

QUETIAPINE RBX Tablets

Quetiapine fumarate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about **QUETIAPINE RBX** quetiapine tablets.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking **QUETIAPINE RBX** against the benefits it is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What QUETIAPINE RBX is used for

The name of your medicine is **QUETIAPINE RBX**.

QUETIAPINE RBX contains the active ingredient quetiapine.

Quetiapine belongs to a group of medicines called antipsychotics. It interacts with a large number of molecules in the brain, helping to correct chemical imbalances which may cause mental illness.

QUETIAPINE RBX is used to treat mental illnesses such as:

- Schizophrenia, an illness causing hallucinations (like hearing unexplained voices), strange and frightening thoughts, changes in how you act, and feelings of being lonely and confused.
- Bipolar disorder, an illness resulting in sustained mood swings, either feeling very high (mania) or low (depressions). During mania, patients experience episodes of overactivity, elation or irritability. During depression, patients may feel depressed, guilty, lack of energy, appetite loss, and have trouble sleeping.
- **if you have an allergy to quetiapine or any of the inactive ingredients listed at the end of this leaflet.** Symptoms of an allergic reaction may include skin rash, itchiness or hives, shortness of breath, wheezing or difficulty breathing, swelling of the tongue, lips, face or other parts of the body.
- **after the expiry date printed on the pack.** If you take it after the expiry date has passed, it may not work as well.
- **if the packaging is torn or shows signs of tampering.**

Your doctor may have prescribed **QUETIAPINE RBX** for another reason.

Ask your doctor if you have any questions about why **QUETIAPINE RBX** has been prescribed for you.

QUETIAPINE RBX is not addictive.

QUETIAPINE RBX is available only with a doctor's prescription.

Before you take QUETIAPINE RBX

When you must not take it

Do not take QUETIAPINE RBX

If you are not sure whether you should start taking **QUETIAPINE RBX**, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, any other substances such as foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- heart or blood vessel problems or a family history of heart or blood vessel problems. These include low blood pressure, stroke, problems with your circulation, any condition that affects blood flow to the brain, fast or irregular heart beat or a history of heart attack.
- epilepsy (seizures or fits)
- tremor, rigidity, gait and posture disturbance (Parkinson's Disease)
- liver problems

- if you have had low levels of white blood cell count in the past (which may or may not have been caused by other medicines)
- diabetes or if you have a risk of getting diabetes or a family history of diabetes (your doctor may check your blood sugar levels before and during treatment with **QUETIAPINE RBX**)
- declined mental abilities and memory loss (dementia or related behaviour disorders), especially in elderly patients

Tell your doctor if you are pregnant or intend to become pregnant.

QUETIAPINE RBX should be used in pregnancy only if the potential benefits justifies the potential risk to the foetus. However, if you need to be given **QUETIAPINE RBX** during your pregnancy, your doctor will discuss with you the benefits and risk of taking it.

Tell your doctor if you are breast-feeding or plan to breast-feed.

Lactating women need to avoid breast-feeding while taking **QUETIAPINE RBX**, as it is not known if quetiapine passes into breast milk.

QUETIAPINE RBX is not recommended for use in children/adolescents under the age of 18 years. There is not enough information on its effects in children and adolescents.

Tell your doctor if you are lactose-intolerant.

QUETIAPINE RBX contains lactose. If you have been told by your doctor that you have intolerance to some sugars, speak to your doctor before taking this medicine.

Tell your doctor or mental health professional if you have any mental/mood changes or suicidal thoughts. Depression and other mental illnesses can lead to suicide.

It is important to discuss all the risks of treating depression and mental illness as well as the risks of not treating it. You should discuss all treatment choices with your doctor, not just the use of antidepressants.

You may find it helpful to tell a relative or close friend that you are depressed, and ask them to read this leaflet. You and your caregivers need to monitor for any worsening of depression and/or emergence of thoughts of suicide, suicidal behaviour or thoughts of self-harm, and to seek medical advice immediately if these symptoms are present.

If you have not told your doctor or pharmacist about any of the above tell them before you start taking QUETIAPINE RBX.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines you can buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and **QUETIAPINE RBX** may interfere with each other. These include:

- medicines used to treat anxiety, depression, mood swings, attention deficit hyperactivity disorder (ADHD) or other mood disorders
- lorazepam, a medicine that helps you sleep
- carbamazepine and phenytoin, medicines to treat epilepsy
- thioridazine, a medicine used to treat mental illness
- levodopa, and dopamine agonists which are medicines used for Parkinson's disease
- medicines used for fungal infections e.g. ketoconazole
- certain antibiotics e.g. erythromycin, rifampicin

- medicines used for HIV infections
- medicines used to treat high blood pressure (including diuretics or fluid tablets) or heart disease
- medicines used to treat inflammation e.g. glucocorticoids
- stimulants e.g. amphetamines

These medicines may be affected by **QUETIAPINE RBX**, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking **QUETIAPINE RBX**.

