

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

SERTRALINE TEVA 50 mg Film-coated Tablets

Each film-coated tablet contains:
Sertraline (as hydrochloride) 50 mg

SERTRALINE TEVA 100 mg Film-coated Tablets

Each film-coated tablet contains:
Sertraline (as hydrochloride) 100 mg
For information on inactive and allergenic ingredients in the preparation, see section 2 – "Important information about some of the ingredients in this medicine" and section 6 – "Further information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

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

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

What should I know about the medicine?

Antidepressants and anti-anxiety medicines increase the risk of suicidal behavior and thoughts in children, adolescents and young adults up to the age of 25. When starting treatment with the medicine, patients of all ages and their relatives should monitor behavioral changes such as: worsening of the depression, suicidal thoughts, aggression and the like. If changes such as these occur, refer to the doctor immediately (see section 2).

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for the treatment of symptoms of depression in patients with or without a history of mania. After achieving an adequate response, continued treatment with the medicine is effective in preventing recurrence of the primary depressive episode or of additional recurrent depressive episodes.

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

2. BEFORE USING THE MEDICINE Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine (detailed in section 6).
- You are taking, or have taken, medicines from the monoamine oxidase inhibitor group (such as: selegiline, moclobemide) or monoamine oxidase inhibitor-like medicines (such as linezolid). Wait at least one week after completing treatment with sertraline before starting treatment with monoamine oxidase inhibitors. Similarly, wait at least two weeks after completing treatment with monoamine oxidase inhibitors before starting treatment with sertraline.
- You are concomitantly taking a medicine called pimozide (a medicine intended for mental disorders such as psychosis).

Special warnings regarding use of the medicine

Before treatment with Sertraline Teva, tell the doctor if:

- You suffer, or have suffered in the past, from epilepsy or a history of seizures. Inform the doctor immediately if a seizure occurs.
- You have suffered in the past from manic depressive disorder (bipolar disorder) or schizophrenia. Inform the doctor immediately if a manic episode occurs.
- You have or have had thoughts of harming yourself or suicidal thoughts (see below in this section "Suicidal thoughts and worsening of your depression or anxiety disorder").
- You have serotonin syndrome. In rare cases, this syndrome may occur when you are taking certain medicines at the same time as this preparation (for symptoms, see section 4 – "Side Effects"). Your doctor would have told you if you have suffered from this syndrome in the past.
- You have low blood sodium levels, since treatment with Sertraline Teva may cause this. Inform the doctor if you are taking certain medicines for treatment of hypertension, as these medicines may alter blood sodium levels. Be particularly careful in elderly people; they are at higher risk.
- You suffer from a liver disease. In this case, the doctor may decide to reduce the dosage of the medicine administered.
- You suffer from diabetes. Taking this preparation may affect your blood glucose levels, and there may therefore be a need to adjust the dosage of your medicines for the treatment of diabetes.
- You have a history of bleeding disorders (tendency to develop bruises), or if you are pregnant (see "Pregnancy, breastfeeding and fertility" section) or you are taking blood thinners (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 kinds of glaucoma (elevated eye pressure).
- You suffer from a heart rhythm irregularity, following an electrocardiogram (ECG), known as prolonged QT interval.
- You suffer from heart disease, low blood potassium or magnesium levels, a family history of a prolonged QT interval, slow heart rate and concomitant use of medicines that prolong the QT interval.

Akathisia/Restlessness:

Use of the medicine has been linked to a troublesome restlessness and an urge to move, when the patient is often unable to sit or stand still (akathisia). This effect occurs mostly during the first few weeks of treatment. Increasing the dosage may be harmful, so if you develop such effects, you should inform your doctor.

Withdrawal symptoms:

Side effects linked to stopping treatment are common (withdrawal symptoms), particularly when treatment is stopped suddenly (see sections 3 and 4). The risk of the occurrence of withdrawal symptoms depends on the duration of treatment, the dosage and the rate at which the dosage of the medicine is reduced. Generally, the severity of these symptoms is mild to moderate. However, these symptoms can be serious in some patients. These symptoms mostly occur in the first few days after stopping treatment. In general, these symptoms wear off on their own and gradually disappear within two weeks. In some patients, they may continue for longer (two-three months or even longer). When stopping treatment with the medicine, it is recommended to reduce the dosage gradually over several weeks or months, and you should always consult the doctor regarding the most appropriate way to stop 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 harming yourself or suicidal thoughts. These effects are more likely to occur when first starting to take antidepressants, as it takes time before they begin to have an effect, usually about two weeks, but sometimes even longer. **You may be more likely to think in such a way:**

- **If you have previously had suicidal thoughts or thoughts about harming yourself.**
- **If you are a young adult.** Data from clinical trials have shown an increased risk of suicidal behavior in adults under 25 years of age with psychiatric conditions that were treated with antidepressants.

