

<p>Driving and using machines</p> <p>Psychotropic drugs such as sertraline may influence your ability to drive or use machines. You should therefore not drive or operate machinery, until you know how this medication affects your ability to perform these activities.</p> <p>3. How to take Sertraline tablets</p> <p>Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.</p> <p>The recommended dose is:</p> <p>Adults:</p> <p><u>Panic disorder, Social anxiety disorder and Post-Traumatic Stress Disorder:</u></p> <p>For panic disorder, social anxiety disorder and post traumatic stress disorder, treatment should be started at 25 mg/day, and increased to 50 mg/day after one week. The daily dose then may be increased in 50 mg increments over a period of weeks. The maximum recommended dose is 200 mg/day.</p> <p><u>Depression and Obsessive Compulsive Disorder:</u> For depression and OCD, the usual effective dose is 50 mg/day. The daily dose may be increased in 50 mg increments and at intervals of at least one week over a period of weeks. The maximum recommended dose is 200 mg/day.</p> <p>Use in Children and adolescents:</p> <p>Sertraline tablets must only be used to treat children and adolescents suffering from OCD aged 6-17 years old.</p> <p>Obsessive Compulsive Disorder:</p> <p>Children aged 6 to 12: the recommended starting dose is 25 mg daily. After one week, your doctor may increase this to 50 mg daily. The maximum dose is 200 mg daily.</p> <p>Adolescents aged 13 to 17: the recommended starting dose is 50 mg daily. The maximum dose is 200 mg daily.</p> <p>If you have liver or kidney problems, please tell your doctor and follow the doctor's instructions.</p> <p>Method of administration:</p> <p>Sertraline tablets may be taken with or without food. Take your medication once daily either in the morning or evening.</p> <p>Your doctor will advise you on how long to take this medication for. This will depend on the nature of your illness and how well you are responding to the treatment. It may take several weeks before your symptoms begin to improve. Treatment of depression should usually continue for 6 months after improvement.</p> <p>If you take more Sertraline tablets than you should</p> <p>If you accidentally take too much Sertraline tablets contact your doctor at once or go to the nearest hospital casualty department. Always take the labelled medicine package with you, whether there is any medication left or not.</p> <p>Symptoms of overdose may include drowsiness, nausea and vomiting, rapid heart rate, shaking, agitation, dizziness and in rare cases unconsciousness.</p> <p>If you forget to take sertraline tablets</p> <p>If you forget to take a dose, do not take the missed dose. Just take the next dose at the right time. Do not take a double dose to make up for a forgotten dose.</p> <p>If you stop taking Sertraline tablets</p> <p>Do not stop taking Sertraline tablets without consulting your doctor first. Your doctor will want to gradually reduce your dose of Sertraline over several weeks, before you finally stop taking this medicine. If you suddenly stop taking this medicine you may experience side effects such as dizziness, numbness, sleep disturbances, agitation or anxiety, headaches, feeling sick, being sick and shaking. If you experience any of these side effects, or any other side effects whilst stopping taking Sertraline tablets please speak to your doctor.</p> <p>If you have any further questions on the use of this product, ask your doctor or pharmacist.</p> <p>4. Possible side effects</p> <p>Like all medicines, this medicine can cause side effects, although not everybody gets them. Nausea is the most common side effect. The side effects depend on the dose and often disappear or lessen with continued treatment.</p> <p>Tell your doctor immediately:</p> <p>If you experience any of the following symptoms after taking this medicine, these symptoms can be serious.</p> <ul style="list-style-type: none">• Allergic reaction or allergy, which may include symptoms such as an itchy skin rash, breathing problems, wheezing, swollen eyelids, face or lips.• If you develop a severe skin rash that causes blistering (erythema multiforme), (this can affect the mouth and tongue). These may be signs of a condition known as Stevens Johnson Syndrome, or Toxic Epidermal Necrolysis (TEN). Your doctor will stop your treatment in these cases.• If you develop yellow skin and eyes which may mean liver damage.