
PRODUCT MONOGRAPH
INCLUDING PATIENT MEDICATION INFORMATION



- DEPRESSION TREATMENT/
MAJOR DEPRESSIVE DISORDER (MDD)
- Via Oral

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Sertraline

Hcl Tablets

25 MG, 50 MG & 100 MG

Sertraline is used to treat depression, obsessive-compulsive disorder, anxiety disorders (including panic disorder and social anxiety disorder), post-traumatic stress disorder (PTSD), and premenstrual dysphoric disorder (PMDD).

PATIENT INFORMATION LEAFLET: Information for the user
SERTRALINE HYDROCHLORIDE 50 & 100 mg TABLETS
Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet you may need to read it again.
- If you have further questions, please ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. What Sertraline Tablets are and what they are used for
2. What you need to know before you take Sertraline Tablets
3. How to take Sertraline Tablets
4. Possible side effects
5. How to store Sertraline Tablets
6. Contents of the pack and further information

1. WHAT SERTRALINE TABLETS ARE AND WHAT THEY ARE USED FOR

Sertraline Tablets is one of a group of medicines called selective serotonin reuptake inhibitors (SSRIs). These work by bringing the level of serotonin in the brain, back up to normal. Low levels of serotonin are thought to be a cause of depression and related disorders.

Sertraline can be used to treat:

- Depression and prevention of recurrence of depression in adults
- Social anxiety disorder in adults
- Obsessive-compulsive disorder (OCD) in adults, children and adolescents aged 6 -17
- Post traumatic stress disorder (PTSD) in adults
- Panic disorder in adults

Depression is a clinical illness with symptoms like feeling sad, unable to sleep properly or to enjoy life as you used to.

OCD and Panic disorders are illnesses linked to anxiety with symptoms like being constantly troubled by persistent ideas (obsessions) that make you carry out repetitive rituals (compulsions).

PTSD is a condition that can occur after a very emotionally traumatic experience and has some symptoms that are similar to depression and anxiety.

Social anxiety disorder (social phobia) is an illness linked to anxiety. It is characterized by feelings of intense anxiety or distress in social situations (for example talking to strangers, speaking in front of groups of people, eating or drinking in front of others or worrying that you might

behave in an embarrassing manner).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SERTRALINE TABLETS

Do not take Sertraline Tablets if:

- you are **allergic (hypersensitive)** to **sertraline** or **any of the other ingredients** in the tablets (these are listed in Section 6, contents of the pack and other information).
- you are taking or have taken a **monoamine oxidase inhibitor** drug (MAOI) such as selegiline or moclobenide or a MAOI like drug (such as linezolid) for depression. If you stop treatment with sertraline you must wait until at least one week before you start treatment with an MAOI.
- you are taking a medicine called **pimozide** (a medicine for the treatment of mental disorders such as schizophrenia or psychosis).

Warnings and precautions

Talk to your doctor before you take Sertraline Tablets if you suffer from or have suffered in the past from any of the following:

- **epilepsy, a history of seizures.** or are receiving ECT (electroconvulsive therapy). If you have a fit (seizure) contact your doctor immediately.
- if you have suffered from **manic depressive illness (bipolar disorder) or schizophrenia.** If you have a manic episode, contact your doctor immediately.
- **diabetes** as taking Sertraline Tablets may alter your blood glucose levels and your insulin/medication may need adjusting
- if you have suffered from a **bleeding disorder** or have been taking medicines which thin the blood (e.g. acetylsalicylic acid (aspirin), or warfarin) or may increase the risk of bleeding
- if you have or have previously **had thoughts of harming or killing yourself** (see below – Thoughts of suicide and worsening of your depression or anxiety disorder)
- **serotonin syndrome.** In rare cases this syndrome may occur when you are taking certain medicines at the same time as sertraline. (For symptoms see Section 4 Possible side effects). Your doctor will have told you whether you have suffered from this in the past.
- **if you have low sodium levels in your blood,** since this can occur as a result of treatment with Sertraline Tablets. You should tell your doctor if you are taking medicines for hypertension, since these medicines may also alter the sodium levels in your blood.
- **take special care if you are elderly** as you may be at more risk of having low sodium levels in your blood.
- **liver disease;** Your doctor may decide that you should have a lower dose of Sertraline Tablets.
- **if you are a child or adolescent under 18 years old.** Sertraline Tablets should only be used to treat children and adolescents aged 6 – 17 years old, suffering from obsessive compulsive disorder (OCD). If you are being treated for this disorder, your doctor will want to monitor you closely (see below Use in children and adolescents).
- if you are having electro-convulsive therapy (ECT)
- if you currently have or have a history of angle-closure glaucoma (rapid build-up of pressure in the eye)

