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

The medicine is dispensed with a doctor's prescription only

Mirta Teva 30 mg

Film-coated tablets

Composition:

Each tablet of **Mirta Teva 30 mg** contains:

Mirtazapine 30 mg

For a list of inactive ingredients and allergens in the medicine see section 2 – "Important information about some of the ingredients of the medicine" and section 6 – "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have other 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 it seems to you 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 monitor for 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?

Mirta Teva is used to treat depression.

Therapeutic class: a preparation from the SNRIs group.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to mirtazapine or to any of the other ingredients the medicine contains (detailed in section 6 "Additional information"). In this case, you should talk to your doctor as soon as possible before starting to use **Mirta Teva**.
- You are taking or have recently taken (within the past two weeks) medicines called monoamine oxidase inhibitors (MAOIs).

Do not take Mirta Teva or tell your doctor before taking it:

If you have previously developed a severe skin rash, peeling, blisters on the skin and/or mouth ulcers after taking **Mirta Teva** or other medicines.

Special warnings regarding the use of the medicine

Before starting treatment with **Mirta Teva**, talk to your doctor or pharmacist.

Children and adolescents

Mirta Teva is not intended for use in children and adolescents below the age of 18 years, because efficacy has not been demonstrated. In addition, you should know that patients under the age of 18 years who take medicines from this group have a higher risk of side effects such as suicide attempt, suicidal thoughts and hostility (especially aggression, oppositional behavior and anger). However, the doctor may prescribe **Mirta Teva** to patients under the age of 18 years if he thinks it is in their best interest. If the doctor has prescribed you **Mirta Teva** and you are under the age of 18 years and want to discuss it, please refer back to your doctor. You should inform the doctor if any of the symptoms listed above occur or worsen, when patients under the age of 18 years take **Mirta Teva**. In addition, the long-term effects of **Mirta Teva** in this age group regarding growth, sexual maturation and cognitive and behavioral development have not been proven yet. Furthermore, significant weight gain during treatment with **Mirta Teva** has been observed more frequently in this age group, as compared to adults.

Thoughts of suicide and worsening of your depression

If you are depressed, you can sometimes have thoughts of self-harm or suicidal thoughts. These may be increased when first starting to take antidepressants, since these medicines all take time to start working, usually about two weeks, but sometimes longer. You may be more likely to think like this:

- If you have previously had thoughts of self-harm or suicidal thoughts.
- If you are a young adult. Information from clinical trials has demonstrated an increased risk of suicidal behavior in adults aged less than 25 years with psychiatric conditions, who were treated with antidepressants.

If you have thoughts of self-harm or suicidal thoughts at any time, contact your doctor or proceed directly to a hospital. You may find it helpful to share with a relative or a close friend that you are depressed, ask them to read this leaflet. You can ask them to tell you if they think your depression is getting worse or if they are concerned about changes in your behavior.

Also, caution should be exercised with Mirta Teva:

- If you have or have ever had any of the following conditions (tell your doctor about these conditions before taking **Mirta Teva**, if you have not done so yet):
  - Seizures (epilepsy). If you develop seizures or your seizures become more frequent, stop taking **Mirta Teva** and contact your doctor immediately.
  - Serious skin reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction accompanied by an increase in white blood cells (eosinophilia) and systemic symptoms (DRESS), which have been reported while using mirtazapine. If one or more of the symptoms described occur, stop taking **Mirta Teva** and contact your doctor immediately. If you have ever developed serious skin reactions, **do not** start treatment with **Mirta Teva**.
  - Liver disease, including jaundice. If jaundice develops, stop taking **Mirta Teva** and contact your doctor immediately.
  - Kidney disease.
  - Heart disease or low blood pressure.
  - Schizophrenia. If psychotic symptoms, such as paranoid thoughts, become more frequent or worsen, contact your doctor immediately.
  - Manic depression (alternating periods of feeling elated/overactivity and depressed mood). If you start feeling elated or overexcited, stop taking **Mirta Teva** and contact your doctor immediately.
  - Diabetes (you may need to adjust your dose of insulin or the dosage of other antidiabetic medicines).
  - Eye disease, such as increased intraocular pressure (glaucoma).
  - Difficulty in passing urine (urinating), which might be caused by an enlarged prostate.
  - Certain types of heart conditions that may change your heart rate, a recent heart attack, heart failure, or if you are taking certain medicines that may affect heart rate.
- If you develop signs of an infection such as unexplained high fever, sore throat and mouth ulcers. **Stop taking Mirta Teva and consult your doctor immediately regarding a blood test.** In rare cases, these symptoms can be signs of disturbances in blood cell production in the bone marrow. While rare, these symptoms usually occur after 4-6 weeks of treatment.
- If you are an elderly person, you may be more sensitive to the side effects of antidepressants.

