

PACKAGE LEAFLET: INFORMATION FOR THE USER

Lusert 50 mg film-coated tablets

Lusert 100 mg film-coated tablets

Sertraline

Read all of this leaflet carefully before you start taking this medicine.

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

In this leaflet:

1. What Lusert is and what it is used for
2. Before you take Lusert
3. How to take Lusert
4. Possible side effects
5. How to store Lusert
6. Further information

1. WHAT LUSERT IS AND WHAT IT IS USED FOR

Lusert 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.

Lusert 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 Lusert.

2. BEFORE YOU TAKE LUSERT

Do not take Lusert

- If you are allergic (hypersensitive) to sertraline or any of the other ingredients of Lusert.
- 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).

Take special care with Lusert

Medicines are not always suitable for everyone. Tell your doctor before you take Lusert, 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 levels in your blood, since this can occur as a result of treatment with Lusert. 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 levels in your blood (see above).
- Liver disease; your doctor may decide that you should have a lower dose of Lusert.
- Diabetes; your blood glucose levels may be altered due to Lusert 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 a 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 (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. Lusert 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 convulsive therapy (ECT).
- If you have eye problems, such as certain kinds of glaucoma (increased pressure in the eye).

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 longer (2-3 months or more). When stopping treatment with Lusert 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:

Lusert 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 Lusert to a patient under 18 if it is in the patient's interest. If your doctor has prescribed Lusert 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 Lusert, you should inform your doctor. Also, the long-term safety of Lusert with regard to growth, maturation and cognitive and behavioural development in this age group has not yet been demonstrated.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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

Taking Lusert 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 Lusert together with MAOIs.
- Medicines to treat mental disorders (pimozide). Do not use Lusert 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 used in anaesthesia or to treat chronic pain (fentanyl).
- Medicines to treat migraines (e.g. sumatriptan).
- Blood thinning medicine (warfarin).
- Medicines to treat pain/arthritis (Non steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, acetylsalicylic acid (aspirin)).
- Sedatives (diazepam).
- Diuretics.
- Medicines to treat epilepsy (phenytoin, phenobarbital, carbamazepine).
- Medicines to treat diabetes (tolbutamide).
- Medicines to treat excessive stomach acid and ulcers (cimetidine, omeprazole, lansoprazole, 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 regulate the rate and rhythm of the heart (such as flecainide, propafenone).
- Medicines to treat high blood pressure or angina pectoris (diltiazem, verapamil).
- Medicines for bacterial infections (such as erythromycin, clarithromycin, telithromycin).
- Medicines for fungal infections (such as ketoconazole, itraconazole, posaconazole, voriconazole, fluconazole).
- Medicines for prevention of nausea and vomiting (aprepitant).

Taking Lusert with food and drink

Lusert tablets can be taken with or without food. Alcohol should be avoided whilst taking Lusert. 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

Ask your doctor or pharmacist for advice before taking any medicine.

The safety of Lusert has not fully been established in pregnant women. Lusert 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 Lusert. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Lusert 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 is excreted in human breast milk. Lusert should only be used in women during lactation, 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.

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Driving and using machines

Psychotropic drugs such as Lusert 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.

3. HOW TO TAKE LUSERT

Always take Lusert exactly as your doctor has told you. Lusert tablets may be taken with or without food. Take your medication once daily either in the morning or evening. You should 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:

Lusert 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. Treatment of depression should usually continue for 6 months after improvement.

If you take more Lusert than you should

If you accidentally take too much Lusert 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 heartrate, shaking, agitation, dizziness and in rare cases unconsciousness.

If you forget to take Lusert

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 Lusert

Do not stop taking Lusert unless your doctor tells you to. Your doctor will want to gradually reduce your dose of Lusert 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 Lusert, 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, Lusert 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 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 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 are not able to sit or stand still after you start to take Lusert. 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 "Take special care with Lusert").