If, at any time, you have thoughts of harming yourself or suicidal thoughts, contact your doctor or proceed to a hospital immediately. You may find it useful to share with a relative or close friend that you are depressed or suffering 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 has gotten worse, or if they are worried about changes in your behavior.

Problems with sexual function:

Medicines such as Sertraline Teva (also called SSRIs) could cause symptoms of problems with sexual function (see section 4). In some cases, these symptoms continued even after treatment was stopped.

Children and adolescents:

Sertraline Teva is not intended for children and adolescents under 18 years of age.

Drug interactions:

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

Certain medicines affect the way Sertraline Teva works, or Sertraline Teva itself can reduce the effectiveness of other medicines taken at the same time.

Do not use this medicine if you are being treated with the following medicines:

Medicines called monoamine oxidase inhibitors, such as: moclobemide (to treat depression) and selegiline (to treat Parkinson's disease), linezolid (an antibiotic), methylene blue (to treat high levels of methemoglobin in the blood), medicines to treat mental disorders such as psychosis (pimozide).

Taking Sertraline Teva together with these medicines may cause serious side effects.

Tell your doctor if you are taking the following medicines:

- Medicines containing amphetamines (used to treat attention deficit hyperactivity disorder (ADHD), narcolepsy and obesity).
- Preparations 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.
- Preparations for treatment of severe pain (such as tramadol).
- Medicines used for anesthesia or for treatment of chronic pain (such as: fentanyl, mivacurium and succinylcholine).
- Preparations for treatment of migraine (such as sumatriptan).
- Blood thinning medicines (warfarin).
- Medicines for treatment of pain/arthritis (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 excessive acidity, peptic ulcer or heartburn (cimetidine, omeprazole, lansoprazole, pantoprazole, rabeprazole).
- Medicines for treatment of mania and depression (lithium).
- Other medicines for 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 treatment of hypertension, chest pain, or to regulate the rate and rhythm of the heart (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, micafungin).
- Medicines for treatment of HIV/AIDS and hepatitis C (protease inhibitors such as: ritonavir, telaprevir).
- Medicines to prevent nausea and vomiting after an operation or chemotherapy (aprepitant).
- Medicines known to increase the risk for changes in the heart's electrical activity (such as: anti-psychotics and certain antibiotics).

Use of the medicine and food:

The medicine can be taken with or without food. Swallow the tablet with a little water.

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

Use of the medicine and alcohol consumption:

Avoid consumption of alcohol during treatment with the medicine.

Pregnancy, breastfeeding and fertility:

Pregnancy:

If you are pregnant or breastfeeding, think you are pregnant or planning a pregnancy, consult with your doctor before using this medicine.

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

If you take Sertraline Teva 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. You should notify your doctor or midwife if you are taking Sertraline Teva during pregnancy. Taking it during pregnancy, particularly in the last trimester, may increase the risk of a serious condition in newborns, called persistent pulmonary hypertension of the newborn (PPHN). This condition makes the baby 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, refer to your doctor immediately.

Other symptoms from which the newborn baby could suffer usually appear during the first 24 hours after birth. The symptoms include: breathing difficulty, blue discoloration of the skin, skin that is too cold or too hot, blue lips, vomiting or feeding problems, excessive tiredness, sleeping difficulties, continuous crying, stiff or lax muscles, tremor, agitation or fits, increased reflexes, irritability, decrease in blood sugar level.

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

Breastfeeding:

There is proof that sertraline is secreted into breast milk. Do not use Sertraline Teva if you are breastfeeding, unless the doctor considers that the benefit of the medicine outweighs any possible risk to your baby.

Fertility:

Studies performed in animals have determined that certain medicines such as Sertraline Teva may impair sperm quality. Theoretically, this may impair fertility, but impairment of human fertility has not been observed as yet.

Driving and operating machinery:

Use of this medicine may impair your ability to drive or operate machinery. 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 in this medicine:

This medicine contains less than 23 mg of sodium per tablet, and is therefore considered to be sodium free.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen for the preparation. The dosage and treatment regimen will be determined by the doctor only.

The usual dose is generally 50 mg once a day, in the morning or in the evening. 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 once a day.

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

The improvement in symptoms may occur only after a few weeks. In general, the treatment for depression should be continued for 6 months after improvement occurs.

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

Do not exceed the recommended dose!

The medicine can be taken with or without food. Sertraline Teva 50 mg: The tablets can be halved at the score line.

