PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

# Sertraline 25 mg Film-coated 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 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 (see section 4).

**What is in this leaflet**

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


## 1. WHAT SERTRALINE IS AND WHAT IT IS USED FOR

**What it is used for**
Sertraline 25 mg Film-coated Tablets (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.

Sertraline 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 disorder (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 characterised 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 sertraline.

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

**Do not take sertraline if you are:**
- allergic to sertraline or any of the other ingredients of this medicine (listed in section 6).
- 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 until at least 1 week before you start treatment with a MAOI. After stopping treatment with a MAOI, you must wait at least 2 weeks before you can start treatment with sertraline.
- taking another medicine called pimozide (a medicine for mental disorders such as psychosis).

Do not take if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before you take sertraline.

**Warnings and precautions**
Medicines are not always suitable for everyone. Talk to your doctor or pharmacist before taking sertraline if you suffer from or have suffered in the past from any of the following conditions:
- epilepsy or a history of seizures (fits). If you have a fit (seizure), contact your doctor immediately.
- manic depressive illness (bipolar disorder) or schizophrenia. If you have a manic episode, contact your doctor immediately.
- thoughts of harming or killing yourself (see below -Thoughts of suicide and worsening of your depression or anxiety disorder).
- the use of buprenorphine together with sertraline can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and sertraline").
- low sodium levels 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.
- 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.
- if you have a history of bleeding disorders (tendency to develop bruises), or if you are pregnant (see Pregnancy, breast-feeding and fertility section) or have been taking medicines which thin the blood (e.g. acetylsalicyclic 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 section below - Children and adolescents).
- if you are having electro-convulsive therapy (ECT).
- eye problems, such as certain kinds of glaucoma (increased pressure in the eye).
- an abnormality of your heart tracing after an electrocardiogram (ECG) known as prolonged QT interval.
- heart disease, low potassium levels or low magnesium levels, family history of QT prolongation, low heart rate and concomitant use of medications which prolong QT interval.

**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 relating to stopping treatment (withdrawal reactions) are common, particularly if the treatment is stopped suddenly (see section 3 - If you stop taking sertraline and section 4). 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.

**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 2 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 is getting worse, or if they are worried about changes in your behaviour.

**Sexual problems**
Medicines like sertraline (SSRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.

**Children and adolescents**
Sertraline should not usually be used in children and adolescents less than 18 years old, except for patients with 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 to a patient under 18 if it is in the patient's interest. If your doctor has prescribed sertraline 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, you should inform your doctor.
The long-term safety of sertraline in regard to growth, maturation and learning (cognitive) and behavioural development was evaluated in a long term study in more than 900 children aged 6 to 16 years of age who were monitored over a 3 year period. Overall, the results of the study showed that children treated with Sertraline developed normally other than mild weight gain in those treated with a higher dose.

**Other medicines and sertraline**
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Some medicines can affect the way sertraline works, or sertraline itself can reduce the effectiveness of other medicines taken at the same time.

Taking sertraline 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), the antibiotic linezolid and methylene blue (to treat high levels of methaemoglobin in the blood). Do not use sertraline together with these medicines
- Medicines to treat mental disorders such as psychosis (pimozide). Do not use sertraline together with pimozide.

