

Patient package insert according to Pharmacists' Regulations (Preparations) – 1986

This medicine can be sold with a physician's prescription only

Lustral® Tablets 50 mg

Lustral® Tablets 100 mg

Film-coated tablets

Each tablet contains sertraline as hydrochloride 50 or 100 mg, respectively.

Inactive ingredients and allergens in the medicine – see section 6 “Additional information” and in section 2 “Important information about some of the ingredients of the medicine”.

Read this entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist.

This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them, even if you think that their medical condition is similar to yours.

This medicine is not intended for use in children and adolescents under the age of 18 years.

Antidepressants increase the risk for suicidal behavior and thoughts in children, adolescents and young adults.

At the beginning of treatment with the medicine, patients of all ages and their relatives should pay attention to behavioral changes such as: worsening of depression, suicidal thoughts, aggression and the like.

If such changes occur, refer to the doctor immediately.

1. What is the medicine intended for?

The medicine is intended for the treatment of depression symptoms in patients with or without a history of mania. After achieving a satisfactory response, continued treatment with the medicine is effective in preventing recurrence of the initial depressive episode or further recurring depressive episodes.

Therapeutic group: the medicine belongs to the class of SSRIs, selective serotonin reuptake inhibitors.

2. Before using the medicine

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient (sertraline), or to any of the other ingredients this medicine contains (see section 6).
- You are taking or have taken medicines from the monoamine oxidase inhibitors group (such as: selegiline, moclobemide) or medicines similar to monoamine oxidase inhibitors (such as: linezolid). Wait at least one week between completing treatment with sertraline and starting treatment with monoamine oxidase inhibitors. Furthermore, you should wait at least two weeks between completing treatment with monoamine oxidase inhibitors and starting treatment with sertraline.
- You are concomitantly taking a medicine called pimozide (a medicine intended for mental disorders such as psychosis).

Special warnings regarding the use of the medicine

Before treatment with Lustral, inform the doctor if:

- You suffer or have suffered in the past from epilepsy or have a history of convulsions. Inform the doctor immediately if a convulsion occurs.
- You have suffered in the past from manic-depressive disorder (bipolar disorder) or from schizophrenia. Inform the doctor immediately if a manic episode occurs.
- You have or have had thoughts of self-harm or suicidal thoughts (see further down in this section “**Suicidal thoughts and worsening of your depression or anxiety disorder**”).
- You have serotonin syndrome or neuroleptic malignant syndrome. In rare cases, this syndrome may appear when you are taking certain medicines concomitantly with this preparation (for symptoms, see section 4 “Side effects”). Your doctor should inform you if you have suffered from this syndrome in the past.
- You have low levels of sodium in the blood, since treatment with **Lustral** may cause this. Inform the doctor if you are taking certain medicines for treatment of high blood pressure, since these medicines may also change the level of sodium in the blood.
- You are elderly, the risk of low levels of sodium in the blood is higher (see above).
- You suffer from a liver disease. The doctor may decide on reducing the dosage of **Lustral**.
- You suffer from diabetes. Taking **Lustral** may affect the glucose levels in the blood, and therefore, the dosage of your diabetes medicines may need to be adjusted.
- You have a history of bleeding disorders (tendency to develop hematomas), or if you are pregnant (see section “Pregnancy, breastfeeding and fertility”) or if you are taking blood thinning medicines (such as: acetylsalicylic acid [aspirin] or warfarin) or medicines that may increase the risk of bleeding.
- You are being treated with electroconvulsive therapy (ECT).
- You suffer from eye problems, such as certain types of glaucoma (increased eye pressure).
- You have been told that you have an abnormality in your cardiac tracing after an electrocardiogram (ECG) test, known as QT interval prolongation.
- You suffer from a heart disease, from low levels of potassium or magnesium, you have a family history of QT interval prolongation, or you have a slow heart rate and you concomitantly use medicines that prolong the QT interval.

Akathisia/restlessness

Use of the medicine has been associated with distressing restlessness and the need to move, often with inability to sit or stand still (akathisia). This effect usually occurs during the first weeks of treatment. Increasing the dosage may be harmful, so if you develop such effects, you should inform your doctor.

