

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

The medicine is dispensed with a doctor's prescription only

**QUETIAPINE INOVAMED
SR 50 MG**

Prolonged-release tablets

Composition:

Each tablet contains:

Quetiapine 50 mg (as fumarate)

**QUETIAPINE INOVAMED
SR 150 MG**

Prolonged-release tablets

Composition:

Each tablet contains:

Quetiapine 150 mg (as fumarate)

**QUETIAPINE INOVAMED
SR 200 MG**

Prolonged-release tablets

Composition:

Each tablet contains:

Quetiapine 200 mg (as fumarate)

**QUETIAPINE INOVAMED
SR 300 MG**

Prolonged-release tablets

Composition:

Each tablet contains:

Quetiapine 300 mg (as fumarate)

**QUETIAPINE INOVAMED
SR 400 MG**

Prolonged-release tablets

Composition:

Each tablet contains:

Quetiapine 400 mg (as fumarate)

For inactive ingredients and allergens please see "Further Information" in Section 6. Also, see "Important information about some of the ingredients of the medicine" in Section 2 of this leaflet.

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 for the treatment of your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their ailment is similar.

The medicine is not intended for children and adolescents below the age of 18.

The medicine is not intended for elderly people who suffer from dementia.

• Antidepressants and anti-anxiety medicines increase the risk of suicidal behavior and thoughts among children, adolescents and young adults up to the age of 25. When beginning treatment with the 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, refer immediately to the 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 states 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 Inovamed SR if:

• you are sensitive (allergic) to the active ingredient or to any of the other ingredients contained in the medicine. See Section 6 "Further Information" and Section 2 "Important information about some of the ingredients of the medicine".

• you are taking the following medicines:

- medicines for treating acquired immune deficiency 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, refer to the doctor before taking Quetiapine Inovamed SR.

Special warnings regarding use of Quetiapine Inovamed SR

Before treatment with Quetiapine Inovamed SR, tell the doctor if:

• you have low blood pressure.

• you have liver problems.

• you have ever had seizures.

• you have had a stroke, particularly if you are elderly.

• you have had a low white blood cell count in the past (which may or may not have been caused by use of other medicines).

• you or a family member have or have had heart problems in the past, such as heart rhythm disorders, weakening of the heart muscle or inflammation of the heart, or if you are taking medicines that affect the heart rate.

• you or a family member have a medical history of blood clots, as medicines of this type are involved in creating blood clots.

• you have diabetes, or if you are at risk of developing diabetes. In such a case, the doctor may test your blood sugar levels while you are being treated with Quetiapine Inovamed SR.

• Do not take Quetiapine Inovamed SR if you are an elderly person with dementia, because Quetiapine Inovamed SR 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 have or have had: a condition of short interruptions in breathing while sleeping at night (called "sleep apnea") and you 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 bladder (urinary retention), have an enlarged prostate, a blockage in your intestines, or increased pressure inside your eye. These conditions are sometimes caused by medicines (called "anticholinergics") that affect the way nerve cells function, in order to treat certain medical conditions.

• you have a history of alcohol or drug addiction.

• you 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 the doctor immediately if you experience any of the following after taking Quetiapine Inovamed SR:

• 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 feeling of sleepiness, which can increase the risk of accidental falls in elderly people.

• Fits (seizures).

• A long-lasting and painful erection.

Inform the doctor as soon as possible if you experience any of the following after taking Quetiapine Inovamed SR:

• Fever, signs of flu, sore throat, or any other inflammation, as this could be a result of a very low white blood cell count, which may require stopping treatment with Quetiapine Inovamed SR and/or administration of treatment.

• Constipation along with persistent abdominal pain, or constipation which has not responded to medicinal treatment, as this may lead to a more serious blockage of the bowel.

• 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 Inovamed SR since it takes time until the medicine starts to work, usually about two weeks but sometimes longer. These thoughts may also be increased if you suddenly stop the treatment. These thoughts are more likely 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. Sharing the feeling of depression with a relative or close friend can help, and ask them to read this leaflet. You can ask them to tell you if they feel 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 can be life-threatening or fatal, are very rare and have been reported by patients treated 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 syndrome that causes extensive peeling of the skin.

• DRESS syndrome – Drug Reaction with Eosinophilia and Systemic Symptoms which includes flu-like symptoms, that also include rash, fever, swollen glands and abnormal blood test results (including increased white blood cells level [eosinophilia] and increased liver enzyme level).

• Acute Generalized Exanthematous Pustulosis (AGEP) – small blisters filled with pus.

• Erythema Multiforme (EM) – skin rash with itchy-red irregular spots.

Stop taking Quetiapine Inovamed SR immediately if you suffer from these symptoms and inform your doctor or seek medical treatment.

• Weight gain

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

Children and adolescents

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

Drug Interactions

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

Do not take Quetiapine Inovamed SR if you are taking any of the following medicines:

• Medicines for the treating acquired immune deficiency syndrome (AIDS)

• Azole medicines (for treating fungal infections)

• Erythromycin or clarithromycin (for treating infections)

• Nefazodone (for treating depression)

Tell your doctor or the 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 rhythm, 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 can cause constipation

• Medicines (called anticholinergics) that affect the way nerve cells function in order to treat certain medical conditions

Refer to your doctor before you stop taking any of your medicines.

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 Inovamed SR can 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 consume. A combination of Quetiapine Inovamed SR and alcohol can cause sleepiness.

