MAOI within 2 weeks of stopping sertraline hydrochloride oral solution unless directed to do so by your physician.
- Do not start sertraline hydrochloride oral solution if you stopped taking an MAOI in the last 2 weeks unless directed to do so by your physician.

People who take sertraline hydrochloride oral solution 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 oral solution? Ask if you are not sure.

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

- Are taking certain drugs such as:
  - Medicines used to treat migraine headaches such as:
    - triptans
  - Medicines used to treat mood, anxiety, psychotic or thought disorders, such as:
    - tricyclic antidepressants
    - lithium
    - diazepam
    - SSRIs
    - SNRIs
    - antipsychotic drugs
    - valproate
  - Medicines used to treat seizures such as:
    - phenytoin
  - Medicines used to treat pain such as:
    - tramadol
  - Medicines used to thin your blood such as:
    - warfarin
  - Medicines used to control your heartbeat such as :
    - propafenone
    - flecainide
    - digitoxin
  - Medicines used to treat type II diabetes such as:
    - tolbutamide
  - Cimetidine used to treat heartburn
  - Over-the-counter medicines or supplements such as:
    - Aspirin or other NSAIDs
    - tryptophan
    - St. John’s Wort
- have liver problems
- have kidney problems
- have heart problems
- have or had seizures or convulsions
- have bipolar disorder or mania
- have low sodium levels in your blood
- have a history of a stroke
- have high blood pressure
- have or had bleeding problems
- are pregnant or plan to become pregnant. It is not known if sertraline hydrochloride oral solution will harm your unborn baby. Talk to your healthcare provider about the benefits and risks of treating depression during pregnancy.
- are breast-feeding or plan to breast-feed. Some sertraline hydrochloride 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 non-prescription medicines, vitamins, and herbal supplements. 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.

If you take sertraline hydrochloride oral solution, you should not take any other medicines that contain sertraline (sertraline hydrochloride, etc.).

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 must be diluted before use:
  - Follow the instructions carefully
  - 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 get emergency treatment.

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 using 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?"**
- **Feeling anxious or trouble sleeping**

Common possible side effects in people who take sertraline hydrochloride oral solution include:

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

- feeling tired or fatigued
- agitation

Other side effects in children and adolescents include:
- abnormal increase in muscle movement or agitation
- nose bleed
- urinating more often
- urinary incontinence
- aggressive reaction
- heavy menstrual periods
- 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 between 20° to 25°C (68° to 77°F).
- 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 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 about sertraline hydrochloride oral solution call 1-800-206-7821.

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.

Orap® is a registered trademark of Teva Pharmaceuticals USA.
Coumadin® is a registered trademark of Bristol Myers Squibb.
Jantoven® is a registered trademark of Upsher-Smith Laboratories Inc.
Antabuse® is a registered trademark of Duramed Pharmaceuticals, Inc. and Ayerst, McKenna & Harrison Limited.

Medication Guides available at www.northstarrxllc.com/products or call 1-800-206-7821.

Manufactured for: Northstar Rx LLC
Memphis, TN 38141
Toll Free: 1-800-206-7821

Manufactured by: Aurobindo Pharma Limited
Hyderabad-500 072, India

M.L.No.: 19/HD/AP/95/F/R

Revised: 03/2016