

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about Quetiapine Sandoz.

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 will have weighed the risks of you taking Quetiapine Sandoz 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 Quetiapine Sandoz is used for

This medicine is used to treat mental illnesses 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 over activity, elation or irritability. During depression, patients may feel depressed or guilty, lack energy, lose their appetite and have trouble sleeping.

How Quetiapine Sandoz works

It contains the active ingredient quetiapine fumarate and belongs to a group of medicines called antipsychotics. It works by correcting chemical imbalances in the brain, which may cause mental illness.

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

Your doctor may prescribe 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.

It is not addictive.

This medicine is available only with a doctor's prescription.

Before you take Quetiapine Sandoz

When you must not take it

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

- quetiapine, the active ingredient or to any of the ingredients listed at the end of this leaflet under product description
- any other similar medicines.

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
- feeling faint.

Do not take this medicine if you are pregnant or breastfeeding unless your doctor says so. Ask your doctor about the risks and benefits involved.

It is not known if it is safe for you to take this medicine while you are pregnant. If it is necessary for you to take this medicine, your doctor will discuss the risks and benefits of taking it with you.

It is recommended that you do not breastfeed while taking this medicine, as this medicine passes into breast milk.

Do not give Quetiapine Sandoz to children or adolescents unless recommended by your doctor.

The effects of Quetiapine Sandoz 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.

Quetiapine Sandoz, 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. In clinical studies with this group of medicines for the treatment of dementia and behavioural disturbances in the elderly, have suggested an increase risk of cardiovascular adverse events including stroke, and increased mortality risk for elderly patients has been reported.

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 high or slow blood pressure, stroke, problems with your circulation, or any condition that affects blood flow to the brain, or a history of heart attack or the way your heart beats
- 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 Sandoz
- epilepsy, seizures or fits
- dementia or related behavioural disorders (especially in elderly patients)
- low white blood cell count
- urinary retention (a condition where you can't completely empty your bladder)
- enlarged prostate
- a blockage in your intestines

- increased pressure inside your eyes or glaucoma
- sleep apnoea - a condition where you stop breathing for short periods during normal nightly sleep
- 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 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. Patients (and caregivers of patients) need to monitor for any worsening of their condition and/or the emergence of thoughts of suicide or suicidal behaviour or thoughts of harming themselves and to seek medical advice immediately if these symptoms present.

Before your doctor starts you on Quetiapine Sandoz your doctor may want to take some tests (e.g. blood tests, blood pressure, weight or height measurements). These tests may help to prevent side effects.

Tell your doctor if you are lactose intolerant.

Taking other medicines

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

Some medicines and Quetiapine Sandoz may interfere with each other. These include:

- medicines used to treat anxiety, depression, mood swings, attention deficit hyperactivity disorder (ADHD) or other mood disorders
- medicines used to help you sleep (lorazepam)
- medicines for epilepsy such as phenytoin or carbamazepine
- medicines for high blood pressure (diuretics or 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)
- other antipsychotic medicines such as thioridazine
- medicines used to treat Parkinson's disease
- stimulants such as amphetamines
- medicines used to treat inflammation (glucocorticoids)
- medicines that have anticholinergic (muscarinic effects).

These medicines may be affected by Quetiapine Sandoz, 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 and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

If you have not told your doctor about any of the above, tell him/her before you start taking Quetiapine Sandoz.

How to take Quetiapine Sandoz

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 instructions, ask your doctor or pharmacist for help.

How much to take

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

Quetiapine Sandoz 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 (eg liver problems), other medicines you are taking and how you may react to Quetiapine Sandoz. 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.

When to take Quetiapine Sandoz

Take your medicine once or twice a day depending on your condition.

Your doctor will tell you how you should take it.

Swallow your tablets whole with a full glass of water.

You can take your medicine with or without food.

How long to take Quetiapine Sandoz

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

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

Do not stop taking it unless your doctor tells you to - even if you feel better.

If you forget to take it

Take your dose as soon as you remember, and continue to take it as you would normally.

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.

Do not take a double dose to make up for the dose you have missed.

This may increase the chance of an unwanted side effect.

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

If you have trouble remembering when 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 Quetiapine Sandoz. Do

this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include feeling drowsy, sleepy, dizzy or a fast heartbeat.

While you are taking Quetiapine Sandoz

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Quetiapine Sandoz.

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 need to have any medical tests (including urine drug screening) while you are taking this medication, tell your doctor.

It may affect the results of some tests.

If you become pregnant while taking Quetiapine Sandoz, tell your doctor immediately.

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

Your doctor will check your progress and may want to do some blood tests from time to time. This helps to prevent unwanted side effects.

