

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

The medicine is dispensed with a doctor's prescription only

## **SERENADA<sup>®</sup> 50, 100**

### **Coated tablets**

#### **Composition:**

Each **Serenada 50** coated tablet contains:

Sertraline (as hydrochloride) 50 mg

Each **Serenada 100** coated tablet contains:

Sertraline (as hydrochloride) 100 mg

For a list of inactive and allergenic ingredients in the preparation, please see in section 2 "Before using the 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 and adolescents under 18 years of age.**

#### **What should I know about the medicine?**

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

When starting treatment with the medicine, patients of all ages and their relatives should monitor behavioral changes such as: worsening of depression, suicidal thoughts, aggression and the like. If such changes occur, refer to a doctor immediately.

#### **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 a satisfactory response, continued treatment with the medicine is effective in preventing relapse of the initial depressive episode or recurrence of further 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 2 “Important information about some of the ingredients of the medicine” and section 6 “Further information”).
- You are taking, or have taken, monoamine oxidase inhibitors (MAOI) (such as selegiline, moclobemide) or MAOI-like drugs (such as linezolid). Wait at least one week after completing treatment with sertraline and starting treatment with MAOIs. Similarly, wait at least two weeks after completing treatment with MAOIs and beginning treatment with sertraline.
- You are concomitantly taking a medicine called pimozone (a medicine intended for mental disorders such as psychosis).

### **Special warnings regarding use of the medicine**

#### **Before beginning treatment with Serenada, tell the doctor if:**

- You are suffering, or have suffered in the past, from epilepsy or a history of seizures. Notify the doctor immediately if a seizure occurs.
- You have suffered in the past, from manic depressive disorder (bipolar disorder) or schizophrenia. Notify the doctor immediately if you have a manic episode.
- 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 should let you know if you have suffered from this syndrome in the past.
- You have low blood sodium levels, since treatment with **Serenada** may cause this. Tell the doctor if you are taking certain medicines to treat hypertension, as these medicines may also alter the blood sodium levels. Be particularly careful in elderly people; they are at higher risk.
- You have liver disease. In this case, the doctor may decide to lower the dosage of the medicine administered.
- You have diabetes. Taking this preparation may affect your blood glucose levels and there may therefore be a need to adjust the dosage of your anti-diabetic medicines.
- You have a history of bleeding disorders (tendency to develop bruises), or you are pregnant (see “Pregnancy, breastfeeding and fertility” in this section) or if you are taking blood thinners (such as acetylsalicylic acid [aspirin], or warfarin) or may increase the risk of bleeding.
- You are being treated with electroconvulsive therapy (ECT).
- You have eye problems, such as certain kinds of glaucoma (increased intraocular pressure).
- You have an irregularity of your heart rhythm, following an electrocardiogram (ECG), known as prolonged QT interval.

- You have heart disease, low potassium levels or low magnesium levels, family history of QT interval prolongation, slow heart rate and concomitant use of medicines which prolong QT interval.

### **Akathisia/Restlessness**

Use of the medicine has been linked to a distressing restlessness and need to move, often without the ability to sit or stand still (akathisia). This effect mostly occurs 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 related to discontinuation of treatment are common (withdrawal symptoms), particularly if the treatment is stopped suddenly (see in section 3 “If you stop taking the medicine” and section 4 “Side effects”). The risk of withdrawal symptoms depends on the length of treatment, 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 may be serious in some patients. They mostly occur within 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 last longer (2-3 months or even more). When stopping treatment with the medicine, it is recommended to reduce the dosage gradually over a period of several weeks or months, and you should always consult with the doctor regarding the best way to discontinue treatment.

### **Suicidal thoughts and worsening of your depression or anxiety disorder**

If you are depressed and/or have anxiety disorders, you may sometimes have thoughts of harming yourself or suicidal thoughts. These effects may occur more often when starting to use antidepressants, since it takes time until they begin to have an effect, usually about two weeks or even longer.