Tell your doctor about these other medicines before you take QUETIAPINE RBX.

How to take QUETIAPINE RBX

Follow all directions given to you by your doctor or pharmacist carefully.

These may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to take

Your doctor or pharmacist will tell you how much **QUETIAPINE RBX** you will need to take each day and how long to take it. This depends on your condition and whether or not you are taking any other medicines.

Starting dose is usually low and will be gradually increased by your doctor. Your doctor will recommend a dose especially for you. This will depend on various factors including your age, condition being treated, other medical conditions (e.g. liver problems), other medicines you are taking and how you may react to **QUETIAPINE RBX**. Your doctor will monitor your condition and may change your dose depending on how you respond to it. Your doctor will use the lowest dose for the least amount of time to keep you well.

How long to take it

Continue taking QUETIAPINE RBX for as long as your doctor tells you.

QUETIAPINE RBX helps control your condition, but does not cure it. Therefore you must take **QUETIAPINE RBX** every day. Do not stop taking it unless your doctor tells you to, even if you feel better.

How to take it

Swallow **QUETIAPINE RBX** tablets whole with a full glass of water.

When to take it

QUETIAPINE RBX is taken once or twice daily.

Take your prescribed dose at the same time each day.

QUETIAPINE RBX can be taken with or without food.

If you forget to take it

- If it is almost time for your next dose (within 6 hours), skip the dose you missed and take your next dose when you are meant to.
- Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.

- Do not take a double dose to make up for the dose you missed. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble in remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Tel. 131126) for advice, or go to Accident & Emergency at your nearest hospital if you think that you or anyone else may have taken too much **QUETIAPINE RBX**. Keep these numbers handy in case of an emergency. Take this leaflet or some tablets with you so your doctor will know what you have taken. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take more **QUETIAPINE RBX** than you should, you may feel drowsy, sleepy or dizzy, or have a fast or slow heart beat.

While you are taking QUETIAPINE RBX

Things you must do

It is important that you remember to take **QUETIAPINE RBX** daily and at the dose prescribed by your doctor.

Tell all doctors, dentists and pharmacists who are treating you that you are taking **QUETIAPINE RBX**.

While you are taking **QUETIAPINE RBX** tell your doctor or pharmacist before you start any new medicine.

If you become pregnant while taking **QUETIAPINE RBX**, tell your doctor immediately.

If you need to have any medical tests while you are taking **QUETIAPINE RBX**, tell your doctor.

QUETIAPINE RBX may affect the results of some tests.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking **QUETIAPINE RBX**.

Be sure to keep all of your doctor's appointments so that your progress can be checked. Your doctor will check your progress and may conduct some blood tests from time to time. These tests may help to prevent unwanted side effects.

If you or someone you know is showing any of the following warning symptoms of suicide while taking QUETIAPINE RBX, contact your doctor or a mental health professional immediately or go to the nearest hospital for treatment:

- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts of self-harm
- increase in aggressive behaviour, irritability or agitation
- worsening of depression

Occasionally the symptoms of depression may include thoughts of suicide or self-harm. These symptoms may continue or get worse during the early stages of treatment until the effect of the medicine becomes apparent.

All mentions of suicide or violence must be taken seriously.

Things you must not do

Do not give QUETIAPINE RBX to anyone else, even if their symptoms seem similar or they have the same condition as you.

Do not take QUETIAPINE RBX to treat any other complaints unless your doctor tells you to.

Do not stop taking QUETIAPINE RBX or lower the dosage, even if you are feeling better, without checking with your doctor.

If you stop taking QUETIAPINE RBX suddenly, your condition may worsen or your chance of getting an unwanted side effect may increase.

To prevent this, your doctor may gradually reduce the amount of QUETIAPINE RBX you take each day before stopping completely.

Do not take any medicines that cause drowsiness while you are taking QUETIAPINE RBX, unless recommended by your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how QUETIAPINE RBX affects you.

QUETIAPINE RBX may cause drowsiness or dizziness in some people. Make sure you know how you react to QUETIAPINE RBX before you do anything that could be dangerous if you are not alert.

Be careful when drinking alcohol while taking QUETIAPINE RBX.

Combining QUETIAPINE RBX and alcohol can make you more sleepy or dizzy. Your doctor may suggest you to avoid alcohol while you are being treated with QUETIAPINE RBX.

If QUETIAPINE RBX makes you feel light-headed, dizzy or faint, be careful when getting up from a sitting or lying position.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Avoid getting over-heated or dehydrated. Do not over-exercise, in hot weather stay inside in a cool place, stay out of the sun, do not wear too much or heavy clothing, drink plenty of water. Keep warm in cool weather.

QUETIAPINE RBX may affect the way your body reacts to temperature changes.

Avoid drinking large quantities of grapefruit juice.

This medicine may be affected by grapefruit juice.

Please talk to your doctor or pharmacist about these things if you have any concerns.

