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

The medicine is dispensed with a doctor's prescription only

Quetiapine Teva 25 mg
Quetiapine Teva 100 mg
Quetiapine Teva 200 mg
Quetiapine Teva 300 mg
Film-coated tablets

Composition:
Each film-coated tablet of Quetiapine Teva 25 mg contains:
Quetiapine (as fumarate) 25 mg
Each film-coated tablet of Quetiapine Teva 100 mg contains:
Quetiapine (as fumarate) 100 mg
Each film-coated tablet of Quetiapine Teva 200 mg contains:
Quetiapine (as fumarate) 200 mg
Each film-coated tablet of Quetiapine Teva 300 mg contains:
Quetiapine (as fumarate) 300 mg
For the list of inactive ingredients and allergens in the preparation see section 2 - "Important information about some 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 additional questions, refer to the doctor or the pharmacist.
This medicine has been prescribed for treatment of your illness. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar.
This medicine is not intended for use in children and adolescents under the age of 18.
The medicine is not intended for elderly people who suffer from dementia.

- Antidepressants and anti-anxiety medicines increase the risk for suicidal behavior and thoughts in children, adolescents and young adults up to the age of 25. Upon 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, aggressiveness and the like. If such changes occur, contact the doctor immediately.
- Elderly patients with dementia-related psychosis who are treated with antipsychotic medications are at an increased risk of death.

1. What is the medicine intended for?

Quetiapine Teva is intended for the treatment of:
- Schizophrenia.
- Manic episodes associated with bipolar disorders.
- Depressive episodes associated with bipolar disorders.

Quetiapine Teva is not indicated for the prevention of recurrence of manic or depressive episodes
Therapeutic class:
Antipsychotic medicines.
Schizophrenia is a disease in which you can hear or feel things that do not exist, believe in things that are not real or experience an unusual feeling of suspicion, anxiety, confusion, guilt, stress or depression.
Mania is a condition in which you feel very excited, cheerful, agitated, enthusiastic, overactive or experience a decline in your sense of judgment and aggressiveness.
Bipolar disorder is a condition in which you may feel sad all the time or you may find yourself depressed, experience guilt, lack of energy, loss of appetite or inability to sleep.
The doctor may instruct you to continue the treatment with Quetiapine Teva even if you feel better.

2. Before using the medicine

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any one of the other ingredients the medicine contains, see section 2 - "Important information about some ingredients of the medicine" and section 6 - "Additional information".
- You are taking the following medicines:
  - Medicines for the treatment of acquired immunodeficiency syndrome HIV.
  - Medicines from the azole family (for the treatment of fungal infections).
  - Erythromycin or clarithromycin (for the treatment of infections).
  - Nefazodone (for treatment of depression).

If you are not sure, consult the doctor or pharmacist before taking Quetiapine Teva.

Special warnings regarding the use of the medicine:
Before treatment with Quetiapine Teva, inform the doctor if:
- You or someone in your family suffer or have suffered in the past from heart problems, such as: problems with heart rate, weakening of the heart muscle or inflammation of the heart or if you are taking medicines that affect the heart rate.
- You have low blood pressure.
- You have suffered in the past from a stroke, especially if you are elderly.
- You have liver problems.
- You have ever had seizures.
- You have diabetes or if you are at risk of developing diabetes. In this case, the doctor may check your blood sugar levels while you are being treated with Quetiapine Teva.
- You have suffered in the past from a low white blood cell count (possibly as a result of other medicines).
- Do not take Quetiapine Teva if you are an elderly person with dementia, as Quetiapine Teva may increase the risk of stroke or in some cases may increase the risk of death in elderly people with dementia.
- You are an elderly person suffering from Parkinson's disease/parkinsonism.
- You or someone in your family have a history of blood clots, since medicines such as Quetiapine Teva are involved in the formation of blood clots.
- You have or have had a condition of short pauses in breathing during nighttime sleep (called sleep apnea) and you are taking medicines that slow down normal brain activity.
- You have or have had a condition of inability to completely empty your bladder (urinary retention), enlarged prostate, intestinal obstruction or elevated intraocular pressure. These conditions are sometimes caused by medicines (called anticholinergics) which affect the way nerve cells function in order to treat a certain medical condition.
- You have a history of addiction to alcohol, medicines or drugs.

