

Package Leaflet: Information for the User

Quetiapine Rosemont 20mg/ml Oral Suspension

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Quetiapine Oral Suspension is and what it is used for

The full name of your medicine is Quetiapine Rosemont 20mg/ml Oral Suspension. In this leaflet the shorter name quetiapine is used.

This medicinal product contains quetiapine fumarate. This belongs to a group of medicines called anti-psychotics.

Quetiapine can be used to treat several illnesses, such as:

- Bipolar depression: where you feel sad. You may find that you feel depressed, feel guilty, lack energy, lose your appetite or can't sleep
- Mania - where you may feel very excited, elated, agitated, enthusiastic or hyperactive or have poor judgment, including being aggressive or disruptive.
- 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.

Your doctor may continue to prescribe quetiapine even when you are feeling better.

2. What you need to know before you take Quetiapine Oral Suspension

Do not take quetiapine if:

- you are allergic to quetiapine fumarate or any of the other ingredients of this medicine (listed in Section 6).
- you are taking any of the following:
 - medicines for HIV infection, such as nelfinavir

- medicines for fungal infections, such as ketoconazole
- erythromycin or clarithromycin, for infections
- nefazodone, for depression.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking quetiapine.

Warnings and precautions

Talk to your doctor or pharmacist before taking quetiapine 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
- you have low blood pressure
- you have had a stroke, especially if you are elderly
- you have problems with your liver
- you have ever had a fit (seizure)
- 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
- 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)
- you are an elderly person with dementia (loss of brain function). If you are, quetiapine should not be taken because the group of medicines that quetiapine belongs to may increase the risk of stroke, or in some cases the risk of death, in elderly patients with dementia
- you are an elderly person with Parkinson's disease/parkinsonism
- you, or someone in your family has a history of blood clots as medicines like these have been associated with formation of blood clots
- 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")
- 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 "anticholinergics") that affect the way nerve cells function in order to treat certain medical conditions.
- you have a history of alcohol or drug abuse.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking quetiapine.

Tell your doctor immediately if you experience any of the following after taking quetiapine

- 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 and 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 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.

Taking high doses of Quetiapine Oral Suspension, if you are an adult with a low body weight (50kg), could mean that you take in too much propylene glycol. (See section 2 - Important information about some of the ingredients of Quetiapine Oral Suspension). Your doctor may lower your dose if this applies to you.

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.

Severe cutaneous adverse reactions (SCARS)

Severe cutaneous reactions (SCARS) which can be life threatening or fatal have been reported very rarely with treatment of 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), a more severe form causing extensive peeling of the skin
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) consists of flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes).

Stop using quetiapine if you develop these symptoms and contact your doctor or seek medical attention immediately.

Weight gain

Weight gain has been seen in patients taking quetiapine. You and your doctor should check your weight regularly during treatment.

Children and adolescents

Quetiapine should not be used by children and young people under 18 years.

Other medicines and Quetiapine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, and herbal medicines. This is because quetiapine can affect the way some other medicines work. Also, some other medicines can affect the way quetiapine works.

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

- medicines for HIV infection, such as nelfinavir
- medicines for fungal infections, such as ketoconazole
- erythromycin or clarithromycin, for infections
- nefazodone, for depression.

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

- carbamazepine or phenytoin, for epilepsy
- high blood pressure medicines
- barbiturates, for 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 tablets) or certain antibiotics (drugs to treat infections)
- medicines that can cause constipation
- medicines called “anticholinergics” that affect the way the nerve cells function in order to treat certain medical conditions.

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

Effects on Urine Drug Screens

If you have a urine drug screen during treatment with quetiapine, you may get a positive result for methadone or drugs for depression called tricyclic antidepressants (TCAs). This may happen even if you are not taking methadone or TCAs. The results will need to be confirmed by a more specific test.

Quetiapine with food, drink and alcohol

- Quetiapine can be taken with or without food
- Be careful how much alcohol you drink. This is because drinking alcohol while taking quetiapine can make you feel sleepy.
- Do not have grapefruit or drink grapefruit juice while you are taking quetiapine. It can affect the way the medicine works.

Pregnancy, breast-feeding and fertility

- If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby ask your doctor for advice before taking quetiapine. You should not take quetiapine during pregnancy unless this has been discussed with your doctor
- Quetiapine should not be taken if you are breast-feeding.

- The following symptoms which can represent withdrawal may occur in newborn babies of mothers that have used quetiapine 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.

Driving and using machines

Quetiapine may make you feel sleepy. Do not drive, or use any tools or machines, until you know how this medicine affects you.

Important information about some of the ingredients of Quetiapine Oral Suspension

Quetiapine Oral Suspension contains:

- Methyl and propyl parahydroxybenzoates. These may cause an allergic reaction. This allergy may happen some time after starting the medicine.
- Propylene glycol. This medicine contains 31.91mg propylene glycol in each ml.
- Sodium – This medicine contains 10.5mg sodium (main component of cooking/table salt) in each ml. This is equivalent to 0.53% of the recommended maximum daily dietary intake of sodium for an adult. Talk to your doctor or pharmacist if you need 37 or more ml daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

3. How to take Quetiapine Oral Suspension

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The recommended dose is shown under 'How much to take'.