Sertraline can affect the results of some blood, urine or other tests. It may not affect all tests. If you have a blood or urine test done, tell the doctor or medical staff that you are taking Sertraline Tablets.

Restlessness/Akathisia The use of sertraline has been linked to a distressing restlessness and need to move, often being unable to sit or stand still (akathisia). This is most likely to occur during the first few weeks of treatment. Increasing the dose may be harmful so if you develop such symptoms you should talk to your doctor.

Withdrawal reactions Side effects related to stopping treatment (withdrawal reactions) are common, particularly if the treatment is stopped suddenly (see Section 3 If you stop taking Sertraline Tablets and Section 4 Possible side effects). The risk of withdrawal symptoms depends on the length of treatment, dosage and the rate at which the

dose is reduced. Generally such symptoms are mild to moderate.

However, they can be serious in some patients. They normally occur within the first few days after stopping treatment. In general such symptoms disappear on their own and wear off within 2 weeks. In some patients they may last longer (2-3 months or more). When stopping treatment with sertraline it is recommended to reduce the dose gradually over a period of several weeks or months and you should always discuss the best way of stopping treatment with your doctor.

Important information about Sertraline Tablets and thoughts of suicide and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think thoughts like this:

- If you have previously had thoughts about killing or harming yourself.
- If you are a young adult.

Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away.**

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Use in children and adolescents Sertraline should not normally be used in children and adolescents less than 18 years old, except for patients with Obsessive Compulsive Disorder (OCD). Patients under 18 have an increased risk of undesirable effects, such as suicide attempt, thoughts of harming or killing themselves (suicidal thoughts) and hostility (mainly aggressiveness, oppositional behaviour and anger) when they are treated with this class of medicines. Nevertheless it is possible that your doctor decides to prescribe Sertraline Tablets to a patient under 18 if it is in the patient's best interest. If your doctor has prescribed Sertraline Tablets to you and you are less than 18 years old and you want to discuss this, please contact him/her. Furthermore, if any of the symptoms listed above appear or worsen while you are taking Sertraline Tablets, you should inform your doctor. Also, the long term safety of Sertraline Tablets with regard to growth, maturation and learning (cognitive) and behavioral development in this age group has not yet been demonstrated.

Other medicines and Sertraline Tablets

Tell your doctor, pharmacist or nurse if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Sertraline Tablets can affect the way some medicines work. Also some medicines can affect the way sertraline works.

Taking Sertraline Tablets together with the following medicines may cause serious side effects:

- Medicines called monoamine oxidase inhibitors (MAOIs), like moclobemide (to treat depression) and selegiline (to treat Parkinson's disease) and the antibiotic linezolid. **Do not use Sertraline Tablets together with these medicines.**
- Medicines to treat mental disorders such as schizophrenia or psychosis (pimozide). **Do not use Sertraline Tablets together with pimozide.**

Tell your doctor is you are taking any of the following medicines:

- products containing the amino acid tryptophan (used to treat depression, anxiety and other mental disorders)
- diazepam (a sedative)
- lithium (used to treat mania and depression)
- medicines used in anaesthesia or to treat chronic pain (fentanyl).
- tricyclic antidepressants such as imipramine and other medicines to treat depression (such as