There is no information regarding chewing and crushing.

Sertraline Teva 100 mg: The tablets can be halved at the score line.

There is no information regarding chewing and crushing.

If you accidentally take a higher dosage

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

Signs of an overdose may include: drowsiness, nausea and vomiting, rapid heart rate, agitation, tremor, dizziness, and in rare cases loss of consciousness.

If you forget to take the medicine

If you forgot to take this medicine at the required time, skip the forgotten dose and take the next dose at the scheduled time. Never take a double dose instead of the forgotten dose!

Adhere to the treatment regimen as recommended by the doctor.

If you stop taking the medicine

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting a doctor. The doctor will instruct you on how to stop the treatment gradually over several weeks, before you finally stop taking the medicine. Abrupt discontinuation of the medicine may be accompanied by effects such as: dizziness, numbness, sleep disturbances, anxiety or agitation, headaches, nausea and vomiting, tremor. If you experience any of these side effects or other side effects upon discontinuation of the 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 regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Sertraline Teva 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 lessen with continued treatment.

Tell the doctor immediately:

If you experience any of the following symptoms after taking this medicine; these symptoms could be serious.

- If you develop a severe skin rash that causes blistering (erythema multiforme) (this can also affect the mouth and tongue). These may be signs of Stevens-Johnson Syndrome or Toxic Epidermal Necrolysis. Your doctor will stop your treatment in these cases.
- Allergic reaction or allergy, which may include symptoms such as: an itchy skin rash, breathing difficulties, wheezing, swollen eyelids, face or lips.
- If you experience restlessness, confusion, diarrhea, high fever, high 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 this medicine. In this case, the doctor may stop your treatment.
- If your skin and eyes turn yellow, which may indicate liver damage.
- If you experience symptoms of depression with thoughts of self-harm, or suicidal thoughts.
- If you start to get a feeling of restlessness and are not able to sit or stand still after you started taking this medicine. You should tell the doctor if you start to feel restless.
- If you have a fit (seizure).
- If you had a manic episode (see section 2 – "Special warnings regarding use of the medicine").

The following side effects have been observed in clinical studies in adults, and during use of the medicine after it was marketed.

Very common side effects

Effects that occur in more than one user in ten:

Insomnia, dizziness, sleepiness, headache, diarrhea, nausea, dry mouth, ejaculation failure, fatigue.

Common side effects

Effects that appear in 1-10 in 100 users:

- Catching a cold, sore throat, runny nose.
- Decreased appetite, increased appetite.
- Anxiety, depression, agitation, decreased sexual interest, nervousness, feeling strange, nightmare, teeth grinding.
- Tremor, muscular movement disorders (such as: moving a lot, tense muscles, difficulty walking, muscle stiffness, spasms and involuntary muscle movements)*, numbness and tingling, muscle tension, lack of attention, altered taste.
- Visual disturbances.
- Ringing in the ears.
- Palpitations.
- Hot flushes.
- Yawning.
- Indigestion, constipation, abdominal pain, vomiting, flatulence.
- Increased sweating, rash.
- Back pain, joint pain, muscle pain.
- Menstrual irregularities, erection problems.
- Malaise, chest pain, weakness, fever.
- Weight gain.
- Injury.

Uncommon side effects

Effects that appear in 1-10 in 1,000 users:

- Inflammation of the intestine, ear infection.
- Tumor.
- Hypersensitivity, seasonal allergy.
- Decreased thyroid hormone levels.
- Suicidal thoughts, suicidal behavior*, psychotic disorder, abnormal thoughts, apathy, hallucinations, aggression, euphoric sensation, paranoia.
- Forgetfulness, decreased sensation, involuntary muscle contractions, fainting, moving a lot, migraine, convulsion, dizziness while standing up, impaired coordination, speech disorder.
- Dilated pupils.
- Ear pain.
- Fast heartbeat, heart problems.
- Bleeding (such as stomach bleeding)*, hypertension, flushing, blood in the urine.
- Shortness of breath, nose bleed, breathing difficulties, wheezing.
- Tarry stools, tooth disorders, inflammation of the esophagus, tongue problems, hemorrhoids, increased salivation, difficulty swallowing, burping, tongue disorder.
- Swollen eyes, hives, hair loss, itching, purple spots on the skin, skin problem accompanied by blisters, dry skin, facial swelling, cold sweat.
- Osteoarthritis, muscle twitching, muscle cramps*, muscular weakness.
- Increase in frequency of urination, difficulty urinating, inability to urinate, urinary incontinence, increase in urination, nighttime urination.
- Sexual dysfunction in men and women, significant vaginal bleeding, vaginal bleeding.
- Swelling of legs, chills, difficulty walking, thirst.
- Increase in liver enzyme levels, weight loss.

