

Package leaflet: Information for the user

Quetiapine Rowex 200 mg Prolonged-Release Tablets

Quetiapine Rowex 300 mg Prolonged-Release Tablets

Quetiapine Rowex 400 mg Prolonged-Release Tablets

Quetiapine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Quetiapine Rowex is and what it is used for
2. What you need to know before you take Quetiapine Rowex
3. How to take Quetiapine Rowex
4. Possible side effects
5. How to store Quetiapine Rowex
6. Contents of the pack and other information

1. What Quetiapine Rowex is and what it is used for

Quetiapine Rowex contains the active substance quetiapine. This belongs to a group of medicines called anti-psychotics. Quetiapine Rowex can be used to treat several illnesses, such as:

- Schizophrenia: where you may hear or feel things that are not there, believe things that are not true or feel unusually suspicious, anxious, confused, guilty, tense or depressed.
- Mania: where you may feel very excited, elated, agitated, enthusiastic or hyperactive or have poor judgment including being aggressive or disruptive.
- Bipolar depression and major depressive episodes in major depressive disorder: where you feel sad. You may find that you feel depressed, feel guilty, lack energy, lose your appetite or can't sleep.

When Quetiapine Rowex is being taken to treat major depressive episodes in major depressive disorder, it will be taken in addition to another drug being used to treat this illness.

Your doctor may continue to prescribe Quetiapine Rowex even when you feel better.

2. What you need to know before you take Quetiapine Rowex

Do not take Quetiapine Rowex if

- you are allergic to quetiapine or any of the other ingredients of this medicine (listed in section 6)

- you are taking any of the following medicines:
 - some medicines used to treat HIV infections
 - azole medicines (medicines used to treat fungal infections)
 - erythromycin or clarithromycin (medicines used to treat bacterial infections)
 - nefazodone (medicine used to treat depression).

Do not take Quetiapine Rowex if the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Quetiapine Rowex.

Warnings and precautions

Talk to your doctor or pharmacist before taking Quetiapine Rowex:

- if you, or someone in your family, have or have had any heart problems, for example heart rhythm problems, weakening of the heart muscle or inflammation of the heart or if you are taking any medicines that may have an impact on the way your heart beats
- if you have low blood pressure
- if you have had a stroke, especially if you are elderly
- if you have problems with your liver
- if you have ever had a fit (seizure)
- if you have diabetes or have a risk of getting diabetes. If you do, your doctor may check your blood sugar levels while you are taking Quetiapine Rowex.
- if you know that you have had low levels of white blood cells in the past (which may or may not have been caused by other medicines)
- if you are an elderly person with dementia (loss of brain function). If you are, Quetiapine Rowex should not be taken because the group of medicines that Quetiapine Rowex belongs to may increase the risk of stroke, or in some cases the risk of death, in elderly people with dementia.
- if you are an elderly person with Parkinson's disease/parkinsonism
- if you or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots
- if you have or have had a condition where you stop breathing for short periods during your normal nightly sleep (called "sleep apnoea") and are taking medicines that slow down the normal activity of the brain ("depressants")
- if you have or have had a condition where you can't 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 "anti-cholinergics") that affect the way nerve cells function in order to treat certain medical conditions.
- if you have a history of alcohol or drug abuse.

Tell your doctor immediately if you experience any of the following after taking Quetiapine Rowex:

- A combination of fever, severe muscle stiffness, sweating or a lowered level of consciousness (a disorder called "neuroleptic malignant syndrome"). Immediate medical treatment may be needed.
- Uncontrollable movements, mainly of your face or tongue.
- Dizziness or a severe sense of feeling sleepy. This could increase the risk of accidental injury (fall) in elderly patients.
- Fits (seizures).

- A long lasting and painful erection (priapism).

These conditions can be caused by this type of medicine.