• If you experience agitation, confusion, diarrhoea, high temperature and blood pressure, excessive sweating and rapid heartbeat. These are symptoms of Serotonin Syndrome. In rare cases this syndrome may occur when you are taking certain medicines at the same time as sertraline. Your doctor may wish to stop your treatment.• If you have a manic episode (see section 2 "Warning and precaution").• If you have a fit (seizure).• If you experience depressive symptoms with ideas of harming or killing yourself (suicidal thoughts).• If you start to get feelings of restlessness and are not able to sit or stand still after you start to take sertraline tablets. You should tell your doctor if you start to feel restless. <p>The following side effects were seen in clinical trials in adults and after marketing.</p> <p>Very common (may affect more than 1 in 10 patients):</p> <p>Insomnia, dizziness, sleepiness, headache, diarrhoea, feeling sick, dry mouth, ejaculation failure, fatigue.</p> <p>Common (may affect upto 1 in 10 patients)</p> <ul style="list-style-type: none">• depression, feeling strange, nightmare, anxiety, agitation, nervousness, decreased sexual interest, teeth grinding,• numbness and tingling, shaking, muscle tense, abnormal taste, lack of attention,• muscular movement problems (such as moving a lot, tense muscles, difficulty walking and stiffness, spasms and involuntary movements of muscles)• chest cold, Sore throat, runny nose• visual disturbance• ringing in ears• palpitations• hot flush• yawning• abdominal pain, vomiting, constipation, upset stomach, gas,• rash, increased sweating• muscle pain, back pain, joint pain• menstrual irregularities, erectile dysfunction• injury• Decrease appetite, increase appetite <p>Uncommon (may affect 1 in 100 patients):</p> <ul style="list-style-type: none">• hypersensitivity, seasonal allergy,• low thyroid hormones,• convulsion, involuntary muscle contractions, abnormal coordination, moving a lot, amnesia, decreased feeling, speech disorder, dizziness while standing up, passing out, migraine,• enlarged pupils,• hallucination, lack of caring, thinking abnormal, suicidal thoughts, suicidal behaviour, psychotic disorder,	<ul style="list-style-type: none">• aggression, euphoric mood, paranoia,• ear pain,• fast heartbeat, heart problem,• breathing difficulty, possible wheezing, shortness of breath, nose bleed,• eye swelling, purple spots on skin, face oedema, hair loss, cold sweat, dry skin, hives, itching,• inflammation of the oesophagus, difficulty swallowing, haemorrhoids, increased saliva, tongue disorder, burping, tarry stools, tooth disorder, tongue problem• osteoarthritis, muscular weakness, muscle twitching, muscle cramps• night time urination, increase in urination, increase in frequency of urination, problem urinating unable to urinate, urinary incontinence,• vaginal haemorrhage, sexual dysfunction, female sexual dysfunction,• swelling in legs, chills, difficulty weakness, thirst,• increase in liver enzyme levels, weight decreased,• Gastroenteritis, ear infection• Tumour• Cases of suicidal ideation and suicidal behaviours have been reported during sertraline therapy or early after treatment discontinuation (see section 2) <p>Rare (may affect up to 1 in 1,000 patients):</p> <ul style="list-style-type: none">• diverticulitis, swollen lymph glands, decrease in clotting cells", decrease in white blood cells",• severe allergic reaction,• endocrine problems",• high cholesterol, problems controlling blood sugar levels (diabetes), low blood sugar, increase in blood sugar levels", low blood salt",• physical symptoms due to stress or emotions, terrifying abnormal dreams", drug dependence, sleep walking, premature ejaculation,• coma, abnormal movements, difficulty moving, increased sensation, sudden severe headache (which may be a sign of a serious condition known as Reversible Cerebral Vasoconstriction Syndrome (RCVS))", sensory disturbance,• spots in front of eyes, glaucoma, double vision, light hurts eye, blood in the eye, unequal sized pupils", vision abnormal", tear problem,• heart attack, light-headedness, fainting, or chest discomfort which could be signs of changes in the electrical activity (seen on electrocardiogram) or abnormal rhythm of the heart", slow heartbeat,• poor circulation of arms and legs,• breathing fast, progressive scarring of lung tissue (Interstitial Lung