



Package leaflet: information for the user

Sertralax 50 mg film-coated tablets

Sertraline hydrochloride

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 any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Sertralax is and what it is used for
2. What you need to know before you take Sertralax
3. How to take Sertralax
4. Possible side effects
5. How to store Sertralax
6. Contents of the pack and other information

1. What Sertralax is and what it is used for

Sertralax contains sertraline as active substance. Sertraline is one of a group of medicines called Selective Serotonin Re-uptake Inhibitors (SSRIs); these medicines are used to treat depression and/or anxiety disorders.

Sertralax can be used to treat:

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

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).

Your doctor has decided that this medicine is suitable for treating your illness.

You should ask your doctor if you are unsure why you have been given Sertralax.

2. What you need to know before you take Sertralax

Do not take Sertralax:

- If you are allergic to sertraline or any of the other ingredients of this medicine (listed in section 6).
- If you are taking or have taken medicines called monoamine oxidase inhibitors (MAOIs such as selegiline, moclobemide) or MAOI like drugs (such as linezolid). If you stop treatment with sertraline, you must wait at least one week before you start treatment with a MAOI. After stopping treatment with MAOI, you must wait at least 2 weeks before you can start treatment with sertraline.
- If you are taking another medicine called pimozide (an antipsychotic medicine).

Warnings and precautions

Medicines are not always suitable for everyone. Tell your doctor before you start your treatment with Sertralax, if you suffer from or have suffered in the past from any of the following conditions:

- 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 tell you whether you have suffered from this in the past.
- If you have low sodium level in your blood, since this can occur as a result of treatment with sertraline. You should also tell your doctor if you are taking certain medicines for hypertension, since these medicines may also alter the sodium level in your blood.
- Take special care if you are elderly as you may be more at risk of having low sodium level in your blood (see above).
- Liver disease; your doctor may decide that you should have a lower dose of sertraline.
- Diabetes; your blood glucose levels may be altered due to sertraline and your diabetes medicines may need to be adjusted.
- Epilepsy (fit) or history of seizures. 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.
- 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).
- If you have suffered from bleeding disorders 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 are a child or adolescent under 18 years old. Sertraline 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- Children and adolescents).
- If you are having electro-convulsive therapy (ECT).

Restlessness/Akathisia

The use of sertraline has been linked to akathisia (a distressing restlessness

and need to move, often being unable to sit or stand still). This is most likely to occur during the first few weeks of treatment. Increasing the dose in patients that get these symptoms may be harmful.

Withdrawal reactions

Side effects relating to stopping treatment are common, particularly if the treatment is stopped suddenly (see 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 according to the patient's individual requirements.

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 of the treatment with antidepressants, since all these medicines take time to work, usually about two weeks but sometimes longer.

You may be more likely to think 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 are getting worse, or if they are worried about changes in your behaviour.

Increased risk of bone fracture has been observed in patients treated with this kind of medicines.

Children and adolescents

Sertraline should not usually 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, 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 Sertralax to a patient under 18 if it is in the patient's interest. If your doctor has prescribed Sertralax to a patient that is 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 a patient that is less than 18 years old is taking Sertralax, you should inform your doctor. Also, the long-term safety of Sertralax in regard to growth, maturation and learning (cognitive) and behavioural development in this age group has not yet been demonstrated.

Other medicines and Sertralax

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Some medicines can affect the way Sertralax works, or Sertralax itself can reduce the effectiveness of other medicines taken at the same time.

Taking Sertralax 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 together with MAOIs.
- Medicines to treat mental disorders (pimozide). Do not use sertraline together with pimozide.

Talk to your doctor if you are taking the following medicines

- Herbal medicine containing St. John's Wort (*Hypericum perforatum*). The effects of St. John's Wort may last for 1-2 weeks. Talk to your doctor.
- Products containing the amino acid tryptophan.
- Medicines to treat severe pain (e.g. tramadol).
- Medicines to treat migraines (e.g. sumatriptan).
- Blood thinning medicines (warfarin).
- Medicines to treat pain/arthritis (Non-steroidal anti-inflammatory drugs (NSAID) such as ibuprofen, acetylsalicylic acid (aspirin)).
- Sedatives (diazepam).
- Diuretics.
- Medicines to treat epilepsy (phenytoin).
- Medicines to treat diabetes (tolbutamide).
- Medicines to treat excessive stomach acid and ulcers (cimetidine).
- Medicines to treat mania and depression (lithium).
- Other medicines to treat depression (such as amitriptyline, nortriptyline).
- Medicines to treat schizophrenia and other mental disorders (such as perphenazine, levomepromazine and olanzapine).

Sertralax with food and drink

Sertralax tablets can be taken with or without food.

Alcohol should be avoided whilst taking sertraline.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

The safety of sertraline has not been fully established in pregnant women. Sertraline will only be given to pregnant women if, in doctor's judgement, benefit for the mother is greater than any possible risk for the developing of

the baby. Women capable of having children should use a reliable method of contraception when taking sertraline.

Make sure your midwife and/or doctor know you are on Sertralax. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Sertralax may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breath 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.

