Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) – 986

The medicine is dispensed with a doctor's prescription only

Quetiapine Sandoz® 50 mg PRT
Prolonged release tablets

Composition:
Each tablet contains
quetiapine (as fumarate) 50 mg

Quetiapine Sandoz® 150 mg PRT
Prolonged release tablets

Composition:
Each tablet contains
quetiapine (as fumarate) 150 mg

Quetiapine Sandoz® 200 mg PRT
Prolonged release tablets

Composition:
Each tablet contains
quetiapine (as fumarate) 200 mg

Quetiapine Sandoz® 300 mg PRT
Prolonged release tablets

Composition:
Each tablet contains
quetiapine (as fumarate) 300 mg

Quetiapine Sandoz® 400 mg PRT
Prolonged release tablets

Composition:
Each tablet contains
quetiapine (as fumarate) 400 mg

Inactive ingredients and allergens: see section 2 sub-section "Important information about some of the ingredients of the medicine" and section 6 "Further information".

Read the entire leaflet carefully before you start using this medicine.
This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist. This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.
The medicine is not intended for children and adolescents below the age of 18 years.
The medicine is not intended for elderly people who suffer from dementia.

- Antidepressants and antianxiety medicines increase the risk of suicidal behavior and thoughts among children, adolescents and young adults up to 25 years of age. When starting treatment with this medicine, patients of all ages and their relatives, must monitor behavioral changes, such as worsening of depression, suicidal thoughts, aggressiveness, etc. If changes such as these occur, immediately contact your doctor.
- Elderly patients who suffer from dementia-related psychosis, and are being treated with antipsychotics, have an increased risk of death.

1. What is the medicine intended for?
- to treat schizophrenia.
- to treat manic episodes associated with bipolar disorders.
- to treat depression associated with bipolar disorders.
- to treat depression together with an additional antidepressant.

Therapeutic group:
Antipsychotics.

2. Before using the medicine
Do not use Quetiapine Sandoz PRT if:

- you are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (please see section 6 – "Further Information")
- you are taking any of the following medicines:
  - medicines for treating acquired immunodeficiency syndrome (HIV)
  - medicines from the azole family (to treat fungal infections)
  - erythromycin or clarithromycin (to treat infections)
  - nefazodone (to treat depression)

If you are not sure, contact your doctor or pharmacist before taking Quetiapine Sandoz PRT.

Special warnings regarding use of Quetiapine Sandoz PRT
Before treatment with Quetiapine Sandoz PRT, tell your doctor if:
- you or any of your family members have or have had heart problems, such as heart rhythm problems, weakening or inflammation of the heart muscle, or if you are taking medicines that affect the heart rate.
- you have low blood-pressure.
- you have had a stroke, especially if you are elderly.
- you have liver problems.
- you have ever had a fit (seizure).
- you have diabetes, or if you are at risk of developing diabetes. In such a case, your doctor may test your blood sugar levels while you are being treated with Quetiapine Sandoz PRT.
- you have had a low white blood cell count in the past (which may or may not have been caused by using other medicines).
- do not take Quetiapine Sandoz PRT if you are elderly and have dementia, because Quetiapine Sandoz PRT may increase the risk of stroke, or in some cases, it may increase the risk of death in elderly people with dementia.
- you are an elderly person with Parkinson's disease/parkinsonism.
- you or someone else in your family have a history of blood clots, as medicines like these have been associated with the formation of blood clots.
- you have or have had a condition of short breathing interruptions during your nightly sleep (called sleep apnea) and are taking medicines that slow down the normal activity of the brain.
- you have or have had a condition of inability to completely empty your urinary bladder (urinary retention), have an enlarged prostate, bowel obstruction, or increased intraocular pressure. These conditions are sometimes caused by medicines (called anticholinergics) that affect the way nerve cells function in order to treat a certain medical condition.
- you have a history of alcohol or drug abuse.

