

Sertraline Hcl Cas No. : 79559-97-0

Sertraline is used to treat depression, panic attacks, obsessive compulsive disorders, post-traumatic stress disorder, social anxiety disorder (social phobia), and a severe form of premenstrual syndrome (premenstrual dysphoric disorder). It is known as a selective serotonin reuptake inhibitor (SSRI).

Active Pharmaceuticals Ingredients Manufacturers



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Taj Pharmaceuticals Ltd.**Sertraline Hcl****CAS No. : 79559-97-0**Molecular Formula C₁₇H₁₇Cl₂N.HCl

Molecular Weight 342.69

CAS Registry Number 79559-97-0

Chemical dataFormula C₁₇H₁₇Cl₂N

Mol. mass 306.229 g/mol

SMILES eMolecules & PubChem

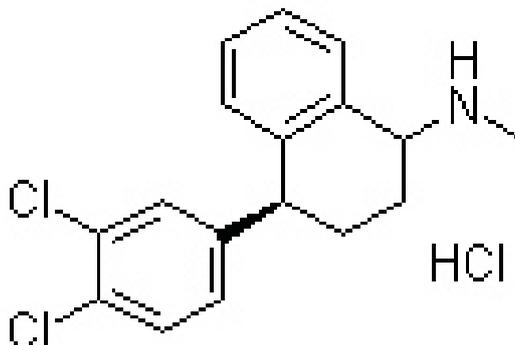
Pharmacokinetic data

Bioavailability 44%

Metabolism N-demethylation (liver)

Half life Approximately 26 hours

Excretion Renal



Sertraline hydrochloride is a white crystalline powder that is slightly soluble in water and isopropyl alcohol, and sparingly soluble in ethanol.

Sertraline hydrochloride is supplied for oral administration as scored tablets containing sertraline hydrochloride equivalent to 25, 50 and 100 mg of sertraline and the following inactive ingredients: dibasic calcium phosphate dihydrate, D & C Yellow #10 aluminum lake (in 25 mg tablet), FD & C Blue #1 aluminum lake (in 25 mg tablet), FD & C Red #40 aluminum lake (in 25 mg tablet), FD & C Blue #2 aluminum lake (in 50 mg tablet), hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, sodium starch glycolate, synthetic yellow iron oxide (in 100 mg tablet), and titanium dioxide.

Sertraline hydrochloride oral concentrate is available in a multidose 60 mL bottle. Each mL of solution contains sertraline hydrochloride equivalent to 20 mg of sertraline. The solution contains the following inactive ingredients: glycerin, alcohol (12%), menthol, butylated hydroxytoluene (BHT). The oral concentrate must be diluted prior to administration

DOSAGE

A standard dose of Sertraline is 50 to 200 mg per day. It is taken once a day, either in the morning or evening, and may be taken with or without food. Take this medication by mouth, usually once daily or as directed by your doctor. This medication may make you sleepy or wakeful. Therefore, depending on how this medication affects you, your doctor may direct you to take the entire dose once daily either in the morning or evening.

The tablet form of this medication may be taken with or without food. The capsule form is usually taken with food after breakfast or after your evening meal as directed by your doctor. The dosage is based on your medical condition and response to therapy. To reduce your risk of side effects, your doctor may start you at a low dose and gradually increase your dose. Usually, the daily dose will not be more than 200 milligrams. Follow your doctor's instructions carefully. Do not take more or less medication or take it more frequently than prescribed. Your condition will not improve any faster and your risk of side effects will increase. Use this medication regularly in order to get the most benefit from it.

To help you remember, use it at the same time each day. It is important to continue taking this medication as prescribed even if you feel well. Do not stop taking this medication without consulting your doctor.



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SIDE EFFECTS

Nausea, dizziness, dry mouth, loss of appetite, increased sweating, drowsiness, diarrhea, upset stomach, or trouble sleeping may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly.

Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Tell your doctor immediately if any of these unlikely but serious side effects occur: unusual or severe mental/mood changes (e.g., agitation, nervousness, suicidal thoughts), decrease in sexual ability (ejaculation delay), decreased interest in sex, uncontrollable shaking (tremor), unusual weight loss.