Tell your doctor as soon as possible if you have:

- 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 Quetiapine Rowex to be stopped and/or treatment to be given.
- Constipation along with persistent abdominal pain, or constipation which has not responded to treatment, as this may lead to a more serious blockage of the bowel.
- **Thoughts of suicide and worsening of your depression**
If you are depressed you may sometimes have thoughts of harming or killing yourself. These may be increased when first starting treatment, since these medicines all take time to work, usually about two weeks but sometimes longer. These thoughts may also be increased if you suddenly stop taking your medication. You may be more likely to think like this if you are a young adult. Information from clinical trials has shown an increased risk of suicidal thoughts and/or suicidal behaviour in young adults aged less than 25 years with depression.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away. You may find it helpful to tell a relative or close friend that you are depressed, and ask them to read this leaflet. You might ask them to tell you if they think your depression is getting worse, or if they are worried about changes in your behaviour.

Weight gain

Weight gain has been seen in patients taking Quetiapine Rowex. You and your doctor should check your weight regularly.

Children and adolescents

Quetiapine Rowex is not for use in children and adolescents below 18 years.

Other medicines and Quetiapine Rowex

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Do not take Quetiapine Rowex if you are taking any of the following medicines

- Some medicines used to treat HIV infections.
- Azole medicines (medicines used to treat fungal infections).
- Erythromycin or clarithromycin (medicines used to treat bacterial infections).
- Nefazodone (medicine used to treat depression).

Tell your doctor if you are taking any of the following medicines:

- Epilepsy medicines (like phenytoin or carbamazepine).
- High blood pressure medicines.
- Barbiturates (medicines used to treat difficulty sleeping).
- Thioridazine or lithium (other anti-psychotic medicines).
- Medicines that have an impact on the way your heart beats, for example, drugs that can cause an imbalance in electrolytes (low levels of potassium or magnesium) such as diuretics (water pills) or certain antibiotics (medicines used to treat bacterial infections).
- Medicines that can cause constipation.

- Medicines (called “anti-cholinergics”) that affect the way nerve cells function in order to treat certain medical conditions.

Before you stop taking any of your medicines, please talk to your doctor first.

Quetiapine Rowex with food, drink and alcohol

- Food: see section 3 under “Method of administration”
- Be careful how much alcohol you drink. This is because the combined effect of Quetiapine Rowex and alcohol can make you sleepy.
- Do not drink grapefruit juice while you are taking Quetiapine Rowex. It can affect the way the medicine works.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should not take Quetiapine Rowex during pregnancy unless this has been discussed with your doctor. The following symptoms which can represent withdrawal may occur in newborn babies, of mothers who have used Quetiapine Rowex in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

Quetiapine Rowex should not be taken if you are breast-feeding.

Driving and using machines

Your tablets may make you feel sleepy and dizzy. Do not drive or use any tools or machines until you know how the tablets affect you.

Quetiapine Rowex contains lactose

Quetiapine Rowex contains lactose which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Quetiapine Rowex contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per prolonged release tablet, that is to say essentially ‘sodium-free’.

Effect on Urine Drug Screens

If you are having a urine drug screen, taking Quetiapine Rowex may cause positive results for methadone or certain drugs for depression called tricyclic antidepressants (TCAs) when some test methods are used, even though you may not be taking methadone or TCAs. If this happens, a more specific test can be performed.

3. How to take Quetiapine Rowex

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Quetiapine Rowex is available in 3 different strengths and each strength is a different colour. Even though the dose might stay the same, it might be supplied as different strength tablets. For example one 400 mg tablet (white) or two 200 mg tablets (yellow).

The recommended dose is:

Adults

Your doctor will decide on your starting dose. The maintenance dose (daily dose) will depend on your illness and needs but will usually be between 150 mg and 800 mg.

Elderly people

If you are elderly your doctor may change your dose.

Liver problems

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

Use in children and adolescents

Quetiapine Rowex should not be used by children and adolescents aged under 18 years.

Method of administration:

Oral use.