Drug interactions

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

Do not take Mirta Teva in combination with:

- Monoamine oxidase inhibitors (MAO inhibitors). In addition, do not take **Mirta Teva** during the first two weeks after discontinuing treatment with MAO inhibitors. Also, if you have stopped taking **Mirta Teva**, do not take MAO inhibitors during the next two weeks. Examples of MAO inhibitors are moclobemide, tranylcypromine (both are antidepressants) and selegiline (used for Parkinson's disease).

Exercise caution when taking Mirta Teva in combination with:

- Antidepressants, such as SSRIs, venlafaxine and L-tryptophan or triptans (used for treatment of migraine), tramadol (an analgesic), linezolid (an antibiotic), lithium (for treatment of certain psychiatric conditions), methylene blue (for treatment of high levels of methemoglobin in the blood) and St. John's Wort – Hypericum perforatum preparations (a herbal medicine for depression). In very rare cases, **Mirta Teva** alone or the combination of **Mirta Teva** with these medicines may lead to a condition called serotonin syndrome. Some of the symptoms of this syndrome are: unexplained fever, sweating, increased heart rate, diarrhea, muscle contractions (uncontrollable), tremor, overactive reflexes, restlessness, mood swings and lack of consciousness. If you have a combination of these symptoms, talk to your doctor immediately.
- The antidepressant nefazodone. May increase the levels of **Mirta Teva** in your blood. Inform your doctor if you are using this medicine. It may be necessary to reduce the dose of **Mirta Teva** or increase the dose of **Mirta Teva** again, after discontinuing treatment with nefazodone.
- Medicines for anxiety or insomnia, such as benzodiazepines; medicines for schizophrenia, such as olanzapine; medicines for allergy, such as cetirizine; medicines for severe pain, such as morphine. When combined with the medicines listed above, **Mirta Teva** may increase the drowsiness effect.
- Medicines for infections; medicines for bacterial infections (such as erythromycin), medicines for treatment of fungal infections (such as ketoconazole), medicines for HIV/AIDS (such as HIV protease inhibitors) and medicines for stomach ulcers (such as cimetidine). When combined with **Mirta Teva**, these medicines may increase the levels of **Mirta Teva** in your blood. Inform your doctor if you are using these medicines. It may be necessary to reduce the dose of **Mirta Teva** or to increase the dose of **Mirta Teva** again, after discontinuing these medicines.
- Medicines for epilepsy, such as carbamazepine and phenytoin; medicines for tuberculosis, such as rifampicin. When combined with **Mirta Teva**, these medicines may reduce the levels of **Mirta Teva** in your blood. Inform your doctor if you are using these medicines. It may be necessary to increase the dose of **Mirta Teva**, or reduce the dose of **Mirta Teva** again, after discontinuing these medicines.
- Medicines for prevention of blood clots, such as warfarin. **Mirta Teva** may increase the effects of warfarin on blood clotting. Inform your doctor if you are using this medicine. In case of combination, it is recommended that the doctor carefully monitor coagulation functions.
- Medicines that may affect heart rate such as certain antibiotics and several antipsychotic medicines.

Use of the medicine and alcohol consumption

You may be drowsy if you drink alcohol while taking **Mirta Teva.** It is recommended not to drink alcohol at all.

Use of the medicine and food

Mirta Teva may be taken with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult your doctor or pharmacist before taking this medicine.

Limited experience in administering **Mirta Teva** to pregnant women does not indicate an increased risk. Nevertheless, caution should be exercised when used during pregnancy. If you are using **Mirta Teva** up until the birth or until shortly before the birth, your baby should be supervised for possible side effects.

Make sure the midwife and/or the doctor know you are taking **Mirta Teva**.

When taken during pregnancy, similar medicines (SSRIs) may increase the risk of a serious condition in babies called persistent pulmonary hypertension of the newborn (PPHN), which makes the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the birth of the baby. If this happens to your baby, contact your midwife and/or doctor immediately.

Driving and operating machinery

Mirta Teva may affect your concentration or alertness. Make sure that these abilities are not affected by taking **Mirta Teva** before driving or operating machinery.

Important information about some of the ingredients of the medicine

- **Mirta Teva tablets contain lactose.** If you have been told by your doctor that you have an intolerance to certain sugars, contact your doctor before taking this medicine (see also section 6 – "Additional information").
- **Mirta Teva** contains less than 1 mmol of sodium (23 mg) per tablet, therefore it is 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 about the dosage and how to use the preparation.