Tell your doctor immediately if any of these highly unlikely but very serious side effects occur: easy bruising/bleeding, persistent nausea/vomiting, severe stomach/abdominal pain, black stools, seizures, change in the amount of urine, dark urine, vomit that looks like coffee grounds, yellowing eyes/skin. This medication may rarely cause a very serious condition called serotonin syndrome. The risk increases when this medication is used with certain other drugs such as "triptans" used to treat migraine headaches (e.g., sumatriptan, eletriptan), certain antidepressants including other SSRIs (e.g., citalopram, paroxetine) and SNRIs (e.g., duloxetine, venlafaxine), lithium, tramadol, tryptophan, or a certain drug to treat obesity (sibutramine). Before taking this drug, tell your doctor if you take any of these medications. Serotonin syndrome may be more likely when you start or increase the dose of any of these medications. Seek immediate medical attention if you develop some of the following symptoms: hallucinations, unusual restlessness, loss of coordination, fast heartbeat, severe dizziness, unexplained fever, severe nausea/vomiting/diarrhea, twitchy muscles.

For males, in the very unlikely event you have a painful or prolonged erection lasting 4 or more hours, stop using this drug and seek immediate medical attention, or permanent problems could occur.

A very serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction may include: rash, itching, swelling, severe dizziness, trouble breathing.

PRECAUTIONS

Before taking sertraline, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. Before using this medication, tell your doctor or pharmacist your medical history, especially of: personal or family history of psychiatric disorder (e.g., bipolar/manic-depressive disorder), personal or family history of suicide attempts, kidney disease, liver disease, seizures, thyroid disease (e.g., hypothyroidism).

This drug may make you drowsy; use caution engaging in activities requiring alertness such as driving or using machinery. Avoid alcoholic beverages.

Caution is advised when using this drug in the elderly because they may be more sensitive to the side effects of the drug, such as dizziness. The elderly are also more likely to develop a type of mineral imbalance (hyponatremia), especially if they are also taking "water pills" (diuretics) with this medication. Caution is advised when using this drug in children because they may be more sensitive to the side effects of the drug, especially loss of appetite and weight loss. It is important to monitor weight and growth in children who are taking this drug.





Use this medication only when clearly needed during pregnancy. It may harm an unborn baby. Also, babies born to mothers who have used this drug during the last 3 months of pregnancy may infrequently develop withdrawal symptoms such as feeding/breathing difficulties, seizures, muscle stiffness, or constant crying. If you notice any of these symptoms in your newborn, tell the doctor promptly.

Since untreated depression can be a serious condition, do not stop taking this medication unless directed by your doctor. If you are planning pregnancy, become pregnant, or think you may be pregnant, immediately discuss the benefits and risks of using this medication during pregnancy with your doctor. This drug passes into breast milk and may have undesirable effects on a nursing infant. Consult your doctor before breast-feeding.

DRUG DESCRIPTION

Sertraline hydrochloride is a selective serotonin reuptake inhibitor (SSRI) for oral administration. It has a molecular weight of 342.7. Sertraline hydrochloride has the following chemical name: (1S-cis)-4-(3,4-dichlorophenyl)-1,2,3,4-tetrahydro-N-methyl-1-naphthalenamine hydrochloride. Sertraline hydrochloride is a white crystalline powder that is slightly soluble in water and isopropyl alcohol, and sparingly soluble in ethanol.

Zoloft is FDA approved to treat depression, certain types of social anxiety conditions, posttraumatic stress disorder (PTSD), panic disorder, obsessive-compulsive disorder (OCD), and premenstrual dysphoric disorder (PMDD) in adults over age 18. It is also approved for OCD in children and adolescents age 6-17 years.

For more than 15 years, Zoloft has safely and effectively treated millions of people with depression and certain anxiety conditions. Zoloft is available in multiple strengths, so your doctor can decide a dose for you.

Sertraline is used to treat depression, panic attacks obsessive compulsive disorders (OCD), and post-traumatic stress disorder (PTSD). This medication works by helping to restore the balance of certain natural chemicals in the brain.

This medication has also been used to treat a severe form of premenstrual syndrome (premenstrual dysphoric disorder- PMDD) and a sexual function problem in men (premature ejaculation).

Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to the manufacture of the substances. For any (Control Substance) products Import and Export *** subjected to your country government laws /control substance ACT.

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:

<http://www.tajapi.com>

or by contacting the sponsor, Taj Pharmaceuticals Limited., at:
91 022 30601000.

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