Cases of suicidal thoughts and behavior have been reported during treatment with sertraline or soon after discontinuation of sertraline treatment (see section 2).

Rare side effects

Effects that appear in 1-10 in 10,000 users:

- Diverticulitis, swollen lymph glands, decreased number of platelets*, decreased number of white blood cells*.
- Acute allergic reaction, endocrine problems*.
- High cholesterol, problems controlling blood sugar level (diabetes), low blood sugar levels, increase in blood sugar levels*, low blood sodium level*.
- Physical symptoms due to stress or emotions, terrifying abnormal dreams*, dependence on medicines, sleep walking, premature ejaculation.
- Coma, abnormal movements, difficulty moving, increased sensation, sudden, acute headache (may be a sign of a serious condition involving reversible constriction of cerebral blood vessels)*, sensory disturbance.
- Seeing spots, glaucoma, double vision, sensitivity of the eye to light, blood in the eye, unequal sized pupils*, visual disturbance*, tear problem.
- Heart attack, dizziness, fainting or chest discomfort which could be signs of changes in the electrical activity (seen on electrocardiogram) or irregular rhythm of the heart*, slow heartbeat.
- Impaired blood circulation in the limbs.
- Fast breathing, progressive scarring of lung tissue (interstitial lung disease)*, closing up of the throat, difficulty talking, slow breathing, hiccups.
- Mouth ulcers, pancreatitis*, blood in stools, tongue ulcers, sore mouth.
- Problems with liver function, serious liver dysfunction*, yellowing of the skin and eyes (jaundice)*.
- Skin reaction to sun*, skin edema*, change in hair structure, strange body odor, hair follicle rash, breakdown of muscle tissue*, bone disorder.
- Difficulty urination when beginning to urinate, decreased urination.
- Breast discharge, vaginal dryness, genital discharge, pain and redness of penis and foreskin area, breast enlargement*, prolonged erection.
- Hernia, decreased tolerance to medicines.
- Increase in blood cholesterol levels, abnormal laboratory tests*, changes in sperm quality, problems with clotting*.
- Widening of blood vessels.

Side effects of unknown frequency (effects whose frequency has not yet been determined):

- Jaw lock*.
- Bedwetting*.
- Partial vision loss.
- Inflammation of the colon (causing diarrhea).
- Heavy vaginal bleeding shortly after birth (postpartum hemorrhage), for more information see "Pregnancy, breastfeeding and fertility" under section 2*.

Side effects reported during use of the medicine, after marketing began, are marked by *.

Symptoms that may occur in the case of discontinuation of treatment:

If you suddenly stop taking the medicine, you may develop side effects such as: dizziness, numbness, sleep disturbances, agitation or anxiety, headaches, nausea, vomiting and tremor (see section 3).

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

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

Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

• **Avoid poisoning!** This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.

• Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

• **Storage conditions: Store the medicine in a dry place, below 25°C.**

6. FURTHER INFORMATION

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

Sertraline Teva 50 mg:
Microcrystalline cellulose, dibasic calcium phosphate dihydrate, croscarmellose sodium, povidone, hypromellose, titanium dioxide (E171), magnesium stearate, macrogol, polysorbate, indigo carmine (E132).

Sertraline Teva 100 mg:
Microcrystalline cellulose, dibasic calcium phosphate dihydrate, croscarmellose sodium, povidone, polyvinyl alcohol-part hydrolyzed, magnesium stearate, titanium dioxide (E171), macrogol, talc, iron oxide yellow (E172), iron oxide black (E172).

What the medicine looks like and contents of the package:

Sertraline Teva 50 mg: Light blue, film-coated elliptical shaped tablet, scored on one side and debossed with "9" and "3" on each side of the score-line. Debossed with "7176" on the other side of the tablet.

Quantity in the package: 28 or 30 tablets.

Sertraline Teva 100 mg: Light yellow, film-coated elliptical shaped tablet, scored on one side and debossed with "9" and "3" on each side of the score-line. Debossed with "7177" on the other side of the tablet.

Quantity in the package: 28 or 30 tablets.

Not all package sizes may be marketed.

Name of License Holder and its Address:

Teva Pharmaceutical Industries Ltd., P.O.B. 3190, Petah-Tikva, 49131.

Name of Manufacturer and its Address:

Teva Pharmaceutical Industries Ltd., P.O.B. 3190, Petah-Tikva, 49131.

The leaflet was revised in June 2021 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Sertraline Teva 50 mg: 132.12.30899
Sertraline Teva 100 mg: 132.13.30900

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