

1.3.1 Patient Information Leaflet

PACKAGE LEAFLET: INFORMATION FOR THE USER

[Nationally completed name, 50 mg, film- coated tablets]

[Nationally completed name, 100 mg, film- coated tablets]

Sertraline

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

1. What [nationally completed name] is and what it is used for

[nationally completed name] contains the active ingredient sertraline. 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.

[nationally completed name] 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 [nationally completed name].

2.What you need to know before you take [nationally completed name]

Do not take [nationally completed name]:

- 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 until at least one 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.
- 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 take [nationally completed name], 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 have told 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 [nationally completed name]. 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 [nationally completed name].
- Diabetes; your blood glucose levels may be altered due to [nationally completed name] and your diabetes medicines may need to be adjusted.
- Epilepsy or a 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 suicidal thoughts (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 (eg acetylsalicylic acid (aspirin), or warfarin) or may increase the risk of bleeding.
- If you are a child or adolescent under 18 years old. [nationally completed name] should only be used to treat children and adolescents aged 6-17 years old, suffering from obsessive compulsive disorder. If you are being treated for this disorder, your doctor will want to monitor you closely (see Use in children and adolescents below).
- If you are having electro-convulsive therapy (ECT).
- If you have problems with your eyes, such as certain kinds of glaucoma (increased intraocular pressure).

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 may be harmful to patients who develop such symptoms.

Withdrawal reactions:

Withdrawal reactions when treatment is stopped 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, depending on the patient's needs.

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 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 usually be used in children and adolescents less than 18 years old, except for patients with Obsessive Compulsive Disorder. 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 [nationally completed name] to a patient under 18 if it is in the patient's interest. If your doctor has prescribed [nationally completed name] to a patient 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 when a patient under 18 is taking [nationally completed name], you should inform your doctor. Also, the long-term safety of [nationally completed name] in regard to growth, maturation and cognitive and behavioural development in this age group has not yet been demonstrated.

Other medicines and [nationally completed name] :

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines can affect the way [nationally completed name] works, or [nationally completed name] itself can reduce the effectiveness of other medicines taken at the same time.

Taking [nationally completed name] together with the following medicines may cause serious side effects:

- Medicines called monoamine oxidase inhibitors (MAOIs), like moclobemid (to treat depression) and selegiline (to treat Parkinson's disease) and the antibiotic linezolid. Do not use [nationally completed name] together with MAOIs.
- Medicines to treat mental disorders (pimozide). Do not use [nationally completed name] together with pimozide.

Talk to your doctor if you are taking the following medicine:

- 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 medicine (e.g. warfarin, ticlodipine).
- Medicines to treat pain/arthritis (Non steroidal antiinflammatory drug (NSAID) such as ibuprofen, acetylsalicylic acid (aspirin).
- Sedatives (diazepam).
- Diuretics.
- Medicines to treat epilepsy (e.g. phenytoin, carbamazepine and phenobarbital).
- Medicines to treat diabetes (tolbutamide).
- Medicines to treat excessive stomach acid and ulcers (e.g. cimetidine, lansoprazole, pantoprazole, rabeprazole, omeprazole).
- Medicines to treat mania and depression (lithium).
- Medicines to treat and prevent nausea (such as aprepitant)
- Medicines to treat high blood pressure and angina pectoris (such as diltiazem, verapamil)
- Medicines used to regulate the rate and rhythm of the heart (such as flecainide, propafenone).
- 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 for anesthesia or in the treatment of pain (fentanyl)
- Antibiotics (such as rifampicin, erythromycin, telitromycin and clarithromycin)
- Antifungals (such as ketoconazole, posaconazole, voriconazole, fluconazole and itraconazole)
- Antiretrovirals drugs (protease inhibitors)

[Nationally completed name] with food, drink and alcohol:

[nationally completed name] tablets can be taken with or without food.

Alcohol should be avoided whilst taking [nationally completed name].

You should not drink grapefruit juice. This may slow the amount 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.

Pregnancy

The safety of sertraline has not fully been established in pregnant women. Sertraline should only be given to pregnant women if the doctor considers that the benefit for the mother exceeds any possible risk to the foetus. Women of childbearing potential should employ an adequate method of contraception if taking sertraline.

Make sure your midwife and/or doctor know you are on sertraline. 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 if you have taken sertraline during pregnancy, particularly in the last 3 months of pregnancy. The symptoms usually begin during the first 24 hours after birth. Symptoms include: difficulty in breathing, temporary interruption in breathing, bluish skin, convulsions, being too hot or too cold, difficulty in feeding, vomiting, low level of sugar in the blood, stiff and floppy muscles, abnormally increased reflexes, tremor, extreme nervousness or nervous shaking, irritability, lethargy, constant crying, abnormal drowsiness, difficulty in sleeping. If your baby has any of these symptoms when it is born contact your doctor or midwife who will be able to advise you.

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

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.

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.

[nationally completed name] contains:

If you have been told by your doctor that you have intolerance to some sugars contact your doctor before taking this medicinal product.

