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 worrisome:

- attempts to commit suicide
- acting aggressive or violent
- new or worse depression
- feeling agitated, restless, angry or irritable
- an increase in activity or talking more than what is normal for you
- acting on dangerous impulses
- thoughts about suicide or dying
- new or worse anxiety or panic attacks
- trouble sleeping
- 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
   • restless 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:
   - 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 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:

- are allergic to sertraline or any of the ingredients in sertraline hydrochloride tablets.
- are allergic to some of the ingredients in sertraline hydrochloride tablets. See the end of this Medication Guide for a complete list of ingredients in sertraline hydrochloride tablets.
- have stopped taking an MAOI in the last 2 weeks 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.
- have any of these symptoms, or call 911 if an emergency, especially if severe:
  - confusion, problems concentrating or thinking, or memory problems
  - changes in mood or behavior, including irritability

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
- rapid changes in heart rate or blood pressure
- uncontrolled muscle spasms
- confusion
- stiff muscles
- 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
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. 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 pharmacist for information about sertraline hydrochloride tablets that is written for healthcare professionals.

What are the ingredients in sertraline hydrochloride tablets?

- Active ingredient: sertraline hydrochloride
- Inactive ingredients: tartaric acid; FD&C blue #2 aluminum lake; FD&C red #40 aluminum lake; FD&C blue #1 aluminum lake, FD&C red #40 aluminum lake; 50 mg contains FD&C blue #2 and FD&C red #40 aluminum lake; 25 mg contains FD&C blue #2 and FD&C red #40 aluminum lake; 10 mg contains FD&C blue #2 and FD&C red #40 aluminum lake; and 25 mg contains FD&C blue #2 and FD&C red #40 aluminum lake; and 100 mg contains FD&C blue #2 and FD&C red #40 aluminum lake; and 100 mg contains iron oxide yellow.

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°C to 25°C (68°F to 77°F).

Keep sertraline hydrochloride tablets bottle closed tightly.

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

For more information about sertraline hydrochloride tablets call Northstar Rx LLC at 1-800-206-7821.

What are the possible side effects of 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 O&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, FD&C red #40 aluminum lake; 50 mg contains FD&C blue #2 and FD&C red #40 aluminum lake; and 100 mg contains iron oxide yellow.

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

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

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