- You will take your tablets once a day.
- Do not split, chew or crush the tablets.
- Swallow your tablets whole with a drink of water.
- Quetiapine Rowex can be affected by food. Take your tablets without food (at least one hour before a meal or at bedtime, your doctor will tell you when).
- Do not drink grapefruit juice while you are taking Quetiapine Rowex. It can affect the way the medicine works.

Duration of treatment:

This will be decided by your doctor. Do not stop taking your tablets even if you feel better, unless your doctor tells you.

If you take more Quetiapine Rowex than you should

If you take more Quetiapine Rowex than prescribed by your doctor, you may feel sleepy, feel dizzy and experience abnormal heart beats. Contact your doctor or nearest hospital straight away. Keep the tablets with you.

If you forget to take Quetiapine Rowex

If you forget to take a dose, take it as soon as you remember. If it is almost time to take the next dose, wait until then. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Quetiapine Rowex

If you suddenly stop taking Quetiapine Rowex, you may be unable to sleep (insomnia), or you may feel sick (nausea), or you may experience headache, diarrhoea, being sick (vomiting), dizziness or irritability. Your doctor may suggest you reduce the dose gradually before stopping treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

STOP taking Quetiapine Rowex and contact your doctor immediately or go to the nearest hospital if you experience any of the following serious side effects:

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

- Fits or seizures
- Uncontrollable movements, mainly of your face or tongue.

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

- A combination of high temperature (fever), sweating, stiff muscles, feeling very drowsy or faint (a disorder called “neuroleptic malignant syndrome”).
- A long-lasting and painful erection (priapism).
- Blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing.
- A combination of fever, flu-like symptoms, sore throat, or any other infection with very low white blood cell count (a condition called agranulocytosis).

Very rare side effects, may affect up to 1 in 10,000 people:

- A severe allergic reaction (called anaphylaxis) which may cause difficulty in breathing or shock.
- Rapid swelling of the skin, usually around the eyes, lips and throat (angioedema).
- A serious blistering condition of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome).

Not known, frequency of these side effects cannot be estimated from the available data:

- Serious, sudden allergic reaction with symptoms such as fever and blisters on the skin and peeling of the skin (toxic epidermal necrolysis).
- Skin rash with irregular red spots (erythema multiforme).
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). Widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome). Stop using Quetiapine Rowex if you develop these symptoms and contact your doctor or seek medical attention immediately.

The class of medicines to which Quetiapine Rowex belongs can cause heart rhythm problems, which can be serious and in severe cases may be fatal.

You may experience any of the following side effects listed below. If the side effect is severe or persistent, you should contact your doctor.

Very common side effects, may affect more than 1 in 10 people:

- Dizziness (may lead to falls), headache, dry mouth

- Feeling sleepy (this may go away with time, as you keep taking Quetiapine Rowex (may lead to falls)
- Discontinuation symptoms (symptoms which occur when you stop taking Quetiapine Rowex) include not being able to sleep (insomnia), feeling sick (nausea), headache, diarrhoea, being sick (vomiting), dizziness and irritability. Gradual withdrawal over a period of at least 1 to 2 weeks is advisable.
- Putting on weight
- 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 total cholesterol).

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

- Rapid heartbeat
- Feeling like your heart is pounding, racing or has skipped beats
- Constipation, upset stomach (indigestion)
- Feeling weak
- Swelling of arms or legs
- Low blood pressure when standing up. This may make you feel dizzy or faint (may lead to falls).
- Increased levels of sugar in the blood
- Blurred vision
- Abnormal dreams and nightmares
- Feeling more hungry
- Feeling irritated
- Disturbance in speech and language
- Thoughts of suicide and worsening of your depression
- Shortness of breath
- Vomiting (mainly in the elderly)
- Fever
- Changes in the amount of thyroid hormones in your blood
- Decreases in the number of certain types of blood cells
- Increases in the amount of liver enzymes measured in the blood
- Increases in the amount of the hormone prolactin in the blood. Increases in the hormone prolactin could in rare cases lead to the following:
 - Men and women to have swelling of breasts and unexpectedly produce breast milk.
 - Women to have no monthly period or irregular periods.

