

Quetiapine APOTEX

Quetiapine fumarate

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about this medicine. 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 this medicine against the benefits they expect it will 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 this medicine is used for

Quetiapine is used to treat conditions such as:

- schizophrenia, an illness with disturbances in thinking, feelings and behaviour
- bipolar disorder, an illness in which there are sustained mood swings either up (mania) or down (depression) – during mania, patients experience episodes of overactivity, elation or irritability whilst during depression, patients may feel depressed or guilty, lack energy, lose their appetite and have trouble sleeping

Quetiapine belongs to a group of medicines called antipsychotics. It helps to correct chemical imbalances in the brain.

Ask your doctor if you have any questions about why it has been prescribed for you.

Your doctor may have prescribed this medicine for another reason.

You may find it helpful to tell a friend or relative that you are suffering from these symptoms and ask them to read this leaflet. You might ask them to tell you if they think your symptoms are getting worse, or if they are worried about any other changes in your behaviour.

This medicine is not addictive.

This medicine is available only with a doctor's prescription

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- any medicine containing quetiapine
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not give this medicine to children or adolescents unless recommended by your doctor.

The effects of quetiapine have only been studied in children aged between 10 and 17 years with mania, and in children aged between 13 and 17 years with schizophrenia. There is not enough information on its effects in children to recommend its use in other age groups or for other conditions.

Do not give this medicine to elderly patients unless recommended by your doctor.

Quetiapine, as with other anti- psychotic medicines, is recommended for use with caution in the elderly and is not

approved for treatment of dementia and behavioural disturbances. Clinical studies with this group of medicines for the treatment of dementia and behavioural disturbances in the elderly have suggested an increased risk of cardiovascular adverse events (including stroke) and an increased mortality risk for elderly patients.

Do not take this medicine if you are pregnant.

It is not known if it is safe for you to take quetiapine while you are pregnant as it may affect your developing baby. However, if you need to take it during your pregnancy, your doctor will discuss the risks and benefits of taking it with you.

Do not breastfeed if you are taking this medicine.

It is recommended that you do not breastfeed while taking it, as quetiapine may pass into breast milk and there is a possibility that your baby may be affected.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

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

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

- heart or blood vessel problems or a family history of heart or blood vessel problems including low blood pressure, stroke, problems with the way your heart beats, a history of heart attack, problems with your circulation or any condition that affects blood flow to the brain
- liver problems
- diabetes or a family history of diabetes – patients with diabetes, or who have a higher chance of diabetes should have their blood sugar checked before and during treatment with quetiapine
- epilepsy (seizures or fits)
- dementia or related behavioural disorders (especially in elderly patients)
- low white blood cell count
- sleep apnoea – a condition where you stop breathing for short periods during your normal nightly sleep
- urinary retention – a condition where you can't completely empty your bladder

- an enlarged prostate
- a blockage in your intestines
- increased pressure inside your eyes or glaucoma
- history of alcohol or drug abuse

Tell your doctor or mental health professional if you have any mental/mood changes or suicidal thoughts.

Depression and other mental illnesses can increase the risk of 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.

Patients (and caregivers of patients) need to monitor for any signs of worsening condition and/or the emergence of thoughts of suicide, suicidal behaviour or thoughts of self-harm and to seek medical advice immediately if these symptoms present.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are lactose intolerant.

This medicine contains lactose.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Before starting on quetiapine your doctor may want to take some tests (such as blood tests, blood pressure, weight or height measurements). These tests may help to prevent side effects.

Taking other medicines

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

Some medicines and quetiapine 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, used to help you sleep
- phenytoin or carbamazepine, used for epilepsy
- medicines for high blood pressure (including diuretics/ fluid tablets) or heart conditions
- some antibiotics such as rifampicin and erythromycin
- medicines used for fungal infections such as ketoconazole

- medicines for Human Immunodeficiency Virus (HIV)
- thioridazine, an antipsychotic medicine
- medicines used to treat Parkinson's disease
- stimulants such as amphetamines
- glucocorticoids, used to treat inflammation.
- medicines that have anticholinergic (muscarinic) effects

These medicines may be affected by quetiapine or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take this medicine

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

They may differ from the information contained in this leaflet.

If you do not understand the directions, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how many tablets you will need to take each day and how long you need to take it.

This depends on your condition and whether you are taking any other medicines.

Quetiapine is usually started as a low dose that 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. 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.