If you or someone you know is demonstrating any of the following warning signs of suicide while taking Quetiapine Sandoz, 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 take Quetiapine Sandoz to treat any other complaints unless your doctor tells you to.

Do not give Quetiapine Sandoz 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 Quetiapine Sandoz 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 Sandoz you take each day before stopping completely.

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

Things to be careful of

Be careful driving or operating machinery until you know how Quetiapine Sandoz affects you.

It can make some people dizzy or sleepy. Make sure you know how you react to it before you do anything that could be dangerous if you are dizzy or sleepy. Children should be careful when riding bicycles or climbing trees.

If it 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.

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

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

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 Sandoz 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. Talk to your doctor or pharmacist if you have any concerns.

Talk to your doctor or pharmacist about these things if you think they may bother you.

Side effects

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

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. Some side effects may be related to the dose of Quetiapine Sandoz or may be more likely to occur during long term treatment. Therefore, it is important that you tell your doctor as soon as possible if you notice anything that is making you feel unwell, even if you think the problems are not connected with this medicine. Your doctor may then decide to adjust your dose or use a different medicine.

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, increased appetite
- feeling weak
- dry mouth
- runny or stuffy nose (particularly in children)
- indigestion, upset stomach
- constipation, vomiting (mainly in elderly or children)
- swelling of your hands, feet or ankles

- blurred vision
- abnormal dreams, nightmares
- irritability
- confusion
- shortness of breath, difficulty in breathing and/or tightness in the chest
- fast or irregular heartbeats (palpitations).
- muscle pain or swelling or weakness

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

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

- falling, feeling dizzy or faint on standing up
- flat and red skin lesions or substantial hemorrhages under the skin (purpura)
- 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.

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 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 or peeling of the skin, often accompanied by flu like symptoms, 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, as sometimes seen in allergic reactions) or liver function. These are some of the symptoms of potentially life-threatening conditions called Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS).
- 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)

- 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”).

These are very serious side effects. Stop using Quetiapine Sandoz if you develop these symptoms. You may need urgent medical attention or hospitalisation.

Occasionally, Quetiapine Sandoz may be associated with changes in your liver function or blood (e.g. blood fat levels such as cholesterol or triglycerides, blood sugar levels, blood pressure, thyroid hormone levels, white blood cells). These can only be found when your doctor does tests from time to time to check your progress.

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.

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

After taking Quetiapine Sandoz

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 30°C.

Do not store Quetiapine Sandoz 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 young 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 Sandoz 25 mg are round, peach, film-coated tablets. Available in blisters and bottles# of 60 tablets.

Quetiapine Sandoz 100 mg are round, yellow film coated tablets scored on one side. Available in blisters and bottles# of 90 tablets.

Quetiapine Sandoz 200 mg are round, white film coated tablets scored on one side. Available in blisters and bottles# of 60 tablets.

Quetiapine Sandoz 300 mg are capsule shaped, white film coated tablets scored on

both sides. Available in blisters and bottles# of 60 tablets.

#bottles not currently marketed

Ingredients

Active ingredients:

- Each Quetiapine Sandoz 25 mg tablet contains 25 mg quetiapine fumarate
- Each Quetiapine Sandoz 100 mg tablet contains 100 mg quetiapine fumarate
- Each Quetiapine Sandoz 200 mg tablet contains 200 mg quetiapine fumarate
- Each Quetiapine Sandoz 300 mg tablet contains 300 mg quetiapine fumarate

Inactive ingredients:

- Povidone
- Silicon dioxide
- Calcium hydrogen phosphate dihydrate
- Microcrystalline cellulose (E 460)
- Sodium starch glycollate
- Lactose monohydrate
- Magnesium stearate (E 572)
- Hypromellose
- Macrogol 400
- Titanium dioxide (E 171).

In addition

- Quetiapine Sandoz 25 mg contains iron oxide yellow CI77492 (E 172) iron oxide red CI77491 (E 172)
- Quetiapine Sandoz 100 mg contain iron oxide yellow CI77492 (E 172).

This medicine does not contain sucrose or gluten.

Supplier

Quetiapine is supplied in Australia by:

Sandoz Pty Ltd

ABN 60 075 449 553

54 Waterloo Road,

Macquarie Park, NSW 2113, Australia

Tel: 1800 726 369

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Australian Registration Numbers

Quetiapine Sandoz 25 mg film-coated tablets: AUST R 158104 (blisters)

Quetiapine Sandoz 100 mg film-coated tablets AUST R 158109 (blisters)

Quetiapine Sandoz 200 mg film-coated tablets AUST R 158099 (blisters)

Quetiapine Sandoz 300 mg film-coated tablets AUST R 158106 (blisters)