Withdrawal symptoms

Side effects associated with discontinuing treatment are common (withdrawal symptoms), especially when treatment is stopped abruptly (see sections 3 and 4). The risk of withdrawal symptoms depends on the duration of treatment, dosage and the rate at which the dosage of the medicine is reduced. Usually, the severity of these symptoms is mild to moderate. However, in some patients, the symptoms may be severe. These symptoms mostly appear in the first days after discontinuing treatment. Usually, these symptoms resolve on their own and disappear gradually within two weeks. In some patients, they may last longer (two-three months or even more). When discontinuing treatment with this medicine, it is recommended to reduce the dosage gradually over several weeks or months. You should always consult the doctor regarding the most appropriate way of discontinuing treatment.

Suicidal thoughts and worsening of your depression or anxiety disorder

If you are depressed and/or suffer from anxiety disorders, you may sometimes have thoughts of self-harm or suicidal thoughts. These effects are more likely to appear when first starting antidepressants, since it takes time until they start to have an effect, usually about two weeks, but sometimes even more.

The probability of such thoughts is higher if:

- You have had suicidal thoughts or thoughts of self-harm in the past.
- You are a young adult. Data from clinical studies have shown an increased risk of suicidal behavior in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of self-harm or suicidal thoughts at any time, contact your doctor or refer to the hospital immediately.

You may find it helpful to share with a family member or a close friend that you are depressed or suffer from an anxiety disorder, and ask them to read this leaflet. You may ask them to tell you if they think your depression or anxiety disorder is getting worse, or if they are worried about changes in your behavior.

Sexual dysfunction

Medicines such as **Lustral** (also called SSRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have persisted even after stopping treatment.

Children and adolescents

This medicine is not intended for children and adolescents under the age of 18.

Drug interactions

If you are taking, have recently taken or might take other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

Certain medicines can affect the way **Lustral** works, or **Lustral** itself can decrease the effectiveness of other medicines taken at the same time.

Do not use **Lustral** if you are being treated with the following medicines:

Medicines called monoamine oxidase inhibitors (such as: moclobemide (for the treatment of depression) and selegiline (for the treatment of Parkinson's disease)), linezolid (an antibiotic), methylene blue (for treatment of high levels of methemoglobin in the blood), medicines for treatment of mental disorders such as psychosis (pimozide). Taking **Lustral** together with these medicines may cause serious side effects.

Tell your doctor if you are taking the following medicines:

- Medicines containing amphetamines (used for treatment of attention deficit hyperactivity disorder [ADHD], narcolepsy and obesity).
- Medicines containing the Hypericum herb (St. John's wort) – the effect of the Hypericum herb may last for one to two weeks.
- Products containing the amino acid tryptophan.
- Medicines for treatment of severe or chronic pain (opioids such as: tramadol, fentanyl).
- Medicines used for anesthesia (such as: fentanyl, mivacurium and suxamethonium).
- Medicines for treatment of migraine (such as: sumatriptan).
- Blood thinning medicines (warfarin).

- Medicines for treatment of pain/joint inflammation (such as: metamizole, non-steroidal anti-inflammatory drugs [NSAIDs], such as: ibuprofen, acetylsalicylic acid [aspirin]).
- Sedatives (diazepam).
- Diuretics.
- Medicines for treatment of epilepsy (phenytoin, phenobarbital, carbamazepine).
- Medicines for treatment of diabetes (tolbutamide).
- Medicines for treatment of hyperacidity, stomach ulcer or heartburn (cimetidine, omeprazole, lansoprazole, pantoprazole, rabeprazole).
- Medicines for treatment of mania and depression (lithium).
- Other medicines for the treatment of depression (such as: amitriptyline, nortriptyline, nefazodone, fluoxetine, fluvoxamine).
- Medicines for treatment of schizophrenia and other mental disorders (such as: perphenazine, levomepromazine or olanzapine).
- Medicines for the treatment of hypertension, chest pain or to regulate heart rate and rhythm (such as: verapamil, diltiazem, flecainide, propafenone).
- Medicines for treatment of bacterial infections (such as: rifampicin, clarithromycin, telithromycin, erythromycin).
- Medicines for treatment of fungal infections (such as: ketoconazole, itraconazole, posaconazole, voriconazole, fluconazole).
- Medicines for treatment of HIV/AIDS and hepatitis C (protease inhibitors such as: ritonavir, telaprevir).
- Medicines for prevention of nausea and vomiting following surgery or chemotherapy (aprepitant).
- Medicines known to increase the risk of changes in the electrical activity of the heart (such as: antipsychotic medicines and certain antibiotics).