#### **You may be more likely to think like this:**

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

#### **If you have thoughts of harming yourself or suicidal thoughts at any time, contact your doctor or proceed 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 can ask them to tell you if they think your depression or anxiety disorder got worse, or if they are worried about changes in your behavior.

### **Sexual problems**

Medicines like **Serenada** (also called SSRIs) may cause symptoms of sexual dysfunction (see section 4 “Side effects”). In some cases, these symptoms continued even after treatment was terminated.

### **Children and adolescents**

**Serenada** is not intended for children and adolescents under the age of 18 years.

## Drug interactions

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

Certain medicines may affect the way **Serenada** works, or **Serenada** itself can reduce the effectiveness of other medicines taken at the same time.

Do not use **Serenada** 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 (antibiotic), methylene blue (to treat high levels of methemoglobin in the blood), medicines to treat mental disorders such as psychosis (pimozide).

Taking **Serenada** 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 1-2 weeks.
- Products containing the amino acid tryptophan.
- Preparations to treat severe or chronic pain (opioids such as tramadol, fentanyl).
- Medicines used in anesthesia (such as fentanyl, mivacurium and succinylcholine).
- Preparations to treat migraines (such as sumatriptan).
- Blood thinning medicines (warfarin).
- Medicines to treat pain/ arthritis such as metimazole, nonsteroidal, 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 acidity, peptic ulcer or heartburn (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 or olanzapine).
- Medicines to treat hypertension, chest pain or to regulate the rate and rhythm of the heart (such as verapamil, diltiazem, flecainide, propafenone).
- Medicines to treat bacterial infections (such as rifampicin, clarithromycin, telithromycin, erythromycin).
- Medicines to treat fungal infections (such as ketoconazole, itraconazole, posaconazole, voriconazole, fluconazole).
- Medicines to treat HIV/AIDS virus and hepatitis C (protease inhibitors such as ritonavir, telaprevir).
- Medicines used to prevent nausea and vomiting after an operation or chemotherapy (aprepitant).

- Medicines known to increase the risk of changes in the electrical activity of the heart (such as antipsychotics 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 the course of treatment with the medicine; it 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 the course of treatment with the medicine.

### **Pregnancy, breastfeeding and fertility**

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

#### **Pregnancy**

The safety of **Serenada** has not yet been fully established in pregnant women. **Serenada** will only be given during pregnancy if the doctor considers that the benefit is greater than any possible risk to the fetus.

If you take **Serenada** 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. Let the doctor or the midwife know if you are taking **Serenada** during pregnancy so that they can advise you. 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 causes the baby to breathe more rapidly and to appear bluish. These symptoms usually begin 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 the newborn baby may have usually appear during the first 24 hours after birth.

The symptoms include: trouble breathing, blueish skin, skin that is too cold or too hot, blue lips, vomiting or feeding problems, excessive tiredness, sleeping difficulties, continuous crying, stiff or floppy muscles, tremor, jitters or fits, increased reflexes, irritability, decrease in blood sugar level.

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

#### **Breastfeeding**

There is evidence that **Serenada** is secreted into breast milk. Do not use **Serenada** if you are breastfeeding, unless the doctor thinks that the benefit from the medicine outweighs any possible risk to your baby.

#### **Fertility**

Studies performed in animals have demonstrated that some medicines such as **Serenada** may affect the sperm quality. Theoretically, this may affect fertility, however, no impact on human fertility has 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 of the medicine**

- **This medicine contains lactose** (see section 6 “Further information”). If you have been told by your doctor that you have an intolerance to certain sugars, consult the doctor before taking this medicine.
- **This medicine contains sodium** (see section 6 “Further information”). **Serenada** contains less than 1 millimole (23 mg) sodium per 50 mg or 100 mg film-coated tablet, that is to say, it is essentially considered 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 regarding the dosage and treatment regimen of the preparation.