The dosage and duration of treatment will be determined by the doctor only. The generally accepted dosage is:

The generally accepted starting dose is 15 or 30 mg every day. After a few days, your doctor may advise you which dose is best for you (between 15 and 45 mg per day). Usually, the dose is the same for all ages. However, if you are an elderly person or if you have a kidney or liver disease, your doctor may adjust the dose.

Do not exceed the recommended dose.

When to take Mirta Teva

Take **Mirta Teva** at the same time every day. It is preferable to take **Mirta Teva** as a single dose before bedtime. However, your doctor may suggest that you split the **Mirta Teva** dose – once in the morning and once in the evening before bedtime. The higher dose should be taken before bedtime.

Take the tablets orally.

Swallow the tablet with a little water or juice.

If necessary, the tablet can be halved at the score line. There is no information regarding crushing or chewing of the tablet.

When you can expect to start feeling better:

Usually, **Mirta Teva** will start to work after 1-2 weeks, and after 2-4 weeks you may start to feel better. It is important that you talk to your doctor during the first weeks of treatment regarding the effects of **Mirta Teva**:

2-4 weeks after starting treatment with Mirta Teva, tell your doctor how the medicine has affected you.

If you still do not feel better, your doctor may prescribe you a higher dose. In this case, talk to your doctor again after another 2-4 weeks.

Usually, you will have to continue taking **Mirta Teva** until your depression symptoms have disappeared for 4-6 months.

If you accidentally took a higher dosage of Mirta Teva contact the doctor immediately.

The most common signs of **Mirta Teva** overdose (without other medicines or alcohol) are drowsiness, disorientation and increased heart rate. If you took an overdose or if a child accidentally swallowed this medicine, refer to a doctor or a hospital emergency room immediately and bring the package of the medicine with you.

Additional symptoms of a possible overdose can include changes in the heart rhythm (fast, irregular heartbeat) and/or fainting which may be symptoms of a life-threatening condition called torsade de pointes (ventricular tachycardia).

If you forgot to take the medicine

If you are supposed to take your dose **once a day**:

- Do not take a double dose in order to compensate for the forgotten dose.
  Take the next dose at the usual time.

If you are supposed to take your dose **twice a day**:

- If you forgot to take your morning dose, take it together with your evening dose.
- If you forgot to take your evening dose, do not take it with the following morning dose; skip it and continue with your usual morning and evening doses.
- If you forgot to take both doses, do not attempt to compensate for the forgotten doses. Skip the two doses and continue the next day with your usual morning and evening doses.

If you stop taking the medicine

You can stop taking **Mirta Teva** only after consulting your doctor.

If you stop too early, your depression may come back. Talk to your doctor as soon as you feel better. Your doctor will decide when you can stop the treatment. Do not stop taking **Mirta Teva** suddenly, even if your depression has disappeared. If you stop taking **Mirta Teva** suddenly, you may feel nauseous, dizzy, agitated or anxious and you may have headaches. These symptoms can be prevented by discontinuing the treatment gradually. Your doctor will tell you how to lower the dose gradually.

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

If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. SIDE EFFECTS

As with any medicine, using **Mirta Teva** may cause side effects in some users.

Do not be alarmed when reading the list of side effects. You may not experience any of them.

If you experience any of the following serious side effects, stop taking Mirta Teva and tell your doctor immediately.

Common side effects (may affect up to 1 in 10 people):

- Memory problems, which in most cases go away when the treatment is discontinued.

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

- Sensation of elation or "high" (feelings of mania).

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

- Yellow coloring of the eyes or skin. This may suggest disturbance in liver function (jaundice).
- Severe upper abdominal pain that sometimes occurs with nausea and vomiting (pancreatitis).

Side effects with unknown frequency (frequency cannot be estimated from the available data):