Inform the doctor immediately if you experience one of the following symptoms after taking Quetiapine Teva:
- A combination of fever, severe muscle stiffness, sweating or decreased consciousness (this phenomenon is called "neuroleptic malignant syndrome"). You may need urgent medical treatment.
- Involuntary movements, mainly of the face and tongue.
- Dizziness or if you feel extremely sleepy, which could increase the risk of accidental injury (fall) in elderly people.
- Seizures.
- A long-lasting, continuous and painful erection.
- You have a rapid and irregular heartbeat, even when you are at rest, as well as palpitations, breathing problems, chest pain or unexplained tiredness. Your doctor will need to check your heart and if necessary, will refer you to a cardiologist immediately.

The conditions listed above may be caused by using the group of medicines to which Quetiapine Teva belongs.
Inform the doctor as soon as possible if you experience one of the following:
- Fever, flu-like symptoms, sore throat or any other inflammation, as this could be a result of a very low white blood cell count, which may require stopping the treatment with Quetiapine Teva and/or receiving treatment.
- Constipation accompanied by persistent abdominal pain, or constipation that does not respond to medicinal treatment. This may lead to a more serious condition of intestinal obstruction.
- Suicidal thoughts and worsening of depression:
  If you suffer from depression, you may have suicidal thoughts. These thoughts can intensify at the beginning of treatment with Quetiapine Teva, as it takes time for the medicine to start working, about two weeks and sometimes longer. An increase in suicidal thoughts can also occur if the treatment with Quetiapine Teva is discontinued abruptly. These thoughts are more common in young adults. Information from clinical trials shows an increased risk of suicidal thoughts and/or suicidal behavior in young adults under the age of 25 who suffer from depression. If you have suicidal thoughts, contact your doctor or go to a hospital immediately. Sharing the feeling of depression with a relative or close friend can help, and they should be asked to read this leaflet. You can ask them to tell you if they feel that the depression is getting worse or when they are worried about changes in your behavior.
- **Severe Cutaneous Adverse Reactions (SCARs)**
  There are rare reports of severe cutaneous adverse reactions that can be life-threatening or fatal in patients taking Quetiapine Teva. These reactions are usually manifested in the following symptoms:
  - Stevens-Johnson syndrome (SJS) - a widespread rash on the skin with blisters and peeling skin, especially around the mouth, nose, eyes and genitals.
  - Toxic epidermal necrolysis (TEN) syndrome - a more severe syndrome, which causes extensive peeling of the skin.
  - DRESS syndrome - drug reaction with eosinophilia and systemic symptoms, such as flu-like symptoms combined with rash, fever, enlarged glands and abnormal blood test results (including an increase in white blood cell levels (eosinophilia) and an increase in liver enzyme levels).
  - AGEP (acute generalized exanthematous pustulosis) – small, pus-filled blisters.
  - Erythema multiforme – skin rash with irregular, red and itchy spots.

Stop using Quetiapine Teva immediately if you develop one of these symptoms and tell your doctor or seek immediate medical care.
Weight gain:
Weight gain has been observed in patients taking Quetiapine Teva. You should monitor your weight regularly with your doctor.
Children and adolescents:
Do not use in children and adolescents under the age of 18.
Drug interactions:
If you are taking or have recently taken other medicines, including non-prescription medicines and food supplements, tell the doctor or the pharmacist.
Do not take Quetiapine Teva if you are taking any of the following medicines:
- Medicines for the treatment of acquired immunodeficiency syndrome (AIDS).
- Medicines from the azole family (for the treatment of fungal infections).
- Erythromycin or clarithromycin (for the treatment of infections).
- Nefazodone (for treatment of depression).