Talk to your doctor if you are taking the following medicines:
- Medicines containing amphetamines (used to treat attention deficit hyperactivity disorder (ADHD), narcolepsy, and obesity)
- Herbal medicine containing St. John's Wort *(Hypericum perforatum)*. The effects of St. John's Wort may last for 1-2 weeks
- Products containing the amino acid tryptophan
- Medicines to treat severe or chronic pain (opioids e.g. tramadol, fentanyl and buprenorphine)
- Medicines used in anaesthesia (e.g. fentanyl, mivacurium and suxamethonium)
- Medicines to treat migraines (e.g. sumatriptan)
- Blood thinning medicine (warfarin)
- Metamizole, a medicine used to treat pain and fever
- Medicines to treat pain/arthritis (Non steroidal anti-inflammatory drug (NSAID) such as ibuprofen, acetylsalicylic acid (aspirin))
- Sedatives (diazepam)
- Diuretics (also called 'water' tablets)
- Medicines to treat epilepsy (phenytoin, phenobarbital, carbamazepine)
- Medicines to treat diabetes (tolbutamide)
- Medicines to treat excessive stomach acid, ulcers and heartburn (cimetidine, omeprazole, lanzoprazole, pantoprazole, rabeprazole)
- Medicines to treat mania and depression (lithium)
- Other medicines to treat depression (such as amitriptyline, nortriptyline, nefazodone, fluoxetine, fluvoxamine)
- Medicines to treat schizophrenia and other mental disorders (such as perphenazine, levomepromazine and olanzapine)
- Medicines used to treat high blood pressure, chest pain or regulate the rate and rhythm of the heart (such as verapamil, diltiazem, flecainide, propafenone)
- Medicines used to treat bacterial infections (such as rifampicin, clarithromycin, telithromycin, erythromycin)
- Medicines used to treat fungal infections (such as ketoconazole, itraconazole, posaconazole, voriconazole, fluconazole)
- Medicines used to treat HIV/AIDS and Hepatitis C (protease inhibitors such as ritonavir, telaprevir)
- Medicines used to prevent nausea and vomiting after an operation or chemotherapy (aprepitant)
- Medicines known to increase the risk of changes in the electrical activity of the heart (e.g. some antipsychotics and antibiotics)
- Buprenorphine/opioids. These medicines may interact with sertraline and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.

**Sertraline with food, drink and alcohol**
Sertraline tablets can be taken with or without food. Alcohol should be avoided whilst taking sertraline. Sertraline should not be taken in combination with grapefruit juice, as this may increase the level of sertraline in your body.

**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.

The safety of sertraline has not fully been established in pregnant women. Sertraline 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 take Sertraline near the end of your pregnancy there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor or midwife should be aware that you are taking Sertraline so they can advise you. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like sertraline may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (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 should only be used in women during breast-feeding, if your doctor considers that the benefit exceeds any possible risk to the baby.

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 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.

**Important information about some of the ingredients of Sertraline**

**Sertraline contains lactose**
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

## 3. HOW TO TAKE SERTRALINE

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**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 1 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 1 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**
Sertraline must only be used to treat children and adolescents suffering from OCD aged 6-17 years old.

OCD
**Children aged 6 - 12:** the recommended starting dose is 25 mg daily.
After 1 week, your doctor may increase this to 50 mg daily. The maximum dose is 200 mg daily.
**Adolescents aged 13 - 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.

**Method of administration**
Sertraline tablets may be taken with or without food. Take your medication once daily either in the morning or evening.
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 than you should**
If you accidentally take too much sertraline 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.

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

**If you forget to take sertraline**
Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, do not take the missed dose. Just take the next dose at the right time.

**If you stop taking sertraline**
Do not stop taking sertraline unless your doctor tells you to. 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, 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, 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.

**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 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. 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 "Warnings and precautions").

The following side effects were seen in clinical trials in adults and after marketing.

**Very common (may affect more than 1 in 10 people):**
- Insomnia, dizziness, sleepiness, headache, diarrhoea, feeling sick, dry mouth, ejaculation failure, fatigue.

**Common (may affect up to 1 in 10 people):**
- chest cold, sore throat, runny nose
- decreased appetite, increased appetite
- anxiety, depression, agitation, decreased sexual interest, nervousness, feeling strange, nightmare, teeth grinding
- shaking, muscular movement problems (such as moving a lot, tense muscles, difficulty walking and stiffness, spasms and involuntary movements of muscles)*, numbness and tingling, muscle tense, lack of attention, abnormal taste
- visual disturbance
- ringing in ears
- palpitations
- hot flushes
- yawning
- upset stomach, constipation, abdominal pain, vomiting, gas
- increased sweating, rash
- back pain, joint pain, muscle pain
- menstrual irregularities, erectile dysfunction
- malaise, chest pain, weakness, fever
- weight increased
- injury.