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, nightmares, anxiety, agitation, nervousness, decreased sexual interest, teeth grinding,
- numbness and tingling, shaking, muscle tension, abnormal taste, lack of attention,
- visual disturbance, ringing in ears,
- palpitations, hot flushes, yawning,
- abdominal pain, vomiting, constipation, upset stomach, gas,
- rash, increased sweating, muscle pain, sexual dysfunction, erectile dysfunction, chest pain.

Uncommon side effects (may affect 1 in 100 people):

- Chest cold, runny nose,
- hallucination, feeling too happy, lack of caring, thinking abnormally,
- convulsions, involuntary muscle contractions, abnormal coordination, moving a lot, amnesia, decreased feelings, speech disorders, 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 disorders, 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 decrease, weight increase.

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

- Intestinal problems, 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 myoclonus, difficulty moving, increased sensation, sensory disturbance, glaucoma, tear problems, spots in front of the eyes, double vision, sensitivity to light, blood in the eye, enlarged pupils,
- heart attack, slow heart beat, heart problems, poor circulation in the arms and legs, closing up of throat, breathing fast, breathing slow, difficulty talking, hiccups,
- blood in stools, sore mouth, tongue ulceration, tooth disorders, tongue problems, mouth ulceration, problems with liver function,
- skin problems with blisters, hair rash, hair texture abnormal, skin odour abnormal, bone disorders,
- 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,
- suicidal ideation, suicidal behaviour: cases of suicidal ideation and suicidal behaviours have been reported during sertraline therapy or early after treatment discontinuation (see sections 2.).

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

- Decrease in white blood cells, decrease in clotting cells, low thyroid hormones, endocrine problems, low blood salt, problems controlling blood sugar levels (diabetes), increased in blood sugar levels,
- terrifying abnormal dreams,
- muscular movement problems (such as moving a lot, tense muscles and difficulty walking and stiffness, spasms and involuntary movements of the muscles), passing out, sudden severe headache (which maybe signs of a serious condition known as Reversible Cerebral Vasoconstriction Syndrome (RCVS)),
- vision abnormal, unequal pupils, bleeding problems (such as nose bleed, stomach bleeding, or blood in urine), lung disease that affects the tissue and space around the air sacs of the lungs, pancreatitis, serious liver function problems, yellow skin and eyes (jaundice),
- skin oedema, skin reaction to sun, itching, joint pain, muscle cramps, breast enlargement, menstrual irregularities, swelling in legs, problems with clotting, and severe allergic reactions.

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 Lusert").

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

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

5. HOW TO STORE LUSERT

Keep out of the reach and sight of children. Do not use Lusert after the expiry date which is stated on the packaging. The expiry date refers to the last date of the month.

This medicinal product does not require any special storage conditions. 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. FURTHER INFORMATION

What Lusert contains

- The active substance is sertraline. Each film-coated tablet contains 50 mg or 100 mg sertraline (as sertraline hydrochloride).
- The other ingredients are: calcium hydrogen phosphate dihydrate (E341); microcrystalline cellulose (E460 (i)); sodium starch glycolate (type A); hydroxypropylcellulose (E463); talc (E553 (b)); and magnesium stearate (E572) in the tablet core and hypromellose (E464); titanium dioxide (E171); talc (E553 (b)); and propylene glycol in the film-coating.

What Lusert looks like and contents of the pack

50 mg Tablets are: white, oval, slightly biconvex film-coated tablets with score on one side and "S3" sign on the opposite side. Tablets can be divided into equal halves.

100 mg Tablets are: white, round, slightly biconvex film-coated tablets with bevelled edge and a score on one side. Tablets can be divided into equal halves.

Boxes with 10, 14, 20, 28, 30, 50, 98 and 100 tablets in blisters (Al/PVC) are available. Polyethylene (HDPE) plastic containers with 100 and 250 tablets are available.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland.

PA Number

50 mg: PA 281/121/1
100 mg: PA 281/121/2

Manufacturer

KRKA, d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto, Slovenia.

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

Austria: Sertralin Krka 50 mg - Filmtabletten
Germany: Sertralin Siga 50 mg/100 mg Filmtabletten
Ireland: Lusert 50 mg/100 mg
Netherlands: Sertraline A 50 mg/100 mg

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