Disease)", closing up of throat, difficulty talking, breathing slow, hiccups,• mouth ulceration, pancreatitis", blood in stool, tongue ulceration, sore mouth,• problems with liver function, serious liver function problems", yellow skin and eyes (jaundice)",• skin reaction to sun", skin oedema", hair texture abnormal, skin odour abnormal, hair rash,• breakdown of muscle tissue", bone disorder,• urinary hesitation, decreased urination,• breast discharge, dry vaginal area, genital discharge, red painful penis and foreskin, breast enlargement", prolonged erection,• hernia, drug tolerance decreased,• increase in blood cholesterol levels, abnormal laboratory tests", semen abnormal, problems with clotting",• relaxation of blood vessels procedure,• Spots in front of eyes, glaucoma, double vision, light hurts eye, blood in the eye, unequal sized pupils, vision abnormal, tear problem. <p>Not known: frequency cannot be estimated from the available data:</p> <ul style="list-style-type: none">• lockjaw"• bed wetting"• Partial loss of vision• Inflammation of the colon (causing diarrhoea)• Heavy vaginal bleeding shortly after birth (postpartum haemorrhage); see "Pregnancy, breast-feeding and fertility" in section 2 for more information. <p>Additional Side effects in children and adolescents</p> <p>In clinical trials with children and adolescents, the side effects were generally similar to adults (see above). The most common side effects in children and adolescents were headache, insomnia, diarrhoea and feeling sick.</p> <p>Symptoms that can occur when treatment is discontinued</p> <p>If you suddenly stop taking this medicine you may experience side effects such as dizziness, numbness, sleep disturbances, agitation or anxiety, headaches, feeling sick, being sick and shaking (see section 3. "If you stop taking Sertraline tablets"). An increased risk of bone fractures has been observed in patients taking this type of medicines.</p> <p>Reporting of side effects</p> <p>If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.</p> <p>5. How to store Sertraline Tablets</p> <p>Keep this medicine out of the sight and reach of children.</p> <p>Do not use Sertraline tablets after the expiry date which is stated on the blister and carton as EXP or EXP date. The expiry date refers to the last day of that month.</p> <p>Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.</p> <p>This leaflet does not contain all the information about your medicine. If you have any questions or you are not sure about anything ask your doctor or pharmacist.</p> <p>6. Contents of the pack and other information</p> <p>What Sertraline tablets contains</p> <p>Sertraline 50 mg film-coated tablets contain 50mg sertraline (as hydrochloride) Sertraline 100 mg film-coated tablets contain 100mg sertraline (as hydrochloride)</p> <p>The other ingredients are:</p> <p><i>Tablet cores:</i> Microcrystalline cellulose, Low-substituted hydroxypropyl cellulose (E463), Magnesium stearate (E572), Silica, colloidal anhydrous (E551) <i>Film coating:</i> hypromellose(E464), Microcrystalline cellulose(E460), Macrogol stearate, Titanium dioxide (E171) <i>Polishing:</i> Macrogol</p> <p>What Sertraline tablets looks like and contents of the pack</p> <p>Sertraline 50 mg film-coated tablets are white, oval, half scored, debossed '5' on one half of score of one face and '0' on other half of score in the same face. Sertraline 100 mg film-coated tablets are white, oval, half scored, debossed '1' on one half of score of one face and '00' on other half of score in the same face.</p> <p>Sertraline 50mg and 100mg film-coated tablets are available in packs of 10, 14, 15, 20, 28, 30, 50, 56, 60, 84, 90, 98, 100, 200, 294, 300, or 500 tablets. Not all pack sizes may be marketed.</p> <p>Marketing Authorisation Holder: RIA Generics Limited.,36 Ingleby Way, Wallington, Surrey SM6 9LR, UK</p> <p>Manufacturer: Wave Pharma Limited., 4th floor, Cavendish House, 369 Burnt Oak, Broadway, Edgware, Middlesex HA8 5AW, UK</p> <p>RIA Generics Limited 36 Ingleby Way Wallington SM6 9LR United Kingdom</p> <p>If you would like this leaflet in a different format, please contact the marketing authorisation holder listed above.</p> <p>If you would like to have any further information or want to report any side effects, please email at info@riagenerics.com.</p> <p>This leaflet was last revised in April 2021</p>
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