Taking this medicine

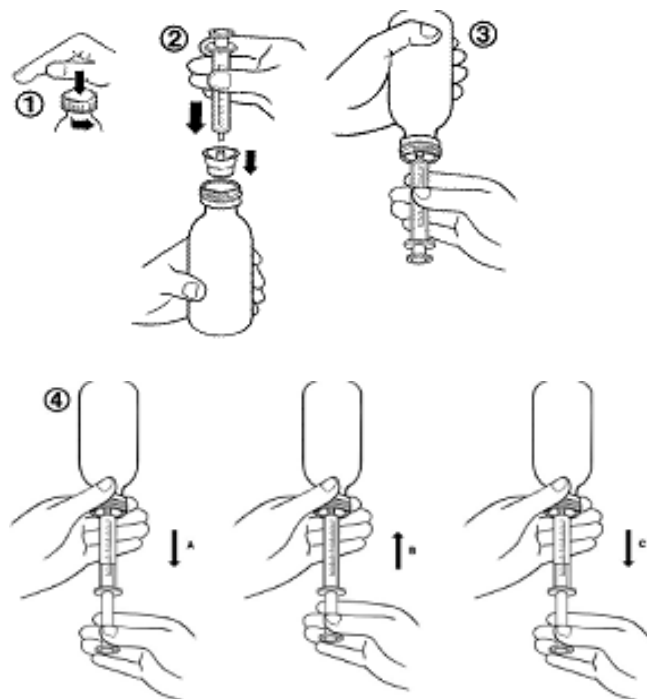
- This medicine contains 20mg of quetiapine in each 1ml of suspension.
- Take this medicine by mouth.
- Always shake the bottle before using it.
- Always use the syringe or cup supplied with the pack. Your doctor will indicate which you should use.
- Quetiapine can be taken with or without food.
- Do not drink grapefruit juice while taking quetiapine. It can affect the way the medicine works.
- Do not stop taking your medicine even if you feel better, unless your doctor tells you to.

Measuring your dose

Instructions for use of the syringe (for doses of 5ml or below)

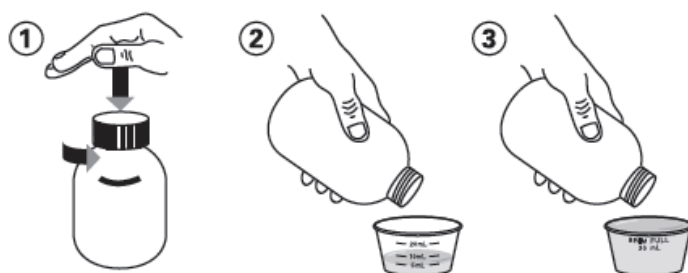
1. To open the bottle, press the cap down and turn it anti-clockwise (figure 1).
2. Put the syringe adaptor into the bottle neck (figure 2).
3. Take the syringe and put it into the adaptor opening (figure 2).
4. Turn the bottle upside down (figure 3).
5. Fill the syringe with a small amount of solution by pulling the plunger down (figure 4A). Then push the plunger upward in order to remove any possible bubbles (figure 4B). Finally, pull the plunger down to the right mark for your dose as prescribed by your doctor. This is given in ml (figure 4C).

6. Turn the bottle the right way up.
7. Remove the syringe from the adaptor. Put the end of the syringe into your mouth and push the plunger slowly back in to take the medicine.
8. Wash the syringe with water and let it dry before you use it again.
9. Close the bottle with the plastic screw cap.



Instructions for use of the cup (for doses above 5ml)

1. To open the bottle, press the cap down and turn it anti-clockwise (figure 1).
2. For 5ml to 25ml doses, pour the medicine into the dosing cup to the required dosing mark (figure 2).
3. For a 30ml dose (brim full), pour the medicine in the dosing cup until the medicine is exactly level with the lip of the cup (figure 3).
4. Wash the dosing cup with water and let it dry before you use it again.
5. Close the bottle with the plastic screw cap.



How much to take

- Your doctor will decide on your starting dose and may gradually increase it.
- A regular dose is usually between 150mg and 800mg each day. This will depend on your illness and needs.
- Depending on your illness, you will either take the medicine:
 - once a day - at bedtime

- twice a day - your doctor will tell you when to take your doses.