Inform your doctor immediately if you feel any of the following after taking Quetiapine Sandoz PRT:
- A combination of fever, acute muscle stiffness, sweating, or reduced consciousness (this is a phenomenon called "neuroleptic malignant syndrome"). You may need urgent medical treatment.
- Involuntary movements, mainly of the face and tongue.
- Dizziness or a severe sense of feeling sleepy, which can increase the risk of accidental falls in elderly people.
- Fits (seizures).
- A Long-lasting and painful erection.
- Have a fast and irregular heartbeat, even when you are at rest, palpitations, breathing problems, chest pain or unexplained tiredness. Your doctor will need to check your heart and if necessary, refer you to a cardiologist immediately.

Inform your doctor as soon as possible if you feel any of the following after taking Quetiapine Sandoz PRT:
- A fever, flu-like symptoms, sore throat, or any other infection, as this could be a result of a very low white blood cell count, which may require discontinuation of Quetiapine Sandoz PRT treatment and/or treatment administration.
- Constipation along with persistent abdominal pain, or constipation which has not responded to medication therapy, as this may lead to a more serious bowel obstruction.

Suicidal thoughts and exacerbated depression
If you are depressed, you may sometimes have suicidal thoughts. Increased suicidal thoughts can occur when first starting treatment with Quetiapine Sandoz PRT, since it takes time for the medicine to start working, about two weeks and sometimes longer. These thoughts may also be increased if you suddenly stop taking your medication. These thoughts are more common in young adults. Information from clinical trials has shown an increased risk of suicidal thoughts and/or suicidal behavior in young adults aged less than 25 years with depression.
If you have suicidal thoughts, contact your doctor or go to a hospital straight away. You may find it helpful to tell a relative or a close friend that you are depressed, and ask them to read this leaflet. You might ask them to tell you if they feel that your depression is getting worse, or if they are worried about changes in your behavior.

Severe Cutaneous Adverse Reactions (SCARs)
Severe cutaneous adverse reactions (SCARs), which may be life threatening or fatal, have been reported very rarely during treatment with this medicine. These are commonly manifested by:
- Stevens-Johnson syndrome (SJS) – a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals.
- Toxic Epidermal Necrolysis (TEN), Lyell's syndrome, a more severe form causing extensive peeling of the skin.
- DRESS syndrome – Drug Reaction with Eosinophilia and Systemic Symptoms syndrome that consists of flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and increased liver enzymes).
- Acute Generalized Exanthematous Pustulosis (AGEP) – small blisters filled with pus.
- Erythema Multiforme (EM) – skin rash with itchy, red irregular spots.

If you experience these symptoms, stop taking Quetiapine Sandoz PRT and inform your doctor or seek medical attention immediately.

Weight gain
Weight gain has been observed in patients taking quetiapine. You and your doctor should monitor your weight regularly.

Children and adolescents
The medicine is not intended for children and adolescents below 18 years of age!

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

Do not take Quetiapine Sandoz PRT if you are taking any of the following medicines:
- medicines for treating acquired immunodeficiency syndrome (HIV)
- azole medicines (to treat fungal infections)
- erythromycin or clarithromycin (to treat infections)
- nefazodone (to treat depression)

Tell your doctor or pharmacist if you are taking:
- medicines for epilepsy (such as phenytoin or carbamazepine)
- medicines for lowering blood pressure
- barbiturates (for insomnia)
- thioridazine or lithium (antipsychotics)
- medicines that affect the heart rate, for instance, medicines that can cause an electrolyte imbalance (low levels of potassium and magnesium), such as diuretics or certain antibiotics (medicines to treat infections)
- medicines that may cause constipation
- medicines (called anticholinergics) that affect the way the nervous system functions in order to treat certain medical conditions

Before you stop taking any of your medicines, contact your doctor.

Use of the medicine and food
- Do not drink grapefruit juice during treatment with this medicine. Grapefruit juice can affect the way the medicine works.
- Quetiapine Sandoz PRT may be affected by food. Therefore, take this medicine at least one hour before eating or prior to bedtime.