- nefazodone, desipramine and amitriptyline)
- medicines to treat schizophrenia and other mental disorders (such as perphenazine, levomepromazine and olanzapine)
- medicines to treat diabetes (tolbutamide)
- warfarin (used to thin the blood)
- cimetidine (used in the treatment of ulcers)
- non-steroidal anti-inflammatory drugs (NSAIDs) for pain relief or arthritis, including aspirin and ibuprofen
- diuretics (also called "water" tablets)
- medicines to treat epilepsy (phenytoin, phenobarbital, carbamazepine)
- serotonergic drugs such as tramadol (a painkiller), sumatriptan (for migraine) or fenfluramine (an appetite suppressant)
- St John's Wort (*Hypericum perforatum*), a herbal remedy. The effects of St John's Wort may last for 1 – 2 weeks
- medicines used to regulate the rate and rhythm of the heart (such as flecainide, propafenone, verapamil, diltiazem)
- medicines used to treat fungal infections (such as ketoconazole, itraconazole, posaconazole, voriconazole, fluconazole)
- medicines used to prevent nausea and vomiting after an operation or chemotherapy (such as aprepitant)

It may still be all right for you to take Sertraline Tablets and your doctor will be able to decide what is suitable for you.

Sertraline Tablets with food, drink and alcohol

Sertraline Tablets can be taken with or without food. Drinking alcohol while being treated with sertraline is not recommended.

Sertraline Tablets should not be taken in combination with grapefruit juice, as this may increase the level of sertraline in your body.

Pregnancy and breast-feeding

If you are pregnant, likely to become pregnant or are breast-feeding, you must tell your doctor before taking this medicine and your doctor will decide if this medicine is right for you.

The safety of sertraline has not been fully established in pregnant women. Sertraline Tablets will only be given to you when pregnant if your doctor considers that the benefit for you is greater than any possible risk to the developing baby. If you are a woman capable of having children you should use a reliable method of contraception (such as the contraceptive pill) when taking sertraline.

Make sure your midwife and/or doctor know you are on Sertraline Tablets. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Sertraline Tablets may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the new born (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your midwife and/or doctor immediately.

Your newborn baby might also have other conditions, which usually begin during the first 24 hours after birth. Symptoms include:

- trouble with breathing,
- a blueish skin or being too hot or cold,
- blue lips,
- vomiting or not feeding properly,
- being very tired, not able to sleep or crying a lot,
- stiff or floppy muscles,
- tremors, jitters or fits,
- increased reflex reactions,
- irritability,
- low blood sugar.

If your baby has any of these symptoms when it is born, or you are concerned about your baby's health, contact your doctor or midwife who will be able to advise you.

There is evidence that sertraline passes into human breast milk. Sertraline Tablets should only be used in women during breast-feeding if your doctor considers that the benefit exceeds any possible risk to the baby.

Ask your doctor or pharmacist for advice before taking any medicine. Some medicines like sertraline may reduce the quality of sperm in

animal studies. Theoretically, this could affect fertility, but impact on human fertility has not been observed as yet.

Driving and using machines

Psychotropic drugs such as Sertraline Tablets may affect your mental or physical ability to drive or use machines. You should not drive or operate machinery until you know how this medicine affects your ability to perform these activities.

3. HOW TO TAKE SERTRALINE TABLETS

Always take Sertraline Tablets exactly as your doctor has told you to do so. Check with your doctor or pharmacist if you are not sure.

Sertraline Tablets may be taken with or without food. Take your medication daily either in the morning or in the evening. The label on the carton will tell you how many tablets you should take and when.

The usual dose for Sertraline Tablets is as follows:

Adults:

Depression and Obsessive Compulsive Disorder

The usual dose for treatment in adults is 50 mg once a day. The daily dose may be increased in 50mg increments and at intervals of at least one week over a period of weeks. The maximum recommended dose is 200 mg/day.