Side Effects

Like other medicines, QUETIAPINE RBX may cause some unwanted side effects.

Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. Some side effects may be related to the dose of QUETIAPINE RBX or may be more likely to occur during long-term treatment.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking QUETIAPINE RBX

Your doctor may then decide to adjust the dose of QUETIAPINE RBX you are taking or change to a different medicine.

Tell your doctor or pharmacist if you notice any of the following side effects and they worry you:

- feeling sleepy
- weight gain, increased appetite
- feeling weak
- dry mouth
- runny or stuffy nose
- indigestion, upset stomach, constipation, vomiting (mainly in elderly)
- swelling of your hands, feet or ankles
- blurred vision
- abnormal dreams, nightmares
- irritability
- shortness of breath, difficulty in breathing and/or tightness in the chest
- fast or irregular heart beats (palpitations)

These side effects are usually mild. Some of these side effects may go away after awhile.

Tell your doctor as soon as possible if you notice the following:

- falling, feeling dizzy or faint on standing up
- difficulty in speaking
- difficulty swallowing
- rapid heart beat
- symptoms of high sugar levels in the blood (including passing large amounts of urine, excessive thirst, increase in appetite with a loss of weight, feeling tired, drowsy, weak, depressed, irritable and generally unwell)
- breast enlargement, unusual secretion of breast milk

These are serious side effects. You may need medical attention.

Tell your doctor or pharmacist immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- long lasting and painful erection
- fainting
- signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal
- very marked drowsiness
- reduced consciousness
- abnormal muscle movements, including difficulty starting muscle movements, shaking, restlessness or muscle stiffness without pain
- worm-like movements of the tongue or other uncontrolled movements of the tongue, mouth, cheeks or jaw which may progress to the arms and legs
- a sudden increase in body temperature, with sweating, or a fast heart beat
- fits (seizures)

- severe allergic reaction (may include severe difficulty breathing, shock, swelling of the face, lips, tongue or other parts of the body, skin rash, hay fever, or you may feel faint)

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Also, some side effects, such as changes in liver function or blood, e.g. increase in amount of certain fats (cholesterol or triglycerides), decrease in the number of certain types of blood cells, and increase in blood sugar levels may occur. Changes in blood pressure and thyroid hormone levels can also occur. These can only be found when your doctor conducts some tests from time to time to check your progress.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

After using it

Storage

Keep QUETIAPINE RBX in the original pack until it is time to take them.

If you take the tablets out of the blister pack they will not keep well.

Keep QUETIAPINE RBX in a cool, dry place where the temperature is below 25°C.

Do not store **QUETIAPINE RBX** or any medicine in the bathroom or near a sink. Do not leave medicines in the car or on window sills. Heat and dampness can destroy some medicines.

Keep QUETIAPINE RBX tablets where children cannot reach it.

A locked cupboard at least one and a half metres (1.5 m) above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking QUETIAPINE RBX, or your medicine has passed its expiry date, ask your pharmacist what to do with any tablets which may be left over.

Product description

What QUETIAPINE RBX looks like

- **QUETIAPINE RBX 25 mg** tablets are peach-coloured, film-coated, round tablets debossed with 'Q1' on one side and plain on the other side. Available in packs of 60 tablets.
- **QUETIAPINE RBX 100 mg** tablets are white, film-coated, round tablets debossed with 'Q3' on one side and plain on other side. Available in packs of 90 tablets.
- **QUETIAPINE RBX 200 mg** tablets are white, film-coated, round tablets debossed with 'Q5' on one side and plain on the other side. Available in packs of 60 tablets.
- **QUETIAPINE RBX 300 mg** tablets are white, film-coated, capsule-shaped tablets debossed with 'Q6' on one side and plain on the other side. Available in packs of 60 tablets.

Ingredients

Active ingredient:

- **QUETIAPINE RBX 25 mg** tablets - 25 mg quetiapine as quetiapine fumarate
- **QUETIAPINE RBX 100 mg** tablets - 100 mg quetiapine as quetiapine fumarate

- **QUETIAPINE RBX 200 mg** tablets - 200 mg quetiapine as quetiapine fumarate
- **QUETIAPINE RBX 300 mg** tablets - 300 mg quetiapine as quetiapine fumarate

Inactive ingredients:

Calcium hydrogen phosphate, lactose, microcrystalline cellulose, povidone, sodium starch glycolate type A, magnesium stearate, hypromellose, titanium dioxide and macrogol 400. In addition the 25 mg tablet contains iron oxide yellow, and the 100, 200 and 300 mg tablets contain purified talc.

Sponsor

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Australia

Australian Registration Numbers

- **QUETIAPINE RBX 25 mg** tablets: AUST R 166434
- **QUETIAPINE RBX 100 mg** tablets: AUST R 166429
- **QUETIAPINE RBX 200 mg** tablets: AUST R 166435
- **QUETIAPINE RBX 300 mg** tablets: AUST R 166420

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