Use of the medicine and food

The medicine can be taken either with or without food.

Do not drink grapefruit juice during treatment with the medicine, since it may increase the level of the medicine in the blood.

Use of the medicine and alcohol consumption

Do not consume alcohol during the period of treatment.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you are pregnant or are planning to become pregnant, consult a doctor before using this medicine.

The safety of sertraline has not yet been fully established in pregnant women. Sertraline will only be given during pregnancy if the doctor considers that the benefit outweighs any possible risk to the fetus.

If you are taking **Lustral** near the end of your pregnancy, there is an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Inform the doctor or midwife if you are taking **Lustral** during pregnancy, so they can advise you. Taking medicines such as **Lustral** during pregnancy, especially in the last trimester, may increase the risk of a serious condition in the newborn called persistent pulmonary hypertension of the newborn (PPHN). This condition causes the baby to breathe faster and appear bluish. These symptoms usually start to appear during the first 24 hours after the baby is born. If this happens to your baby, you should refer to a doctor immediately.

Other symptoms the newborn may suffer from usually appear during the first 24 hours after birth. The symptoms include: difficulty breathing, bluish discoloration of the skin, skin that is too cold or too warm, blue lips, vomiting or feeding difficulties, excessive tiredness, sleeping difficulties, constant crying, muscle stiffness or weakness, tremors, agitation or convulsions, heightened reflexes, irritability, decrease in blood sugar level.

If you notice that your baby has any of these symptoms after birth, or if you are concerned about your baby's condition, contact the doctor.

It has been demonstrated that sertraline is excreted into breast milk. Do not use sertraline if you are breastfeeding, unless the doctor considers that the benefit from the medicine outweighs any possible risk to your baby.

In animal studies, it has been established that certain medicines such as sertraline may impair sperm quality. Theoretically, this can impair fertility, but so far no impact on human fertility has been observed.

Driving and using machines

Using this medicine may impair your ability to drive or use machines. Therefore, do not drive a vehicle or operate dangerous machinery until you know how the medicine affects your ability to perform these activities.

Important information about some of the ingredients of the medicine

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

3. How to use the medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

The dosage and manner of treatment will be determined by the doctor only.

The usual recommended dosage is: 50 mg once a day, in the morning or in the evening. The daily dosage can be increased in increments of 50 mg and at time intervals of at least one week over a period of several weeks. The maximum recommended dosage is 200 mg once a day.

Your doctor will instruct you for how long you should take this medicine. This depends on the nature of your illness and how well you respond to the treatment.

The improvement in symptoms may occur only after a few weeks. Usually, treatment of depression should be continued for 6 months after improvement.

If you suffer from liver or kidney problems, inform your doctor and follow his treatment instructions.

Do not exceed the recommended dose.

Method of administration

The medicine can be taken either with or without food.

The tablet should be swallowed with some water.

Lustral tablets 50 mg: the tablet can be halved. There is no information available regarding crushing/chewing.

Lustral tablets 100 mg: there is no information available regarding crushing/halving/chewing.

If you have accidentally taken a higher dosage

If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

Signs of an overdose may include: drowsiness, nausea and vomiting, rapid heartbeat, restlessness, tremor, dizziness and rarely, loss of consciousness.

If you forgot to take the medicine

If you forgot to take this medicine at the designated time, skip the forgotten dose and take the next dose at the regular time.

Do not take a double dose to make up for the forgotten dose.

Continue with the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop taking this medicine without consulting the doctor.

If you stop taking the medicine

Do not stop treatment with the medicine without consulting a doctor. The doctor will instruct you how to gradually reduce the dosage over several weeks, before you finally stop taking the medicine. Abrupt discontinuation of the medicine may be accompanied by effects such as: dizziness, lack of sensation, sleep disturbances, anxiety or restlessness, headaches, nausea and vomiting, tremor. If you experience any of these side effects or other side effects upon discontinuation of treatment, please inform the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions on the use of this medicine, consult the doctor or pharmacist.

4. Side effects

Like any medicine, the use of **Lustral** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Nausea is the most common side effect. Side effects are dose-dependent and usually disappear or subside with continuous treatment.

