





GENERIC NAME: sertraline

DRUG CLASS AND MECHANISM

Sertraline belongs to a class of drugs called selective serotonin reuptake inhibitors (SSRIs). Other drugs in this class are Prozac (fluoxetine), Paxil (paroxetine), Celexa (citalopram) and Luvox (fluvoxamine). Serotonin is a neurotransmitter (a chemical messenger) produced by nerve cells in the brain that is used by the nerves to communicate with one another. A nerve releases the serotonin it produces into the space surrounding it. The serotonin either travels across the space and attaches to receptors on the surface of nearby nerves or it attaches to receptors on the surface of the nerve that produced it, to be taken up by the nerve and released again (a process referred to as re-uptake). A balance is reached for serotonin between attachment to the nearby nerves and reuptake. Selective serotonin inhibitors block the reuptake of serotonin and therefore change the level of serotonin in the brain.

It is believed that some illnesses such as depression are caused by disturbances in the balance between serotonin and other neurotransmitters The leading theory is that drugs such as sertraline restore the chemical balance among neurotransmitters in the brain. The FDA approved sertraline in December 1991.

PRESCRIPTION: Yes

GENERIC AVAILABLE: Yes

PREPARATIONS: Tablets: 25, 50, and 100 mg; oral concentrate: 20 mg/ml

Sertraline is used for treating depression, obsessive-compulsive disorder (OCD), panic disorder, and post-traumatic stress disorder (PTSD). Sertraline also is used for treating social anxiety disorder and postmenstrual dysphoric disorder (PMDD).

DRUG INTERACTIONS

Serious reactions such as hyperthermia, fluctuations in blood pressure and rigidity of muscles may occur when SSRIs are used in combination with monoamine oxidase inhibitors (MAOI) such as phenelzine, tranylcypromine (Parnate) and isocarboxazid. Therefore, SSRIs should not be used in combination with MAOIs. In addition, SSRIs and MAOIs should not be used within 14 days of each other.

Cimetidine (Tagamet) may increase the levels in blood of sertraline by reducing the elimination of sertraline by the liver. Increased levels of sertraline may lead to more side effects.

Sertraline increases the blood level of pimozide (Orap) by 40%. High levels of pimozide can affect electrical conduction in the heart and lead to sudden death. Therefore, patients should not receive treatment with both pimozide

Through unknown mechanisms, sertraline may increase the blood thinning action of warfarin (Coumadin). The effect of warfarin should be monitored when sertraline is started or stopped.

Sertraline is a selective serotonin reuptake inhibitor (SSRI) used to treat depression, panic attacks, obsessive compulsive disorders (OCD), post-traumatic stress disorder (PTSD), social anxiety disorder (social phobia), and a severe form of premenstrual syndrome (premenstrual dysphoric disorder or PMDD). This medication works by helping to restore the balance of certain natural chemicals in the brain.

OTHER USES

This medication has also been used to treat a type of decreased sexual ability (premature ejaculation) in men.

HOW TO USE

Take this medication by mouth usually once daily with or without food; or as directed by your doctor. It is recommended that you take your dosage at the same time each day, either in the morning or in the evening. Use this medication regularly in order to get the most benefit from it. The dosage is based on your medical condition and response to therapy. 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. It may take up to 4 weeks before the full benefit of this drug takes effect.

SIDE EFFECTS

Nausea, dry mouth, 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 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 serious side effects occur: uncontrollable shaking (tremor), loss of appetite, unusual weight loss. Tell your doctor immediately if any of these unlikely but serious side effects occur: black stools, "coffee ground" vomit, decreased interest in

sex, decrease in sexual ability (ejaculation delay), easy bruising/bleeding. Tell your doctor immediately if any of these highly unlikely but very serious side effects occur: unusual or rapid weight gain, unusual or severe mental/mood changes, seizures. Males - in the unlikely event you experience a painful or prolonged erection, seek immediate medical attention as this is considered a medical emergency. 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. If you notice other effects not listed above, contact your doctor or pharmacist.

OVERDOSE

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly. Symptoms of overdose may include: increased heartbeat, dizziness, agitation.

DOSING

The recommended dose of sertraline is 25-200 mg once daily. Treatment of depression, OCD, panic disorder, PTSD, and social anxiety disorder is initiated at 25-50 mg once daily. Doses are increased at weekly intervals until the desired response is seen.

The recommended dose for PMDD is 50-150 mg every day of the menstrual cycle or for 14 days before menstruation.

Sertraline may be taken with or without food.

MISSED DOSE

If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

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: liver disease, seizures, heart disease, 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. Though uncommon, depression can lead to thoughts or attempts of suicide. Tell your doctor immediately if you have any suicidal thoughts, worsening depression, or any other mental/mood changes (including new or worsening anxiety, agitation, panic attacks, trouble sleeping, irritability, hostile/angry feelings, impulsive actions, severe restlessness, rapid speech). Keep all medical appointments so your healthcare professional can monitor your progress closely and adjust/change your medication if needed. Caution is advised when using this drug in the elderly because they may be more sensitive to the side effects of the drug. The elderly are more susceptible to developing a type of electrolyte imbalance (hyponatremia), especially if they are also taking "water pills" or 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. This medication should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor. If this medication is used during the last 3 months of pregnancy, infrequently your_ newborn may develop symptoms including feeding or breathing difficulties, seizures, muscle stiffness, jitteriness, or constant crying. However, do not stop taking this medication unless your doctor directs you to do so. Report any such symptoms to your doctor promptly. This drug passes into breast milk. Because of the potential risk to the infant, breast-feeding while using this drug is not recommended. Consult your doctor before breast-feeding.

STORAGE

Store at room temperature at 77 degrees F (25 degrees C) away from light and moisture. Brief storage from 59-86 degrees F (15-30 degrees C) is permitted. Do not store in the bathroom. Keep all medicines away from children and pets.

Note: This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around



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