Panic disorder, Social anxiety disorder and Post-Traumatic Stress Disorder

The usual starting dose for treatment in adults is 25 mg once a day. After one week, this should be increased to 50 mg once a day. The daily dose may then be increased in 50 mg increments over a period of weeks. The maximum recommended dose is 200 mg a day.

Children and Adolescents:

Sertraline Tablets must only be used to treat children and adolescents suffering from OCD aged 6 – 17 years old.

Obsessive Compulsive Disorder

Adolescents aged 13 -17 should be started at a dose of 50 mg daily.

Children aged 6 – 12 should be started at a dose of 25 mg once a day increasing to 50 mg daily after one week

The maximum dose is 200 mg daily

Not recommended for use in children under 6 years of age.

Depression

Not recommended for use in children and adolescents under 18 years of age.

If you have liver or kidney problems please tell your doctor and follow the doctor's instructions.

Treatment duration

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.

If you take more Sertraline Tablets than you should:

If you have accidentally taken more than your prescribed dose, contact your nearest casualty department or tell your doctor or pharmacist immediately. Remember to take the pack and any remaining tablets with you. The most common signs and symptoms of overdose are nausea and vomiting, a forceful and rapid heartbeat, tremor, agitation, dizziness and in rare cases, unconsciousness.

If you forget to take Sertraline Tablets

It is important that you take your medicine every day. If you forget to take your medicine, do not take the missed dose. Just take your next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Sertraline Tablets

Do not stop taking Sertraline Tablets unless your doctor tells you to.

Your doctor will want to gradually reduce your dose of Sertraline Tablets over several weeks until you finally stop taking this medicine. If you stop taking Sertraline Tablets suddenly, you may experience side effects such as headaches, dizziness, shaking, feeling or being sick, anxiety, agitation, numbness and sleep disturbances.

If you experience any of these side effects, or any other side effects whilst stopping taking Sertraline Tablets, please speak to your doctor. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Sertraline Tablets can cause side effects although not everybody gets them.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Nausea is the most common side effect. The side effects depend on the dose and often disappear or lessen with continued treatment.

All medicines can cause allergic reactions although serious allergic reactions are very rare. If you get any of the following symptoms after taking these tablets, you should stop taking the tablets and contact your doctor immediately:

- Any sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat
- Rash or itching (especially affecting your whole body)
- Convulsions

Tell your doctor immediately if you develop any of the following symptoms after taking this medicine; these symptoms can be serious.

• 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 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 can occur when you are taking certain medicines at the same time as sertraline. Your doctor may wish to stop your treatment.

• If you develop yellow skin and eyes which may mean liver damage.

• 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.

- If you have a fit (seizure)
- If you have a manic episode (see Section 2 What you need to know about Sertraline Tablets)

The following side effects were seen in clinical trials in adults.

Very common side effects (may affect more than 1 in 10 people):

- insomnia
- dizziness
- sleepiness
- headache
- diarrhoea
- feeling sick
- dry mouth
- ejaculation failure
- fatigue

Common side effects (may affect up to 1 and 10 people):

- sore throat, anorexia, increased appetite
- depression, feeling strange, nightmare, anxiety, agitation, nervousness, decreased sexual interest, teeth grinding
- numbness and tingling, shaking, muscle tense, abnormal taste, lack of attention
- visual disturbance, ringing in ears
- palpitations, hot flush, yawning
- abdominal pain, vomiting, constipation, upset stomach, gas
- rash, increased sweating, muscle pain, sexual dysfunction, erectile dysfunction, chest pain

Uncommon side effects (may affect up to 1 and 100 people):

- chest cold, runny nose
- hallucination, feeling too happy, lack of caring, thinking abnormal
- convulsion, involuntary muscle contractions, abnormal coordination, moving a lot, amnesia, decreased feeling, speech disorder, dizziness

while standing up, migraine

- ear pain, fast heartbeat, high blood pressure, flushing
- breathing difficulty, possible wheezing, shortness of breath, nose bleed
- inflammation of the oesophagus, difficulty swallowing, haemorrhoids, increased saliva, tongue disorder, burping
- eye swelling, purple spots on skin, hair loss, cold sweat, dry skin, hives
- osteoarthritis, muscular weakness, back pain, muscle twitching
- night time urination, unable to urinate, increase in urination, increase in frequency of urination, problem urinating
- vaginal haemorrhage, female sexual dysfunction, malaise, chills, fever, weakness, thirst, weight decreased, weight increased.