Refer to a doctor immediately:

If you experience any of the following symptoms after taking this medicine:

- You develop a severe skin rash that causes the appearance of blisters (erythema multiforme) (may also affect the mouth and tongue). This effect can be a symptom of Stevens-Johnson syndrome or toxic epidermal necrolysis. The doctor will stop the treatment with the medicine in these cases.
- An allergic reaction or allergy, which can include symptoms such as: itchy skin rash, breathing difficulties, wheezing, swelling of the eyelids, face or lips.
- You experience restlessness, confusion, diarrhea, high fever, high blood pressure, increased sweating and fast heartbeat. These are symptoms of serotonin syndrome or neuroleptic malignant syndrome. In rare cases, this syndrome may appear when you are taking certain medicines concomitantly with this medicine. In this case, the doctor may stop the treatment with the medicine.
- Your skin and eyes become yellow, which may indicate liver damage.
- You experience symptoms of depression with thoughts of self-harm or suicidal thoughts.

- You start to experience a feeling of restlessness and cannot sit or stand still after starting to take this medicine. Tell the doctor if you start to feel restless.
 - You experience a fit (convulsion).
 - You have a manic episode (see section 2 “Special warnings regarding the use of the medicine”).
- These symptoms may be severe.

The following side effects were observed in clinical studies in adults and during use of the medicine after marketing.

Very common side effects (effects that occur in more than 1 in 10 users):

Insomnia, dizziness, drowsiness, headache, diarrhea, nausea, dry mouth, ejaculation failure, tiredness.

Common side effects (effects that occur in 1-10 out of 100 users):

- Bronchitis, sore throat, rhinitis.
- Decreased appetite, increased appetite.
- Anxiety, depression, restlessness, decreased libido, agitation, feeling strange, nightmare, teeth grinding.
- Tremor, skeletal muscle disorders (such as: moving a lot, tense muscles, difficulty walking, muscle stiffness, cramps and involuntary muscle movements)*, numbness and tingling, muscle tension, lack of attention, changes in taste.
- Visual disturbances.
- Ringing in the ears.
- Feeling your heartbeats.
- Hot flashes.
- Yawning.
- Indigestion, constipation, abdominal pain, vomiting, flatulence.
- Increased sweating, rash.
- Back pain, joint pain, muscle pain.
- Irregular menstruation, erectile dysfunction.
- Feeling unwell, chest pain, weakness, fever.
- Weight gain.
- Bruising.

Uncommon side effects (effects that occur in 1-10 out of 1,000 users):

- Inflammation of the intestine, ear infection.
- Tumor.
- Hypersensitivity, seasonal allergy.
- Decrease in the level of thyroid hormones.
- Suicidal thoughts, suicidal behavior*, psychotic disorder, abnormal thoughts, apathy, hallucinations, aggressiveness, sensation of euphoria, paranoia.
- Forgetfulness, a decrease in sensation, involuntary muscle cramps, fainting, moving a lot, migraine, convulsion, dizziness when standing up, impaired coordination, speech impairment.
- Dilated pupils.
- Ear pain.
- Fast heartbeat, heart problems.
- Bleeding (such as: stomach bleeding)*, hypertension, flushing, blood in the urine.
- Shortness of breath, nose bleeding, breathing difficulties, wheezing.

- Tarry stool, tooth disorders, inflammation of the esophagus, tongue problems, hemorrhoids, increased drooling, difficulty swallowing, burping, tongue disorder.
- Puffy eyes, hives, hair loss, itch, purple spots on the skin, a skin problem accompanied by blisters, dry skin, swelling in the face, cold sweat.
- Osteoarthritis, muscle spasms, muscle cramps*, muscle weakness.
- Increased frequency of urination, difficulty urinating, not passing urine, incontinence, increased urination, urinating at night.
- Sexual dysfunction in men and women, significant vaginal bleeding.
- Swelling in the legs, chills, difficulty walking, thirst.
- Increased liver enzyme levels, weight loss.
- **Cases of suicidal thoughts and suicidal behavior have been reported during treatment with Lustral or shortly after stopping treatment with Lustral (see section 2).**

Rare side effects (effects that occur in 1-10 out of 10,000 users):