Use of the medicine and alcohol consumption
Be careful how much alcohol you drink. This is because the combined effect of Quetiapine Sandoz PRT and alcohol can make you sleepy.

Pregnancy and breastfeeding
If you are pregnant, think you may be pregnant, planning to become pregnant, or are breastfeeding, consult with a doctor before using this medicine. Do not take Quetiapine Sandoz PRT during pregnancy unless you have discussed this with your doctor. Do not take Quetiapine Sandoz PRT while you are breastfeeding. The following withdrawal symptoms may occur in newborns of mothers who took Quetiapine Sandoz PRT during the last trimester of pregnancy: tremor, muscle stiffness and/or muscle weakness, sleepiness, agitation, breathing problems and difficulty eating. If your baby develops any of these signs, consult the attending doctor.

Driving and using machinery
Using this medicine may make you feel sleepy. Do not drive or operate any dangerous machinery until you know how the medicine affects you.

Important information about some of the ingredients of the medicine
Quetiapine Sandoz PRT contains lactose
The tablets contain lactose, which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking this medicine.
Quetiapine Sandoz 50 mg PRT prolonged release tablets – each tablet contains 14.210 mg lactose (anhydrous).
Quetiapine Sandoz 150 mg PRT prolonged release tablets – each tablet contains 42.630 mg lactose (anhydrous).
Quetiapine Sandoz 200 mg PRT prolonged release tablets – each tablet contains 56.840 mg lactose (anhydrous).
Quetiapine Sandoz 300 mg PRT prolonged release tablets – each tablet contains 85.260 mg lactose (anhydrous).
Quetiapine Sandoz 400 mg PRT prolonged release tablets – each tablet contains 113.680 mg lactose (anhydrous).

Effect on urine tests results
Quetiapine Sandoz PRT can cause a positive result in a urine test for medicines that you are not taking, such as methadone or tricyclic antidepressants (TCAs). These results must be verified using further tests.

3. How should you use the medicine?
Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dosage or about how to take this medicine. The dosage and course of treatment will be determined by your doctor only. Your doctor will adjust the daily dose of the medicine to range between 50 mg and 800 mg, depending on your disease and individual needs.
- **Do not exceed the recommended dose.**
- Take the tablets once a day.
- The dosage will be reduced gradually before stopping treatment.
- Do not stop treatment with the medicine even if you feel improvement in your condition, unless your doctor instructs you.
- Take the medicine on an empty stomach, at least one hour before eating or prior to bedtime.

Method of use:
- **Do not chew, do not crush, and do not split the tablets,** since the tablets are prolonged - release tablets.
- Swallow the tablets whole with water.
- Do not drink grapefruit juice during treatment with Quetiapine Sandoz PRT. It can affect the way the medicine works.

Liver problems
If you have liver problems, your doctor may change your dose.

Elderly
If you are elderly, your doctor may change your dose.

If you have accidentally taken a higher dosage
If you have accidentally taken an overdose, or if a child has accidentally swallowed the medicine, immediately contact a doctor or proceed to a hospital emergency room and bring the medicine package with you. You may feel sleepiness, dizziness, and abnormal heart beats.

If you forget to take the medicine
If you forgot to take the medicine at the scheduled time, take the dose as soon as you remember. Do not take a double dose under any circumstances. Adhere to the treatment recommended by your doctor.

If you stop taking this medicine
If you stop taking the medicine abruptly, you may experience the following symptoms: inability to sleep, nausea, headache, diarrhea, vomiting, dizziness and nervousness. Your doctor can recommend you to gradually reduce the dosage before stopping treatment.

Do not take medicines in the dark! Check the label and dose every time you take a medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects
As with any medicine, use of Quetiapine Sandoz PRT 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.