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

- Allergic reactions that may include raised lumps (weals), swelling of the skin and swelling around the mouth
- Unpleasant sensations in the legs (also called restless legs syndrome)
- Difficulty swallowing
- Sexual dysfunction
- Diabetes
- Change in electrical activity of the heart seen on ECG (QT prolongation)
- A slower than normal heart rate which may occur when starting treatment and which may be associated with low blood pressure and fainting
- Difficulty in passing urine

- Fainting (may lead to falls)
- Stuffy nose
- Decrease in the amount of red blood cells
- Decrease in the amount of sodium in the blood
- Worsening of pre-existing diabetes.

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

- Yellowing of the skin and eyes (jaundice)
- Inflammation of the liver (hepatitis)
- Swelling of breasts and unexpected production of breast milk (galactorrhoea)
- Menstrual disorder
- Walking, talking, eating or other activities while you are asleep
- Body temperature decreased (hypothermia)
- Inflammation of the pancreas
- A condition called “metabolic syndrome” where you may have a combination of three or more of the following: an increase in fat around your abdomen, a decrease in “good cholesterol” (HDL-C), an increase in a type of fat in your blood called triglycerides, high blood pressure and an increase in your blood sugar
- Bowel obstruction
- Increased blood creatine phosphokinase (a substance from the muscles).

Very rare side effects, may affect up to 1 in 10,000 people:

- Severe rash, blisters, or red patches on the skin
- Inappropriate secretion of a hormone that controls urine volume
- Breakdown of muscle fibers and pain in muscles (rhabdomyolysis).

Not known, frequency of these side effects cannot be estimated from the available data:

- Symptoms of withdrawal may occur in newborn babies of mothers who have used Quetiapine Rowex during their pregnancy
- Stroke.

Some side effects are only seen when a blood test is taken. These include changes in the amount of certain fats (triglycerides and total cholesterol) or sugar in the blood, changes in the amount of thyroid hormones in your blood, increased liver enzymes, decreases and increase in the number of certain types of blood cells, decrease in the amount of red blood cells, increased blood creatine phosphokinase (a substance in the muscles), decrease in the amount of sodium in the blood and increases in the amount of the hormone prolactin in the blood. Increases in the hormone prolactin could in rare cases lead to the following:

- Men and women to have swelling of breasts and unexpectedly produce breast milk.
- Women to have no monthly period or irregular periods.

Therefore, your doctor may ask you to have blood tests from time to time.

Side effects in children and adolescents:

The same side effects that may occur in adults may also occur in children and adolescents.

The following side effects have been seen more often in children and adolescents or have not been seen in adults:

Very common side effects, may affect more than 1 in 10 people:

- Increase in the amount of a hormone called prolactin in the blood. This could in rare cases lead to the following:
 - Boys and girls to have swelling of breasts and unexpectedly produce breast milk.
 - Girls to have no monthly period or irregular periods.
- Increased appetite
- Vomiting
- Abnormal muscle movements. These include difficulty starting muscle movements, shaking, feeling restless or muscle stiffness without pain.
- Increase in blood pressure.

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

- Feeling weak, fainting (may lead to falls)
- Stuffy nose
- Feeling irritated.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Quetiapine Rowex

- This medicinal product does not require any special storage conditions.
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the container and blister after EXP. The expiry date refers to the last day of that month.
- After first opening of the bottle: Use within 6 months.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Quetiapine Rowex contains

The active substance is quetiapine (as quetiapine fumarate).

Each Quetiapine Rowex prolonged release tablet contains either 200 mg, 300 mg or 400 mg of quetiapine (as quetiapine fumarate).

The other ingredients are lactose monohydrate, hypromellose, sodium chloride, povidone K-30, talc, magnesium stearate (E470b), hypromellose (E464), titanium dioxide (E171), macrogol 6000.