Fertility

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.

Breast-feeding

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

Driving and using machines

During treatment with Sertralax you may feel drowsy or dizzy. Do not drive nor operate machinery until you know how Sertralax affects your ability to perform these activities.

3. How to take Sertralax

Take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Sertralax tablets can be taken with or without food.

Take your medicine once a day, in the morning or at night.

Ask your doctor or pharmacist if you have further questions.

The recommended dose is:

Adults:

Depression and Obsessive Compulsive Disorder:

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.

Panic disorder, social anxiety disorder and post-traumatic stress disorder:

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.

Children and adolescents

Sertralax must only be used to treat children and adolescents suffering from OCD aged 6-17 years old.

Obsessive Compulsive Disorder:

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.

Adolescents aged 13 to 17: the recommended starting dose is 50 mg daily. The maximum dose is 200 mg daily.

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

Your doctor will tell you the duration of the treatment with this medication. 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.

If you take more Sertralax than you should

If too many tablets are taken by accident, contact your doctor or pharmacist at once.

Symptoms of overdose may include drowsiness, nausea and vomiting, rapid heartbeat, shaking, agitation, dizziness and in rare cases unconsciousness.

If you forget to take Sertralax

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.

If you stop taking Sertralax

Do not stop taking Sertralax unless your doctor tells you to. Your doctor will want to gradually reduce your dose of Sertralax 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 Sertralax, 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, Sertralax can cause side effects, although not everybody gets them.

If you consider that any of the side effects you are experiencing is severe, or if you experience any side effect not listed in this leaflet, 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.

Tell your doctor immediately:

If you experience 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.
- Allergic reaction or allergy, which may include symptoms such as an itchy skin rash, breathing problems, wheezing, swollen eyelids, face or lips.
- 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 you to stop your treatment.

- If you develop yellow skin and eyes, which may mean liver damage.
- If you experience depressive symptoms with suicidal thoughts.
- If you start to get feelings of restlessness and are not able to sit or stand still after you start to take Sertralax. You should tell your doctor if you start to feel restless.

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 and fatigue.

Common side effects (may affect 1 to 10 people in 100):

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 and chest pain.

Uncommon side effects (may affect 1 to 10 people in 1,000):

Chest cold, runny nose, hallucinations, feeling too happy, lack of caring, abnormal thinking, 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, oesophagus problems, swallowing difficulty, 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, inability to urinate, increase in urination, increase in frequency of urination, urination disorder, vaginal haemorrhage, female sexual dysfunction, malaise, chills, fever, weakness, thirst, weight decreased and increased weight.

Rare side effects (may affect 1 to 10 people in 10,000):

Intestine problem, ear infection, cancer, swollen glands, high cholesterol, increased blood sugar, physical symptoms due to stress or emotions, drug dependence, psychotic disorder, aggression, paranoia, suicidal thoughts, sleep walking, premature ejaculation, coma, abnormal movements, moving difficulty, increased sensitivity, sensory disturbance, glaucoma, tear problem, spots in front of eyes, double vision, light hurts eye, blood in the eye, enlarged pupils, heart attack, slow heartbeat, 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 and tongue disorders, mouth ulceration, problems with liver function, skin problem with blisters, hair rash, abnormal hair texture, abnormal skin odour, bone disorder, decreased urination, urinary hesitation, intermittent urination, excessive vaginal bleeding, dry vaginal area, red painful penis and foreskin, genital discharge, prolonged erection, breast discharge, hernia, drug tolerance decreased, walking difficulty, abnormal laboratory tests, abnormal semen, injury, relaxation of blood vessels procedure.

After marketing sertraline, the following side effects have been reported

Decrease in white blood cells, decrease in clotting cells, low level of thyroid hormones, endocrine problems, low blood salt levels, terrifying abnormal dreams, suicidal behaviour, muscular movement problems (such as moving a lot, tense muscles, walking difficulty), syncope, abnormal vision, bleeding problems (such as nose or stomach bleeding or blood in the urine), pancreatitis, serious liver function problems, yellow skin and eyes (jaundice), skin oedema, skin reaction to sun, itch, joint pain, muscle cramps, breast enlargement, abnormalities in menstrual cycle, swollen legs, problems with clotting and serious allergic reactions.

Additional 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.

5. How to store Sertralax

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the pack after EXP. The expiry date refers to the last day of that month.

Store below 30°C.

Do not throw any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Sertralax contains

- The active substance of Sertralax is sertraline (hydrochloride). Each tablet contains 50 mg of sertraline.

The other ingredients are: calcium hydrogen phosphate dihydrate, microcrystalline cellulose, potato sodium starch glycolate, silica colloidal and magnesium stearate. Coating: hypromellose, titanium dioxide (E-171), talc and macrogol 6000.

What Sertralax looks like and contents of the pack

Sertralax 50 mg is presented as white or almost white, round, biconvex, scored and marked film-coated tablets.

Sertralax 50 mg is available in two pack sizes: 30 and 500 film-coated tablets. Tablets are presented in PVC/Aluminum blisters.

Marketing authorization Holder and Manufacturer

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