- Thoughts of self-harm or suicidal thoughts – **contact your doctor immediately or go to a hospital straight away.**
- A skin reaction known as erythema multiforme (itchy, reddish-purple lesions on the skin, especially on the palms of the hands or soles of the feet; hives-like raised swollen areas on the skin; tender areas on the surfaces of the mouth, eyes and genitals, which may be accompanied by fever and tiredness).
- A severe rash, blisters (bullous dermatitis).
- Red lesions on the body in the form of circular patches with a darker center (target-like), usually accompanied by blisters, peeling of the skin, ulcers in the mouth, throat, nose, eyes or genitals. This severe rash is preceded by fever and flu-like symptoms (symptoms of a serious skin reaction called Stevens-Johnson syndrome or toxic epidermal necrolysis).
- Extensive rash, high body temperature and enlarged lymph nodes (DRESS syndrome or hypersensitivity syndrome).
- Signs of infection, such as unexplained high fever, sore throat or mouth ulcers (agranulocytosis). In rare cases, mirtazapine can cause disturbances in the production of blood cells (bone marrow depression). Certain people become less resistant to infection since mirtazapine can cause a temporary deficiency in white blood cells (granulocytopenia). In rare cases, mirtazapine can also cause a temporary deficiency in red and white blood cells as well as platelets (aplastic anemia), platelet deficiency (thrombocytopenia) or increased number of white blood cells (eosinophilia).
- An epileptic seizure (convulsions).
- A combination of symptoms such as unexplained high fever, sweating, increased heart rate, diarrhea, muscle contractions (uncontrollable), tremor, overactive reflexes, restlessness, changes in mood, lack of consciousness and increased salivation. In very rare cases, these can be signs of serotonin syndrome.
- Muscle pain, stiffness and/or weakness, in addition to darkened or discolored urine (rhabdomyolysis).

Other possible side effects of Mirta Teva are:

Very common (may affect more than 1 in 10 people):

- Increased appetite and weight gain.
- Drowsiness or sleepiness.
- Headache.
- Dry mouth.

Common (may affect up to 1 in 10 people):

- Lethargy.
- Dizziness.
- Instability or tremor.
- Nausea.
- Diarrhea.
- Vomiting.
- Constipation.
- Rash or skin eruptions (exanthema).
- Joint pain (arthralgia) or muscle pain (myalgia).
- Back pain.
- Feeling dizzy or fainting when suddenly standing up (orthostatic hypotension).
- Swelling (generally in the ankles or feet) caused by fluid retention (edema).
- Tiredness.
- Vivid dreams.
- Confusion.
- Feeling of anxiety.
- Sleeping problems.

Uncommon (may affect up to 1 in 100 people):

- Abnormal sensations in the skin, e.g., burning, tingling, tickling or numbness (paresthesia).
- Restlessness in the legs.
- Fainting (syncope).
- Numbness in the mouth (oral hyposensitivity).
- Low blood pressure.
- Nightmares.
- Feeling agitated.
- Hallucinations.
- Urge to move.

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

- Muscle twitching or contractions (myoclonus).
- Aggressiveness.

Unknown (frequency cannot be estimated from the available data):

- Abnormal sensations in the mouth (oral paresthesia).
- Swelling of the mouth (oral edema).
- Swelling of the body (generalized edema).
- Localized swelling.
- Low levels of sodium in the blood (hyponatremia).
- Inappropriate secretion of a hormone that regulates water levels in the blood (anti-diuretic hormone).
- Increased salivation.
- Sleep-walking (somnambulism).
- Speech disturbances.
- Increased creatine kinase levels in the blood.
- Difficulty urinating (urinary retention).
- Increased levels of the hormone prolactin in the blood (hyperprolactinemia, including symptoms of enlarged breasts and/or milk secretion from the nipples).
- Prolonged and painful erection (priapism).

Additional side effects in children and adolescents

In children below 18 years of age, the following side effects were commonly observed in clinical studies:

Significant weight gain, hives and increased blood triglycerides.

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 your doctor immediately.

Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il) which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il.

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of the month shown.
- **Store below 30°C.**
- Do not discard medicines in the wastewater or domestic trash. Ask your pharmacist how to discard medicines you no longer use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active ingredient the medicine also contains:

Lactose monohydrate, Pregelatinized maize starch, croscarmellose sodium, silica colloidal anhydrous, magnesium stearate, hypromellose, titanium dioxide, macrogol 8000, iron oxide yellow, iron oxide red, talc

What does the medicine look like and what are the contents of the package?

Mirta Teva tablets are brown film-coated, oval, convex tablets with a score line on both sides, debossed with "I" on one side. The tablets are packed in trays (blister) inside a carton package.

The tablets come in packages of 20, 30, 50, 60 or 100 tablets.

Not all package sizes may be marketed.

Name and address of the license holder and manufacturer:

Teva Israel Ltd.

124 Dvora HaNevi'a St., Tel Aviv 6944020.

Registration number of the medicine in the national drug registry of the Ministry of Health:

Mirta Teva 30 mg: 178-57-37636

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You may contact the license holder for a printed leaflet in English at:
Tevacare@med-trix.com
or by telephone: 1-800-805-005

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