The tables below will help you measuring the exact dose prescribed by your doctor:

Using the Dosing Cup

Measured Amount (ml)	Amount of quetiapine (mg)
5ml	100mg
7.5ml	150mg
10ml	200mg
15ml	300mg
20ml	400mg
25ml	500mg
30ml	600mg

Using the Dosing Syringe

Note: Each 0.25ml mark = 5mg; Each 0.5ml = 10mg

Measured Amount (ml)	Amount of quetiapine (mg)
1ml	20mg
1.25ml	25mg
2ml	40mg
2.5ml	50mg
3ml	60mg
3.75ml	75mg
4ml	80mg
5ml	100mg

Liver problems

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

Elderly people

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

Use in children and adolescents

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

If you take more Quetiapine than you should

- If you take too much quetiapine you may feel sleepy, feel dizzy and experience abnormal heart beats.
- If you take more of this medicine than you should, talk to your doctor or go to the nearest hospital straight away. Take the medicine pack with you.

If you forget to take Quetiapine

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

If you stop taking Quetiapine

- If you stop taking quetiapine suddenly, you may notice the following side effects: difficulty sleeping (insomnia), feeling sick (nausea), headache, diarrhoea, being sick (vomiting), feeling dizzy or irritable.
- Your doctor may suggest you reduce the dose gradually before stopping the 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, quetiapine can cause side effects, although not everybody gets them.

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) (may lead to falls)
- discontinuation symptoms (symptoms which occur when you stop taking quetiapine) 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 hormone prolactin in the blood, which could in rare cases lead to:
 - men and women to have swelling breasts and unexpectedly produce breast milk
 - women to have no monthly periods or irregular periods.

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

- fits or seizures
- allergic reaction - the signs 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
- uncontrollable movements, mainly of your face and tongue
- sexual dysfunction
- diabetes
- changes in the electrical activity of your 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):

- a combination of high temperature (fever), sweating, stiff muscles, feeling very drowsy or faint (a disorder called “neuroleptic malignant syndrome”)
- yellowing of the skin and whites of eyes (jaundice)
- inflammation of the liver (hepatitis)
- menstrual disorder
- a long-standing and painful erection (priapism)
- swelling of breasts and unexpected production of breast milk (galactorrhoea)
- 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 breathing. If you notice any of these symptoms seek medical advice immediately
- 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 have a combination of 3 or more of the following: an increase in a type of 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)
- combination of fever, flu-like symptoms, sore throat and any other infection with very low white blood cell count, a condition called agranulocytosis
- 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
- 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). See section 2.
- inappropriate secretion of a hormone that controls urine volume
- abnormal muscle breakdown and pain in muscles (rhabdomyolysis).

Not known (cannot be estimated from available data):

- skin rash with irregular red spots (erythema multiforme)
- serious, sudden allergic reaction with symptoms such as fever and blisters on the skin and peeling of the skin (toxic epidermal necrolysis). See section 2.
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) which consists of flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes). See section 2.
- symptoms of withdrawal may occur in newborn babies of mothers that have used quetiapine during their pregnancy.
- stroke

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

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 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 the breasts and unexpectedly produce breast milk
- Women to have no monthly or irregular periods.

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

Additional 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 the hormone “prolactin” in the blood. In a small number of cases this could lead to the following:
 - boys and girls to have swelling of the 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland

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Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

5. How to store Quetiapine Oral Suspension

- Keep this medicine out of the sight and reach of children.
- Store in a refrigerator (2 – 8°C).
- Store in the original package (bottle) in order to protect from light.
- Do not use this medicine after the expiry date (month, year) which is stated on the label. The expiry date refers to the last day of that month.
- Do not use 28 days after you first open it. Take it back to the pharmacy.
- Do not use quetiapine if you notice anything wrong with the medicine. Talk to your pharmacist.
- 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 Oral Suspension contains**

- The active substance is quetiapine fumarate. Each 1ml of the suspension contains 20mg quetiapine (as quetiapine fumarate).
- The other ingredients are citric acid monohydrate (E330), disodium phosphate dihydrate, sucralose (E955), simethicone emulsion (including stearate emulsifiers, sorbic acid, benzoic acid, thickeners and water), propylene glycol (E1520), methyl and propyl parahydroxybenzoates (E218 and E216), xanthan gum (E415), lemon flavour (containing propylene glycol) and purified water.

What Quetiapine Oral Suspension looks like and contents of the pack

Quetiapine Oral Suspension is an off-white suspension

Pack: It comes in a brown glass bottle holding 150ml of suspension or 4 x 150ml

Dosing Devices: 5ml purple syringe with 0.25ml markings and bottle adaptor and a 30ml dosing cup.

Marketing Authorisation Holder:

Perrigo Pharma International DAC

The Sharp Building, Hogan Place, Dublin 2,
Ireland.

Manufacturer:

Jenson R+ (Ireland) Ltd, 2 Dublin Landing, N Wall Quay, North Dock, Dublin 1, D01 V4A3, Ireland.

Rosemont Pharmaceuticals Ltd, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.

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

UK/Ireland	Quetiapine Rosemont 20mg/ml Oral Suspension
Spain	Quetiapina Rosemont 20mg/ml Suspensión Oral
Greece	Orocuelia 20 mg/ml πόσιμο εναιώρημα

This leaflet was last revised in 11/2020.