Quetiapine is taken once or twice a day depending on your condition.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If it is almost time to take 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 your medicine as you would normally.

Do not take a double dose to make up for the dose that 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 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 (telephone 13 11 26) for advice or go

to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too many quetiapine tablets you may feel drowsy, sleepy, dizzy or have fast heart beats.

While you are taking this medicine

Things you must do

Tell your doctor or mental health professional immediately, or go to the nearest hospital, if you have any of the following suicidal thoughts or other mental/mood changes:

- 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.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant or start to breastfeed while taking this medicine, tell your doctor immediately.

If you are about to have any urine or blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time (e.g. blood tests, blood pressure, weight or height measurements) to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take this medicine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking quetiapine 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 you take each day before stopping completely.

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

Things to be careful of

Be careful driving or operating machinery until you know how this medicine affects you.

This medicine may cause dizziness, or drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous. Children should be careful when riding bicycles or climbing trees.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, the symptoms of dizziness and drowsiness may be worse. Your doctor may suggest you avoid alcohol while you are being treated with quetiapine.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

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 and drink plenty of water. Keep warm in cool weather.

Quetiapine may affect the way your body reacts to temperature changes.

Avoid drinking large quantities of grapefruit juice.

Quetiapine may be affected by grapefruit juice. Talk to your doctor or pharmacist if you have any concerns.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

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

- feeling sleepy
- weight gain or increased appetite
- feeling weak
- dry mouth
- runny or stuffy nose (particularly in children)
- indigestion, upset stomach, constipation or vomiting (mainly in elderly or children)
- swelling of your hands, feet or ankles
- blurred vision
- abnormal dreams or nightmares
- irritability

- shortness of breath, difficulty in breathing and/or tightness in the chest
- fast or irregular heartbeats (palpitations)

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of 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 or unusual secretion of breast milk

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- long lasting and painful erection

- fainting (particularly in children)
- 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)
- widespread skin rash that may include blistering, fever, swelling of the face and/or swollen lymph nodes (painful, warm, or red lump under your skin – often under your chin, on your neck, groin, armpit or behind your ear) – these symptoms may also be associated with changes in your blood (e.g. white blood cell increase) or liver function (symptoms of a condition called "drug reaction with eosinophilia and systemic symptoms")
- severe upper stomach pain, often with nausea and vomiting (particularly in patients with other risk factors)

such as gallstones, alcohol consumption and/or increased levels of certain fats within the blood) – these are symptoms of pancreatitis

- combination of fever, very marked drowsiness, muscle stiffness, marked increase in blood pressure or heartbeats and reduced consciousness (a disorder called "neuroleptic malignant syndrome")
- symptoms of an allergic reaction including cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some of these side effects such as changes in your liver function or blood (e.g. blood fat levels (cholesterol or triglycerides), blood sugar levels, blood pressure, thyroid hormone levels, or white blood cells) can only be found when your doctor does tests from time to time to check your progress.

Storage and Disposal

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack, they may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store this medicine or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

QUETIAPINE APOTEX film-coated tablets

25 mg

Pink, round, plain on both sides. AUST R 204157.

Available in blister packs of 60.

100 mg

Yellow, round, plain on both sides. AUST R 204158.

Available in blister packs of 90.

200 mg

White to off-white, round, plain on both sides. AUST R 204159.

Available in blister packs of 60.

300 mg

White to off-white, capsule-shaped with '300' debossed on one side and plain on the other. AUST R 204160.

Available in blister packs of 60.

Quetiapine-APOTEX tablets are presented in PVC/aluminium blister packs.

Ingredients

This medicine contains quetiapine fumarate as the active ingredient.

This medicine also contains the following:

- lactose monohydrate
- sodium starch glycollate
- calcium hydrogen phosphate
- povidone
- microcrystalline cellulose
- magnesium stearate
- Opadry complete film coating system 03B84929 pink (25 mg only)
- Opadry complete film coating system 03B52117 yellow (100 mg only)
- hypromellose (200 and 300 mg only)
- macrogol 400 (200 and 300 mg only)
- titanium dioxide (200 and 300 mg only)

This medicine does not contain sucrose or gluten.

Distributor

Apotex Pty Ltd

16 Giffnock Avenue

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Australia

Tel: (02) 8877 8333

Web: www1.apotex.com/au

This leaflet was updated in October 2019.