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

The usual dosage generally is:

Take the medicine once a day in the morning or the evening.

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

An improvement in your symptoms may only occur after a few weeks. In general, the treatment for depression should be continued for approximately 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.

If necessary, the tablet can be halved for immediate use. There is no information regarding crushing or chewing the tablet.

#### **If you accidentally took 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.

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

#### **If you forgot 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 to compensate for 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 condition, do not stop treatment with the medicine without consulting the doctor. The doctor will instruct you on how to stop the treatment gradually over several weeks before you stop taking the medicine altogether. Abrupt discontinuation of the medicine may be accompanied by effects such as dizziness, numbness, sleep disturbances, anxiety or agitation, headaches, nausea and vomiting, shaking. 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 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 **Serenada** may cause side effects in some users. Do not be alarmed by 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 can be serious.

- If you develop a severe skin rash that leads to the onset of blisters (erythema multiforme) (this can also affect the mouth and tongue). These may be symptoms of Stevens-Johnson syndrome or Toxic Epidermal Necrolysis. In these cases, the doctor will stop the treatment with the medicine.
- 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 agitation, confusion, diarrhea, high temperature, 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, your doctor may stop your treatment.
- If your skin and the eyes turn yellow, which may be indicative of liver damage.
- If you experience symptoms of depression with thoughts of harming yourself or suicidal thoughts.
- If you start to get a feeling of restlessness and are not able to sit or stand still after you started to take this medicine. You should tell the doctor if you have started to feel restless.
- If you have a fit (seizure).
- If you had a manic episode (see in 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 (may appear in more than 1 in 10 patients):**

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

##### **Common side effects (may appear in up to 1 in 10 patients):**

- Chest cold, sore throat, runny nose.
- Decreased appetite, increased appetite.
- Anxiety, depression, agitation, decreased sexual interest, nervousness, feeling strange, nightmares, teeth grinding.
- Shaking, muscular movement disorders (such as moving a lot, tense muscles, difficulty walking, muscle stiffness, spasms and involuntary movements of muscles)\*, numbness and tingling, muscle tension, lack of attention, abnormal taste.
- Visual disturbances.
- Ringing in ears.

- Palpitations.
- Hot flushes.
- Yawning.
- Upset stomach, constipation, abdominal pain, vomiting, gas.
- Increased sweating, rash.
- Back pain, joint pain, muscle pain.
- Menstrual irregularities, erectile dysfunction.
- Malaise, chest pain, weakness, fever.
- Weight increased.
- Injury.

**Uncommon side effects (may appear in up to 1 in 100 patients):**

- Gastroenteritis, ear infection.
- Tumor.
- Hypersensitivity, seasonal allergy.
- Low thyroid hormones.
- Suicidal thoughts, suicidal behavior\*, psychotic disorder, abnormal thinking, apathy, hallucination, aggression, euphoric mood, paranoia.
- Amnesia, decreased sensation, involuntary muscle contractions, passing out, moving a lot, migraine, convulsion, dizziness while standing up, abnormal coordination, speech disorder.
- Enlarged pupils.
- Ear pain.
- Fast heartbeat, heart problem.
- Bleeding (such as stomach bleeding)\*, hypertension, flushing, blood in the urine.
- Shortness of breath, nose bleed, breathing difficulty, wheezing.
- Tarry stools, tooth disorder, inflammation of the esophagus, tongue problems, hemorrhoids, increased saliva, difficulty swallowing, burping, tongue disorder.
- Eye swelling, hives, hair loss, itching, purple spots on skin, skin problem with blisters, dry skin, face edema, cold sweat.
- Osteoarthritis, muscle twitching, muscle cramps\*, muscular weakness.
- Increase in frequency of urination, difficulty urinating, unable to urinate, urinary incontinence, increase in urination, nighttime urination.
- Sexual dysfunction in men and women, excessive vaginal bleeding, vaginal hemorrhage.
- Swelling of legs, chills, difficulty walking, thirst.
- Increase in liver enzyme levels, decreased weight.
- **Cases of suicidal thoughts and behavior have been reported during the course of treatment with Serenada or soon after discontinuation of the treatment with Serenada (see in section 2 “Special warnings regarding use of the medicine”).**