Inform the doctor if you are taking:
- Medicines for treatment of epilepsy (such as phenytoin or carbamazepine).
- Medicines for the treatment of high blood pressure.
- Barbiturates (for the treatment of insomnia).
- Thioridazine or lithium (antipsychotic medications).
- Medicines that affect the heart rate, for example, medicines that can cause electrolyte imbalance (low levels of potassium and magnesium), such as diuretic medications or certain antibiotics (medicines that treat infections).
- Medicines that may cause constipation.
- Medicines that affect the function of nerve cells in order to treat certain medical conditions (called anticholinergics).

You must consult with your doctor before discontinuing any of the medicines you are taking.
Use of the medicine and food:
Quetiapine Teva may be taken with or without food.
Do not drink grapefruit juice during treatment with Quetiapine Teva. Grapefruit juice may affect the way the medicine works.
Use of the medicine and Alcohol consumption:
Be careful with the amount of alcohol you consume, as the combination of Quetiapine Teva and alcohol can make you drowsy.
Pregnancy and breastfeeding:
Before taking Quetiapine Teva tell your doctor if you are pregnant, planning a pregnancy or trying to become pregnant.
Do not take Quetiapine Teva during pregnancy unless you have discussed this with your doctor.
Do not use this medicine if you are breastfeeding.
The following symptoms may occur in newborns of mothers who took Quetiapine Teva in the last three months of pregnancy: tremor, muscle stiffness and/or muscle weakness, somnolence, agitation, breathing problems and eating difficulties. If your baby develops one or more of these symptoms, refer to the doctor.
Driving and operating machinery:
The use of this medicine may cause drowsiness.
Do not drive or operate machinery until you know how the medicine affects you.
Important information about some ingredients of the medicine:
Quetiapine Teva contains lactose. Lactose is a type of sugar. If you have an intolerance to lactose or you are unable to digest certain sugars, please inform your doctor before taking Quetiapine Teva.
Quetiapine Teva tablets contain less than 23 mg of sodium per tablet and are therefore considered "sodium-free".
Quetiapine Teva 25 mg and 100 mg tablets contain the yellow coloring agent sunset FCF (Sunset Yellow FCF) which may cause allergic reactions.
Effect on urine test results:
Quetiapine Teva can cause a positive result in urine test for medicines you are not taking, such as: methadone or tricyclic antidepressant preparations. The validity of these results should be verified using additional tests.

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 treatment regimen will be determined only by the doctor.
The doctor will determine your daily dosage of the medicine - between 150 mg and 800 mg, depending on your illness and personal needs.
Do not exceed the recommended dose.
The tablets should be taken once a day before bedtime or twice a day, depending on the disease.
How to take the medicine:
The tablets should be swallowed whole with water, regardless of food.
Do not halve the tablets in the absence of a score line.
There is no information on crushing or pulverizing.
Liver problems:
If you have liver problems, the doctor may change your dosage.
The elderly:
If you are an elderly person, your doctor may change your dosage.
If you accidentally took a higher dosage:
If you accidentally took an overdose or by mistake a child swallowed this medicine, go immediately to the doctor or the emergency room of a hospital and bring the package of the medicine with you. You may feel tiredness, dizziness and abnormal heartbeat.
If you forgot to take the medicine:
If you have forgotten to take this medicine at the required time, do not take a double dose. Take a dose as soon as you remember. Take the next dose at the scheduled time and consult a doctor.
Follow the treatment as recommended by the doctor.
If you stop taking the medicine:
Even if you feel an improvement in your condition, do not stop taking the medicine unless the doctor tells you to.
Abrupt discontinuation of the medicine may cause the following symptoms: inability to sleep, nausea, headaches, diarrhea, vomiting, dizziness and nervousness. Your doctor can recommend gradually reducing the dosage before stopping the medicine.
Do not take medicines in the dark! Check the label and the dose every time you take the 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 Quetiapine 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.
Very common side effects - side effects that occur in more than 1 out of 10 users:
- Dizziness (which may cause a fall).
- Headache.
- Dry mouth.
- Drowsiness (may cause a fall, may pass after some time of taking the medicine).
- Symptoms of stopping the medicine - inability to sleep, nausea, headache, diarrhea, vomiting, dizziness and nervousness. It is recommended to stop the treatment gradually and over a period of 1-2 weeks.
- Weight gain.
- Abnormal muscle movements that include difficulty starting movement, tremor, feeling restless or muscle stiffness without pain.
- Changes in the levels of certain fats in the blood (triglycerides and cholesterol).