**Uncommon (may affect up to 1 in 100 people):**
- gastroenteritis, ear infection
- tumour
- hypersensitivity, seasonal allergy
- low thyroid hormones
- suicidal thoughts, suicidal behaviour+, psychotic disorder, thinking abnormal, lack of caring, hallucination, aggression, euphoric mood, paranoia
- amnesia, decreased feeling, involuntary muscle contractions, passing out, moving a lot, migraine, convulsion, dizziness while standing up, abnormal coordination, speech disorder
- enlarged pupils
- ear pain
- fast heartbeat, heart problem
- bleeding problems (such as stomach bleeding)*, high blood pressure, flushing, blood in urine, nose bleed
- shortness of breath, breathing difficulty, possible wheezing
- tarry stools, tooth disorder, inflammation of the oesophagus, tongue problem, haemorrhoids, increased saliva, difficulty swallowing, burping, tongue disorder
- eye swelling, hives, hair loss, itching, purple spots on skin, skin problem with blisters, dry skin, face oedema, cold sweats
- osteoarthritis, muscle twitching, muscle cramps*, muscular weakness
- increase in frequency of urination, problem urinating, unable to urinate, urinary incontinence, increase in urination, night-time urination
- sexual dysfunction, excessive vaginal bleeding, vaginal haemorrhage, female sexual dysfunction
- swelling in legs, chills, difficulty walking, thirst
- increase in liver enzyme levels, weight decreased.

**+Cases of suicidal ideation and suicidal behaviours have been reported during sertraline therapy or early after treatment discontinuation (see section 2).**

**Rare (may affect up to 1 in 1,000 people):**
- 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 hurting the eyes, blood in the eye, unequal sized pupils*, vision abnormal*, tear problems
- 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
- a form of lung disease where eosinophils (a form of white blood cell) appear in the lung in increased numbers (eosinophilic pneumonia)
- 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.

**Not known: frequency cannot be estimated from the available data:**
- lockjaw*
- bedwetting*
- 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
- muscle weakness an severe muscle pain, which can be a sign of multiple acyl-coenzyme A dehydrogenase deficiency (MADD)-like disorder.

*Side effects reported after marketing.

**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.

**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").

An increased risk of bone fractures has been observed in patients taking this type of medicines.

**Reporting of side effects**
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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. HOW TO STORE SERTRALINE

Keep this medicine out of the sight and reach of children.
This medicine does not require any special storage conditions.
Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not use this medicine if you notice any visible signs of deterioration.

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.

## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

**What Sertraline 25mg Film-coated Tablets contain**
- The active substance is sertraline. Each tablet contains sertraline hydrochloride equivalent to 25 mg of sertraline.
- The other ingredients are
  Core: lactose monohydrate, cellulose microcrystalline, povidone, croscarmellose sodium and magnesium stearate.
  Coating: Hypromellose, macrogol, titanium dioxide E171 and talc.

**What Sertraline 25mg Film-coated Tablets look like and contents of the pack**

Sertraline 25mg film-coated tablets are white to off-white, round, biconvex, film coated tablets with a diameter of 6.0 ± 0.5mm.

The tablets are packed into PVC/PVDC/Alu blisters and cartons and are available in packs of 28.

**Marketing Authorisation Holder and Manufacturer**

**Marketing Authorisation Holder**
Zentiva Pharma UK Limited
12 New Fetter Lane
London
EC4A 1JP
United Kingdom

**Manufacturers**
ZENTIVA k. s., U Kabelovny 130, Dolní Měcholupy 102 37 Prague 10, Czech Republic
or
S.C. ZENTIVA S.A., B-dul Theodor Pallady nr. 50, sector 3, București cod 032266, Romania

**For information in large print, Braille or on CD, telephone +44 (0)800 090 2408**

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