Quetiapine Rowex 200 mg and Quetiapine Rowex 300 mg also contain iron oxide yellow (E172).

What Quetiapine Rowex looks like and contents of the pack

Quetiapine Rowex 200 mg are yellow coloured, round shaped, biconvex film coated tablets, debossed with 'I2' on one side and plain on other.

Quetiapine Rowex 300 mg are light yellow coloured, round shaped, biconvex film coated tablets, debossed with 'Q300' on one side and plain on other.

Quetiapine Rowex 400 mg are white coloured, round shaped, biconvex, film coated tablets debossed with 'I4' on one side and plain on other.

Quetiapine Rowex 200mg, 300mg and 400mg are packed in PVC/PVDC-Alu blister pack and HDPE bottle pack.

Pack sizes blister pack: 6, 10, 20, 28, 30, 50, 60, 90, 100 and 120 tablets per pack.

Pack size bottle pack: 120 tablets (For hospital use and dose dispensing only).

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

LEK S.A. ul. Domaniewska 50 C, 02-672 Warszawa, Poland.

Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

S.C. Sandoz, S.R.L., Str. Livezeni nr. 7A, RO-540472 Targu-Mures, Romania.

Pharmacare Premium Ltd., HHF 003, Hal Far Industrial Estate, Birzebbugia, BBG3000, Malta.

Lek Pharmaceuticals d.d, Trimlini 2D, 9220 Lendava, Slovenia.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Quetheorie 200 mg – Retardtabletten Quetheorie 300 mg – Retardtabletten Quetheorie 400 mg – Retardtabletten
Belgium	Quetiastop 200 mg tabletten met verlengde afgifte Quetiastop 300 mg tabletten met verlengde afgifte Quetiastop 400 mg tabletten met verlengde afgifte
Bulgaria	Quetiapine Sandoz 200 mg Prolonged release tablet Quetiapine Sandoz 400 mg Prolonged release tablet
Germany	Quetiapin - 1A Pharma 200mg Retardtabletten Quetiapin - 1A Pharma 300mg Retardtabletten Quetiapin - 1A Pharma 400mg Retardtabletten
Denmark	Quetiapin Sandoz
Finland	Quetiapin Sandoz
Hungary	Vynterskarum 200 mg retard tabletta Vynterskarum 300 mg retard tabletta Vynterskarum 400 mg retard tabletta
Ireland	Quetiapine Rowex 200 mg Prolonged-Release Tablets Quetiapine Rowex 300 mg Prolonged-Release Tablets Quetiapine Rowex 400 mg Prolonged-Release Tablets
Iceland	Quetiapin Sandoz

Luxembourg	Quetiapin Retard Sandoz 200 mg comprimés à libération prolongée Quetiapin Retard Sandoz 300 mg comprimés à libération prolongée Quetiapin Retard Sandoz 400 mg comprimés à libération prolongée
Netherlands	Quetiapine Sandoz SR 200 mg, tabletten met verlengde afgifte Quetiapine Sandoz SR 300 mg, tabletten met verlengde afgifte Quetiapine Sandoz SR 400 mg, tabletten met verlengde afgifte
Norway	Quetiapin Sandoz
Poland	Quetiapine Sandoz
Portugal	Quetiapina Teclave
Romania	Quetiapină Sandoz 200 mg comprimate cu eliberare prelungită Quetiapină Sandoz 300 mg comprimate cu eliberare prelungită Quetiapină Sandoz 400 mg comprimate cu eliberare prelungită
Sweden	Quetiapin Sandoz
Slovenia	Kvetiapin Lek tablete s podaljšanim sproščanjem Kvetiapin Lek tablete s podaljšanim sproščanjem Kvetiapin Lek tablete s podaljšanim sproščanjem
The United Kingdom	Quesery XL 200 mg Prolonged Release Tablets Quesery XL 300 mg Prolonged Release Tablets Quesery XL 400 mg Prolonged Release Tablets

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