Common side effects - side effects that occur in 1-10 out of 100 users:
- Rapid heartbeat.
- Pounding heartbeat, racing or skipping beats.
- Indigestion or constipation.
- Weakness.
- Swelling of the arms or legs.
- High blood sugar levels.
- Low blood pressure in the transition to standing position (may cause dizziness, fainting and falling).
- Blurry vision.
- Strange dreams and nightmares.
- Increased feeling of hunger.
- Nervousness.
- Speech problems.
- Suicidal thoughts and worsening of depression.
- Shortness of breath.
- Vomiting (especially in the elderly).
- Fever.
- Changes in thyroid hormone levels in the blood.
- Decreased levels of certain types of blood cells in the blood.
- Increase in the level of liver enzymes measured in the blood.
- Increase in the level of the prolactin hormone in the blood. An increase in the prolactin hormone in rare cases can lead to:
  - Swollen breasts in men and women and an unexpected milk production.
  - Cessation of monthly periods in women or irregular periods.

Uncommon side effects - side effects that occur in 1-10 out of 1,000 users:
- Seizures or spasms.
- Allergic reactions that can include raised lumps on the skin, swelling of the skin and swelling around the mouth.
- Restless legs syndrome (an unpleasant sensation in the legs).
- Difficulty swallowing.
- Uncontrolled movements, especially of the face and tongue.
- Difficulties in sexual function.
- Diabetes.
- Changes in the electrical activity of the heart seen on ECG test (QT prolongation).
- Heart rate is slower than usual, which can happen at the beginning of treatment and can be associated with low blood pressure and fainting.
- Difficulty urinating.
- Fainting (may cause falls).
- Nasal congestion.
- Decreased amount of red blood cells.
- Decreased amount of sodium in the blood.
- Exacerbation of existing diabetes.

Rare side effects - side effects that occur in 1-10 out of 10,000 users:
- A combination of fever, sweating, muscle stiffness, severe tiredness or fainting (neuroleptic malignant syndrome).
- Yellowing of the skin and the eyes (jaundice).
- Hepatitis (jaundice).
- A long-lasting painful erection.
- Swollen breasts and an unexpected milk production.
- Disturbances in monthly periods.
- Blood clots in the veins, especially in the legs (manifested by swelling, pain and redness of the leg), which can reach the lungs through the bloodstream and cause chest pain and difficulty breathing. If you notice any of these symptoms, seek medical help immediately.
- Walking, talking, eating and doing other activities while sleeping.
- Decreased body temperature (hypothermia).
- Pancreatitis.
- "Metabolic syndrome" - a condition in which a combination of three or more of the following symptoms may occur: increased abdominal fat, decreased level of the "good cholesterol" (HDL-C), increased blood triglycerides levels, high blood pressure and increased blood sugar levels.
- A combination of fever, flu-like symptoms, sore throat or any other infection accompanied by a very low white blood cell count, a condition called agranulocytosis.
- Intestinal obstruction.
- Increased levels of creatine phosphokinase in the blood (a substance that comes from the muscles).

Very rare side effects - side effects that occur in less than one out of 10,000 patients:
- Severe rash, blisters and red areas on the skin.
- Severe allergic reaction that may manifest as difficulty breathing, or anaphylactic shock.
- Rapid swelling of the skin, usually around the eyes, lips and throat (angioedema).
- Appearance of severe blisters on the skin, mouth, eyes and genitals (Stevens-Johnson syndrome). See warnings section.
- Abnormal secretion of the hormone responsible for urine volume.
- Breakdown of muscle fibers and muscle pain (rhabdomyolysis).