Rare side effects (may affect up to 1 in 1,000 people):

- intestine problem, ear infection, cancer, swollen glands, high cholesterol, low blood sugar
- physical symptoms due to stress or emotions, drug dependence, psychotic disorder, aggression, paranoia, suicidal thoughts, sleep walking, premature ejaculation
- coma, abnormal movements, difficulty moving, increased sensation, sensory disturbance
- glaucoma, tear problem, spots in front of eyes, double vision, light hurts eye, blood in the eye, enlarged pupils
- heart attack, slow heart beat, heart problem, poor circulation of arms and legs, closing up of throat, breathing fast, breathing slow, difficulty talking, hiccups
- blood in stool, sore mouth, tongue ulceration, tooth disorder, tongue problem, mouth ulceration, problems with liver function
- skin problem with blisters, hair rash, hair texture abnormal, skin odour abnormal, bone disorder
- decreased urination, urinary incontinence, urinary hesitation
- excessive vaginal bleeding, dry vaginal area, red painful penis and foreskin, genital discharge, prolonged erection, breast discharge
- hernia, injection site scarring, drug tolerance decreased, difficulty walking, abnormal laboratory tests, semen abnormal, injury, relaxation of blood vessels procedure
- Cases of suicidal ideation and suicidal behaviours have been reported during sertraline therapy or early after treatment discontinuation (see section 2).

After marketing sertraline, the following side effects have been reported:

- decrease in white blood cells, decrease in clotting cells, low thyroid hormones, endocrine problem, low blood salt, problems controlling blood sugar levels (diabetes), increase in blood sugar levels
- terrifying abnormal dreams, suicidal behaviour
- muscular movement problems (such as moving a lot, tense muscles and difficulty walking and stiffness spasms and involuntary movement of the muscles)
- sudden severe headache (which may be a sign of a serious condition known as Reversible Cerebral

Vasoconstriction Syndrome (RCVS)), passing out, passing out

- vision abnormal, unequal sized pupils, bleeding problems (such as nose bleed, stomach bleeding or blood in urine), progressive scarring of the lung tissue (Interstitial Lung Disease)
- skin oedema, skin reaction to sun, itching, joint pain, muscle cramps, breast enlargement, menstrual irregularities, swelling in legs, problems with clotting, bedwetting and severe allergic reaction.

Side effects in children and adolescents

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.

Symptoms that can occur when treatment is discontinued

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 medicine.

Reporting of side effects:

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the 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.

5. HOW TO STORE SERTRALINE TABLETS

Keep all medicines out of the sight and reach of children.

Do not take this medicine after the expiry date shown on the carton.

The expiry date is the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND FURTHER INFORMATION

What Sertraline Tablets contain:

The active substance is sertraline (as hydrochloride). Each tablet contains 50 or 100 mg of sertraline (as hydrochloride).

The other ingredients are microcrystalline cellulose, maize starch, sodium starch glycolate (Type A), magnesium stearate, titanium dioxide (E171), hypromellose and macrogol 6000.

What Sertraline Tablets look like and the contents of the pack:

Sertraline 50 mg Tablets are white, capsular shaped, film-coated tablets, with a break line, embossed on one side with 'TAJ 50' and 'T' on the other side.

Sertraline 100 mg Tablets are white, capsular shaped, film-coated tablets, with SRN embossed on one side and 'TAJ' on the other side.

Your medicine is available in :

Blister packs of 28,30,100 TABLETS & 500 TABLETS.

Marketing Authorisation Holder

Manufactured in India by:

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