Very common side effects (occur in more than 1 in 10 people):
- Dizziness (may cause falls), headache, dry mouth
- Sleepiness (may disappear with continued use of the medicine, may cause falls)
- Weight gain
- Discontinuation symptoms (symptoms which may occur when you stop taking Quetiapine Sandoz PRT) include vomiting, dizziness, nausea, headache, diarrhea, insomnia and agitation. Gradual withdrawal over a period of 1 to 2 weeks is advisable
- Abnormal muscle movements. These include difficulty starting muscle movements, shaking, feeling restless, or muscle stiffness without pain
- Changes in the amount of certain fats (triglycerides and cholesterol)

Common side effects (occur in less than 1 in 10 people):
- Rapid heart rate
- Feeling that your heart is pounding, racing, or has skipped beats
- Constipation, indigestion
- Weakness
- Swelling of the arms or legs
- Low blood pressure in standing position which can result in being dizzy or feeling faint (may cause falls)
- Increase in blood sugar levels
- Blurred vision
- Unusual dreams, nightmares
- Sensation of increased hunger
- Nervousness
- Disturbances in speech and language
- Suicidal thoughts and exacerbated depression
- Shortness of breath
- Vomiting (mainly in the elderly)
- Fever
- Changes in the amount of thyroid hormones in your blood
- Decrease in the amount of certain types of blood cells
- Increase in the amount of liver enzymes measured in the blood
- Increase in the amount of the hormone prolactin in the blood. Increases in the hormone prolactin could in rare cases lead to the following:
  - swelling of the breasts in men and women and unexpected production of breast milk
  - cessation of menstrual periods or irregular menstrual periods in women

Uncommon side effects (occur in less than 1 in 100 people):
- Fits or seizures
- Allergic reactions that may include raised lumps on the skin, swelling of the skin and swelling around the mouth
- Restless-legs syndrome (unpleasant sensation in the legs)
- Difficulty swallowing
- Involuntary movements, mainly of the face or tongue
- Difficulties in sexual function
- Diabetes
- Change in the electric activity of the heart that is detectable in an ECG (prolongation of the QT interval)
- A slower than normal heart rate, which can occur upon starting treatment, and may be associated with low blood pressure and fainting
- Exacerbation of pre-existing diabetes
- Difficulty urinating
- Nasal congestion
- Fainting (may cause falls)
- Decrease in the amount of red blood cells
- Decrease in the amount of sodium in the blood
- Confusion

Rare side effects (occur in the less than 1 in 1,000 people):
- A combination of fever, sweating, muscle stiffness, acute tiredness or fainting (neuroleptic malignant syndrome)
- Yellowing of the skin and eyes (jaundice)
- Inflammation of the liver (hepatitis)
- Prolonged and painful erection
- Swelling of breasts and unexpected production of breast milk
- Blood clots in the veins, particularly in the legs (manifested by swelling, pain, and redness of the leg), which may travel in the blood stream to the lungs, causing chest pain and difficulty in breathing. If you notice any of these symptoms, seek medical advice immediately
- Disruption of the menstrual cycle in women
- Walking, talking, eating, and other activities, while asleep
- Decrease in body temperature (hypothermia)
- Inflammation of the pancreas
- Metabolic syndrome – a condition combining three or more of the following symptoms: increase in abdominal fat, decrease in 'good cholesterol' (HDL-C), increase in blood triglycerides, high blood pressure, and an increase in blood sugar level
- Combination of fever, flu-like symptoms, sore throat or any other infection with a very low white blood cell count, a condition called agranulocytosis
- Bowel obstruction
- Increased blood creatine phosphokinase levels (a substance from the muscles)

Very rare side effects (occur in less than 1 in 10,000 people):
- Severe allergic reaction (called anaphylactic shock) that may include difficulty breathing and shock
- Rapid swelling of the skin, usually around the eyes, lips, and throat (angioedema)
- Severe blistering of the skin, mouth, eyes, and genitals (Stevens-Johnson syndrome). See section 2
- Acute rash, blisters, or red patches on the skin
- Inappropriate secretion of the hormone that controls the urine volume
- Breakdown of muscle fibers and muscle pain (rhabdomyolysis)