Side effects with unknown frequency (side effects whose frequency has not yet been determined):
- Skin rash with unusual red spots (erythema multiforme), see section 2.
- Rapid appearance of areas with red skin dotted with small pustules (small blisters filled with yellow/white fluid called acute generalized exanthematous pustulosis (AGEP)), see section 2.
- A sudden severe allergic reaction with symptoms such as fever, skin blisters and skin exfoliation (TEN). See section 2.
- DRESS syndrome - drug reaction with eosinophilia and systemic symptoms, such as flu-like symptoms combined with rash, fever, enlarged glands and abnormal blood test results (including an increase in white blood cell levels (eosinophilia) and an increase in liver enzyme levels), see section 2.
- Withdrawal symptoms may occur in newborns of mothers who took Quetiapine Teva during pregnancy.
- Stroke.
- Disturbance in the heart muscle (cardiomyopathy).
- Inflammation in the heart muscle (myocarditis).
- Inflammation of the blood vessels (vasculitis), often accompanied by skin rash with small red or purple bumps.

The class of medicines to which Quetiapine Teva belongs may cause heart rhythm problems, which may be serious and life-threatening.
The following side effects were seen in blood tests:
- Changes in the levels of certain fats (triglycerides and total cholesterol).
- Increased blood sugar levels.
- Changes in the amount of thyroid hormones in the blood.
- Increased liver enzymes levels.
- Decreased levels of different blood cells.
- Decreased red blood cell levels.
- Decreased blood sodium levels.
- Increased levels of creatine phosphokinase in the blood (a substance in the muscle).
- Increase in the level of the prolactin hormone in the blood. An increase in the prolactin hormone in rare cases can lead to:
  - Swollen breasts and unexpected milk production in men and women.
  - Cessation of monthly periods in women or irregular periods.

The doctor may ask you to perform blood tests from time to time.
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.
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 that month.
Storage:
The medicine should be stored in a dry place under 25°C.

6. Additional information

In addition to the active ingredient, the medicine also contains:
Tablet core:
Lactose monohydrate, microcrystalline cellulose, calcium hydrogen phosphate dihydrate, povidone, sodium starch glycolate type A, colloidal anhydrous silica, magnesium stearate.
Tablet coating:
Lactose monohydrate (only in 25 mg, 100 mg, 300 mg tablets), hypromellose, titanium dioxide (E171), triacetin, iron oxide yellow (E172) (only in 25 mg, 100 mg, 300 mg tablets), sunset yellow FCF aluminium lake (E110) (only in 25 mg, 100 mg tablets), polydextrose FCC (only in 200 mg tablets), macrogol 8000 (only in 200 mg tablets).
What does the medicine look like and what are the contents of the package:
Quetiapine Teva 25 mg: Light-orange, round, biconvex, film-coated tablet. Debossed with "25" on one side of the tablet and plain on the other side.
Quetiapine Teva 100 mg: Light-orange, round, biconvex, film-coated tablet. Debossed with "100" on one side of the tablet and plain on the other side.
Quetiapine Teva 200 mg: White to off-white, round, biconvex, film-coated tablet. Debossed with "200" on one side of the tablet and plain on the other side.
Quetiapine Teva 300 mg: Pale yellow, caplet shaped, biconvex, film-coated tablet. Debossed with "300" on one side of the tablet and plain on the other side.
Each pack contains 30 tablets.
Name and address of marketing authorization holder and manufacturer:
Teva Israel Ltd.,
124 Dvora HaNevi'a St., Tel Aviv 6944020.
The leaflet was revised in January 2022 in accordance with the Ministry of Health guidelines.
Registration number of the medicine in the national drug registry of the Ministry of Health:
Quetiapine Teva 25 mg: 150.03.33458.
Quetiapine Teva 100 mg: 150.04.33719.
Quetiapine Teva 200 mg: 150.05.33727.
Quetiapine Teva 300 mg: 150.06.33728.

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