**Rare side effects (may appear in up to 1 in 1,000 patients):**

- Diverticulitis, swollen lymph glands, decrease in number of platelets\*, decrease in the number of white blood cells\*.
- Severe allergic reaction.
- Endocrine problems\*.
- High cholesterol, problems controlling blood sugar levels (diabetes), low blood sugar level, increase in blood sugar levels\*, low blood sodium level\*.

- Physical symptoms due to stress or emotions, terrifying abnormal dreams\*, drug dependence, sleep walking, premature ejaculation.
- Coma, abnormal movements, difficulty moving, increased sensation, sudden severe headache (may be a sign of a serious condition involving reversible constriction of cerebral blood vessels)\*, sensory disturbances.
- Seeing spots, glaucoma, double vision, sensitivity of the eye to light, blood in the eye, unequal sized pupils\*, abnormal vision\*, tear problem.
- Heart attack, light-headedness, fainting or chest discomfort which could be symptoms of changes in the electrical activity (seen on electrocardiogram) or abnormal rhythm of the heart\*, slow heartbeat.
- Poor circulation in arms and legs.
- Fast breathing, progressive scarring of lung tissue (interstitial lung disease)\*, closing up of throat, difficulty talking, slow breathing, hiccups.
- A form of lung disease where eosinophils (a type of white blood cell) appear in increased numbers (eosinophilic pneumonia).
- Mouth ulcers, pancreatitis\*, blood in stool, tongue ulcers, sore mouth.
- Problems with liver function, serious liver function problems\*, 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.
- Urinary hesitation, decreased urination.
- Breast discharge, vaginal dryness, genital discharge, pain and redness in the area of the penis and foreskin, breast enlargement\*, prolonged erection.
- Hernia, decreased drug tolerance.
- 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 been determined):**

- Lockjaw\*.
- Bedwetting\*.
- Partial loss of vision.
- Inflammation of the colon (causing diarrhea\*).
- Heavy vaginal bleeding shortly after delivery (postpartum bleeding), see in section 2 “Pregnancy, breastfeeding and fertility”.

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

**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, nervousness or anxiety, headaches, nausea, vomiting and shaking (see in section 3 “If you stop taking the medicine”). An increased risk of bone fractures has been observed in patients taking these types of medicines.

**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](http://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> Additionally, you can report to "[Unipharm Ltd.](#)".

## 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 the 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 below 25°C and in a place protected from light.

## 6. FURTHER INFORMATION

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

Microcrystalline Cellulose, Lactose Monohydrate, Povidone, Sodium Starch Glycolate, Magnesium Stearate, Opadry White Y-1-7000.

### The medicine contains lactose and sodium

Each **Serenada 50** tablet contains 40 mg lactose and approximately 0.13 mg sodium.

Each **Serenada 100** tablet contains 80 mg lactose and approximately 0.26 mg sodium.

What the medicine looks like and the contents of the package:

**Serenada** is packaged in trays (blisters) which are inserted in a carton box. Each package has 7, 10, 14, 15, 28 or 30 tablets. Not all package sizes may be marketed.

**Serenada 50** are white, film-coated, round, biconvex tablets with a break line on one side.

**Serenada 100** are white, film-coated, round, biconvex tablets with a break line on one side.

**Registration holder and address:** Unipharm Ltd., P.O. Box 16545, Tel Aviv, 6116401.

**Manufacturer and address:** Unipharm Ltd., "Mevo Carmel" Industrial Park. Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:

**Serenada 50** - 136 98 31205 01

**Serenada 100** - 136 99 31204 01

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