3. How to take [nationally completed name]

Always take this medicine exactly as your doctor or pharmacist has told you.

[nationally completed name] tablets may be taken with or without food.

Take your medication once daily either in the morning or evening.

Check with your doctor or pharmacist if you are not sure.

The usual 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:

[nationally completed name] 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 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

If you take more [nationally completed name] than you should:

If you accidentally take too much [nationally completed name] 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 [nationally completed name]:

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 [nationally completed name]:

Do not stop taking [nationally completed name] unless your doctor tells you to. Your doctor will want to gradually reduce your dose of [nationally completed name] 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 [nationally completed name], please speak to your doctor.

If you have any further questions on the use of this medicine, 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 are often transient 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 signs of muscle cramps, tremor and high fever. These may be symptoms of a life-threatening neurological disorder called Neuroleptic Malignant Syndrome.
- If you develop yellow skin and eyes which may mean liver damage.
- If you experience depressive symptoms with suicidal ideas.
- If you start to get feelings of restlessness and not be able to sit or stand still after you start to take [nationally completed name]. 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
- Fatigue

Common side effects (may affect up to 1 in 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 in 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
- Oesophageal problem, 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
- Nighttime 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 1000 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, suicidal behavior, 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
- Drug tolerance decreased, difficulty walking
- Abnormal laboratory tests, semen abnormal, injury, relaxation of blood vessels procedure

Not known (frequency cannot be estimated from available data):

- Decrease in white blood cells, decrease in clotting cells, severe allergic reaction, low thyroid hormones, endocrine problem, low blood salt, diabetes mellitus, high blood sugar
- Terrifying abnormal dreams
- Muscular movement problems (such as moving a lot, tense muscles and difficulty walking), fainting, sudden severe headache which may indicate a serious condition, passing out
- Vision abnormal, pupils unequal
- Bleeding problems (such as nose bleed, stomach bleeding, or blood in urine)
- Lung disease
- Pancreatitis, serious liver function problems, yellow jaundice
- Skin oedema, skin reaction to sun, itching
- Joint pain, muscle cramps
- Breast enlargement, menstrual irregularities
- Swelling in legs
- Abnormal clinical laboratory results
- Problems with clotting

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

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.

Reporting of side effects

If you get any side effects, talk to your <doctor> <or> <,> <pharmacist> <or nurse>. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [nationally completed name]

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

This medicinal product does not require any special storage conditions

Do not use this medicine after the expiry date which is stated on the carton, on the blister or on the container after EXP. The expiry date refers to the last day of that month.

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 [nationally completed name] contains

The active substance is: Sertraline hydrochloride.

[nationally completed name 50 mg film-coated tablet]:

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Each tablet contains 50 mg of sertraline (as hydrochloride).

[nationally completed name 100 mg film-coated tablet]:

Each tablet contains 100 mg of sertraline (as hydrochloride).

The other ingredients are: Lactose monohydrate, Cellulose microcrystalline, Sodium starch glycolate (type A), Hydroxypropylcellulose, Magnesium stearate, Hypromellose, Macrogol, Polysorbate 80, Titanium dioxide (E171).

What [nationally completed name] looks like and contents of the pack

[nationally completed name 50 mg film-coated tablet] tablets are white to off-white capsule shaped tablets, convex on one side and a score line on the other side.

The tablets can be divided into equal halves

[nationally completed name 100 mg film-coated tablet]

tablets are white to off-white capsule shaped tablets, convex on one side and a score line on the other side.

The tablets can be divided into equal halves

is available in

PVC/PVDC/Aluminium blister:

10, 14, 15, 20, 28, 30, 50, 100, 100x1 (unit-dose), 200 and 500 tablets.

PP-containers:

250 and 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing authorization holder

[To be completed nationally]

Manufacturer

[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria:	SERTRALIN SANDOZ 50 MG – FILMTABLETTEN SERTRALIN SANDOZ 100 MG - FILMTABLETTEN
Czech Republic:	SERTRALIN SANDOZ 50 MG SERTRALIN SANDOZ 100 MG
Denmark:	SERTRALIN "SANDOZ" SERTRALIN "SANDOZ"
Iceland:	SERTRALIN SANDOZ SERTRALIN SANDOZ
Italy:	SERTRALINA SANDOZ SERTRALINA SANDOZ
Norway:	SERTRALIN SANDOZ 50 MG SERTRALIN SANDOZ 100 MG
Portugal:	SERTRALINA 1APHARMA 50 MG COMPRIMIDOS REVESTIDOS POR PELICULA SERTRALINA 1APHARMA 100 MG COMPRIMIDOS REVESTIDOS POR PELICULA
Slovak Republic:	SERTIVA 50 MG SERTIVA 100 MG
Slovenija:	SERTIVA 50 MG FILMSKO OBLOZENE TABLETE SERTIVA 100 MG FILMSKO OBLOZENE TABLETE
Sweden:	SERTRALIN SANDOZ 50 MG FILMDRAGERAD TABLETT

SERTRALIN SANDOZ 100 MG FILMDRAGERAD TABLETT

This leaflet was last revised in:

2014-04-24