- Diverticulitis, swollen lymph nodes, decline in the number of platelets*, decrease in the number of white blood cells*.
- Acute allergic reaction.
- Endocrine problems*.
- High cholesterol, problems controlling blood sugar balance (diabetes), low blood sugar level, increased blood sugar levels*, low blood sodium level*.
- Physical symptoms due to stress or emotions, terrifying and unusual dreams*, dependence on medicines, sleepwalking, premature ejaculation.
- Coma, abnormal movements, movement difficulty, increased sensation, sudden sharp headache (may be a sign of a serious condition that involves reversible constriction of blood vessels in the brain)*, sensation disorders.
- Seeing spots, glaucoma, double vision, eye sensitivity to light, blood in the eye, different sized pupils*, vision disorder*, tear problem.
- Heart attack, dizziness, fainting or chest discomfort which may be signs of a change in the electrical activity (seen in electrocardiogram) or irregular heart rate*, slowed heartbeat.
- Poor blood flow in the limbs.
- Rapid breathing, progressive scarring of lung tissue (interstitial lung disease)*, throat narrowing, difficulty speaking, slow breathing, hiccups.
- A form of lung disease that involves the appearance of increased number of eosinophils (a type of white blood cell) (eosinophilic pneumonia).
- Mouth ulcers, inflammation of the pancreas*, blood in the stool, tongue ulcers, pain in the mouth.
- Liver function problems, severe liver function impairment*, yellowing of the skin and the eyes (jaundice)*.
- Skin reaction to the sun*, skin edema*, change in hair structure, strange body odor, hair follicle rash.
- Muscle tissue breakdown*, bone disorder.
- Difficulty starting urination, decreased urination.
- Discharge from the breasts, vaginal dryness, genital discharge, pain and redness in the penis and foreskin area, breast enlargement*, prolonged erection.
- Hernia, decreased tolerance to medicines.
- Increased levels of cholesterol in the blood, abnormal laboratory tests*, changes in the quality of sperm, coagulation problems*.
- Widening of blood vessels.

Side effects with unknown frequency (effects for which a frequency has not yet been determined):

- Lockjaw*.
- Bedwetting*.
- Partial loss of vision.
- Inflammation of the large intestine (leading to diarrhea*).
- Heavy vaginal bleeding shortly after birth (postpartum hemorrhage)*, see “Pregnancy, breastfeeding and fertility” in section 2 for additional information.
- Muscle weakness and severe muscle pain, can be a sign of a disorder similar to multiple acyl-coenzyme A dehydrogenase deficiency (MADD)*.

Side effects reported while using the medicine after marketing began are marked with *.

Symptoms that may appear in case of stopping treatment

If you abruptly stop taking the medicine, you may develop side effects such as: dizziness, lack of sensation, sleep disturbances, agitation or anxiety, headaches, nausea, vomiting and tremors (see in section 3 “If you stop taking the medicine”).

In patients taking medicines of this type, an increased risk of bone fractures has been observed.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

Side effects may be reported to the Ministry of Health by clicking on the link “דיווח על תופעות לוואי עקב טיפול תרופתי” found on the homepage of the Ministry of Health website (www.health.gov.il), directing to the online form for reporting side effects, or via the link:

<https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (EXP) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** store below 25°C.

6. Additional information

In addition to the active ingredient, the medicine also contains:

Microcrystalline cellulose, calcium hydrogen phosphate dihydrate, sodium starch glycollate, hydroxypropyl cellulose, hypromellose, magnesium stearate, titanium dioxide, macrogol 400, polysorbate 80, macrogol 8000, purified water.

What the medicine looks like and what the package contains:

Lustral tablets 50 mg: white, capsule-shaped film-coated tablet with a score line, marked with 'ZLT 50' on one side and 'VLE' on the other side.

Lustral tablets 100 mg: white, capsule-shaped film-coated tablet, marked with 'ZLT 100' on one side and 'VLE' on the other side.

Approved package sizes: 20 or 28 film-coated tablets. Not all package sizes may be marketed.

Revised in September 2025 according to MOH guidelines.

Drug registration number at the national drug registry of the Ministry of Health:

Lustral tablets 50 mg: 120-51-27480

Lustral tablets 100 mg: 120-52-27481

Manufacturer and registration holder: Dexcel Pharma Technologies Ltd., 10 Hakidma St.,
Yokneam Illit 2069200, Israel