Side effects of unknown frequency:
- Rash with irregular red spots (erythema multiforme). See section 2
- Rapid appearance of areas of red skin studded with small pustules (small blisters filled with white/yellow fluid called Acute Generalized Exanthematous Pustulosis (AGEP)). See section 2
- Sudden acute allergic reaction with symptoms, such as fever and blisters on the skin, and skin peeling (TEN – Toxic Epidermal Necrolysis). See section 2
- DRESS – Drug Reaction with Eosinophilia and Systemic Symptoms syndrome. It consists of flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and increased liver enzymes). See section 2
- Symptoms of withdrawal may occur in newborn babies of mothers that have taken Quetiapine Sandoz PRT during their pregnancy
- Stroke
- Disorder of the heart muscle (cardiomyopathy)
- Inflammation of the heart muscle (myocarditis)
- Inflammation of blood vessels (vasculitis), often with skin rash with small red or purple bumps

The class of medicines to which Quetiapine Sandoz PRT belongs may cause disturbances in heart rhythm, which may be severe, and in severe cases cause death.

The following side effects have been observed in blood tests:
- Changes in the level of fats in the blood (triglycerides and cholesterol)
- Changes in blood sugar level
- Changes in levels of thyroid hormones
- Increase in the amount of liver enzymes
- Decrease in the number of certain types of blood cells
- Decrease in the number of red blood cells
- Increased blood creatinine phosphokinase (a substance from the muscle)
- Decrease in blood sodium levels
- Increase in the levels of the hormone prolactin in the blood. Rarely, this may lead to:
  - swelling of the breasts in men and women and unexpected production of breast milk
  - cessation of menstrual periods or irregular menstrual periods in women

Your doctor may ask you to have blood tests from time to time.

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

Side effects can be reported to the Ministry of Health by clicking the link "Reporting 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 closed 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) appearing on the package. The expiry date refers to the last day of that month.
Storage conditions:
Do not store this medicine above 25°C.

6. Further information
In addition to the active ingredient, the medicine also contains:
crystalline maltose (Advantose 100), methacrylic acid – ethyl acrylate copolymer (1:1) type A (Eudragit L100-55), lactose anhydrous (SD 250), talc, magnesium stearate vegetable, triethyl citrate (Citrofol)

What does the medicine look like and contents of the pack
Quetiapine Sandoz 50 mg PRT: white to off-white, round biconvex prolonged release tablets, engraved with "50" on one side.
Quetiapine Sandoz 150 mg PRT: white to off-white, oblong biconvex prolonged release tablets, engraved with "150" on one side.
Quetiapine Sandoz 200 mg PRT: white to off-white, oblong biconvex prolonged release tablets, engraved with "200" on one side.
Quetiapine Sandoz 300 mg PRT: white to off-white, oblong biconvex prolonged release tablets, engraved with "300" on one side.
Quetiapine Sandoz 400 mg PRT: white to off-white, oval biconvex prolonged release tablets, engraved with "400" on one side.
Blister pack contains 10, 30, 50, 60 or 100 prolonged-release tablets.
Not all pack sizes may be marketed.

License holder and importer's name and address:
Novartis Israel Ltd., P.O.Box 7126, Tel Aviv.

Revised in July 2022 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Quetiapine Sandoz® 50 mg PRT prolonged release tablets:
166-01-35775-00
Quetiapine Sandoz® 150 mg PRT prolonged release tablets:
166-02-35776-00
Quetiapine Sandoz® 200 mg PRT prolonged release tablets:
166-03-35777-00
Quetiapine Sandoz® 300 mg PRT prolonged release tablets:
166-04-35778-00
Quetiapine Sandoz® 400 mg PRT prolonged release tablets:
166-05-35779-00