Pregnancy, breastfeeding and fertility

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

Driving and using machinery

Using this medicine may cause sleepiness. Do not drive or operate dangerous machinery until you know how the medicine affects you.

Important information about some of the ingredients of the medicine

The tablets contain lactose anhydrous, which is a type of sugar. If you have been told by the doctor that you have an intolerance to lactose or that you are unable to digest certain sugars, consult the doctor before taking this medicine.

Effect on urine test results

• Quetiapine Inovamed SR can cause a positive result in urine tests for medicines that you are not taking, such as: methadone or preparations for depression treatment called tricyclic antidepressants (TCAs). These results should be verified using additional tests.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only. The doctor will adjust the daily dose of the medicine in doses ranging from 50 mg to 800 mg, depending on your disease and personal 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 better, unless instructed so by your doctor.

• Take the medicine at least one hour before eating or before going to sleep.

Method of administration:

• **Do not chew, do not crush, and do not halve the tablets!** This is because the tablets are prolonged-release tablets.

• Swallow the tablets whole with water.

• Do not drink grapefruit juice during treatment with Quetiapine Inovamed SR. 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.

Use in children and adolescents

This medicine is not intended for children and adolescents under the age of 18.

If you accidentally take a higher dosage

If you accidentally have taken 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. You may feel sleepiness, dizziness and abnormal heartbeats.

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 as recommended by the doctor.

If you stop taking the medicine

Sudden discontinuation of the medicine can cause the following symptoms: inability to sleep, nausea, headache, diarrhea, vomiting, dizziness, and nervousness. Your doctor can recommend you to gradually reducing the dosage before stopping treatment.

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

If you have further questions regarding use of the medicine, consult a doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Quetiapine Inovamed SR may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Very common side effects – effects that occur in more than 1 in 10 users:

• Dizziness (may cause falls), headache, dry mouth

• Sleepiness (may disappear with continued use of the medicine, may cause falls)

• Weight gain

• Treatment discontinuation symptoms (symptoms that may occur when you stop taking Quetiapine Inovamed SR) include: vomiting, dizziness, nausea, headache, diarrhea, insomnia and agitation. Gradual withdrawal over a period of 1 to 2 weeks is advisable

• Abnormal muscle movements (including difficulty starting muscle movements, shaking, feeling of restlessness, or muscle stiffness without pain)

• Changes in the levels of certain fats (triglycerides and cholesterol)

Common side effects – effects that occur in 1 in 10 users out of 100:

• 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 dizziness or feeling faint (may cause falls)

• Increase in blood sugar levels

• Blurred vision

• Unusual dreams, nightmares

• Increased feeling of hunger

• Nervousness

• Disturbances in speech and language

• Suicidal thoughts and exacerbated depression

• Shortness of breath

• Vomiting (mainly in the elderly)

• Fever

• Changes in the levels of thyroid hormones in your blood

• Decreases in the levels of certain types of blood cells

• Increases in the level of liver enzymes measured in the blood

• Increase in the level of the hormone prolactin in the blood. Increase in the hormone prolactin could in rare cases lead to the following:

- Swollen breasts in men and women and unexpected production breast milk.

- Cessation of menstruation in women, or irregular menstruation.

Uncommon side effects – effects that occur in 1-10 out of 1,000 users:

• Seizures or fits

• 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

• Uncontrolled movements, mainly of the face and the tongue

• Difficulties in sexual function

• Diabetes

• Change in the electrical activity of the heart that is seen in an ECG test (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 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

Rare side effects – effects that occur in 1-10 out of 10,000 users:

• 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 bloodstream to the lungs causing chest pain and breathing difficulties. If you notice any of these symptoms, seek medical assistance 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 together with a very low white blood cell count, a condition called agranulocytosis

• Bowel obstruction

• Increased blood creatine phosphokinase levels (comes from the muscles)

Very rare side effects – effects that occur in less than 1 out of 10,000 users:

• 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 condition of blistering of the skin, mouth, eyes, and genitals (Stevens-Johnson syndrome)

• Acute rash, blisters, or red patches on the skin

• Abnormal secretion of the hormone that controls the volume of the urine

• Breakdown of muscle fibers and muscle pain (rhabdomyolysis)

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

• Skin rash with itchy-red irregular spots (erythema multiforme). See section 2.

• Rapid appearance of areas of red skin studded with small pustules (small blisters filled with yellow/white fluid called as 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 Syndrome – Drug Reaction with Eosinophilia and Systemic Symptoms which includes flu-like symptoms, that also include rash, fever, swollen glands and abnormal blood test results (including increased white blood cells level [eosinophilia] and increased liver enzyme level). See section 2.

• Symptoms of withdrawal may occur in newborn babies of mothers that have taken Quetiapine Inovamed SR during 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 group of medicines Quetiapine Inovamed SR is part of can cause disturbances in heart rate, which can be serious, and in severe cases cause death. The following side effects have been observed in blood tests:

• Change in levels of fats in the blood (triglycerides and cholesterol)

• Change in blood sugar level

• Changes in levels of thyroid hormones

• Decrease in the amount of certain types of blood cells

• Decrease in the amount of red blood cells

• Increase in the amount of liver enzymes

• Decrease in blood sodium levels

• Increase in creatine phosphokinase levels, comes from the muscles

• 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 unexpectedly production of breast milk.

- cessation of menstruation or irregular menstruation in women.

Your doctor may have you 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 the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage www.health.gov.il that directs you to the online form for reporting side effects