

QUETAPEL

Quetiapine (as quetiapine fumarate) tablets
25 mg, 100 mg, 150 mg, 200 mg and 300 mg



What is in this leaflet

This leaflet answers some common questions about Quetapel.

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 Quetapel 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 Quetapel is used for

Quetapel is used to treat schizophrenia and bipolar disorder. Schizophrenia is an illness with disturbances in thinking, feelings and behaviour. Bipolar disorder is 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. During depression, patients may feel depressed or guilty, lack energy, lose their appetite and have trouble sleeping.

Quetapel contains the active ingredient quetiapine fumarate. It belongs to a group of medicines called anti-psychotics, which improve the symptoms of certain types of mental illness.

Ask your doctor if you have any questions about why this

medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Quetapel is not addictive.

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

Before you take Quetapel

Do not take Quetapel if you have an allergy to:

- any medicine containing quetiapine fumarate
- any of the inactive ingredients in Quetapel, which are 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 a child under the age of 18 years.

Safety and effectiveness in children younger than 18 years have not been established.

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:

- heart problems and/or low blood pressure
- stroke
- problems with your circulation
- high cholesterol
- liver or pancreas problems
- diabetes or high blood sugar
- seizures (fits)
- uncontrollable twitching or jerking movements of the arms and legs
- low white blood cell count
- difficulty in swallowing
- sleep apnoea – temporarily stopping breathing while sleeping
- difficulty passing urine
- an enlarged prostate
- a blockage in your intestines or related conditions
- increased pressure inside your eyes or glaucoma

If you have any of these it may not be appropriate for you to take Quetapel, or you may have to take a lower dose.

Tell your doctor if you or someone else in your family has a history of blood clots.

Medicines like these have been associated with formation of blood clots.

If you drink alcohol, please mention this to your doctor before you start to take Quetapel.

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

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

The following symptoms 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 should contact your doctor.

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

Taking other medicines

DO NOT TAKE QUETAPEL IF YOU ARE TAKING THE FOLLOWING MEDICINES:

- **Protease inhibitors used for Human Immunodeficiency Virus (HIV)**
- **Azole antifungal agents such as ketoconazole, itraconazole, fluconazole, clotrimazole, miconazole and voriconazole**
- **Erythromycin**
- **Clarithromycin**
- **Nefazodone**

THESE MEDICINES AND QUETAPEL WILL INTERFERE WITH EACH OTHER.

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 Quetapel may interfere with each other. These include:

- medicines for anxiety or depression, mood swings, attention deficit hyperactivity disorder (ADHD) or other mood disorders
- stimulants such as amphetamines
- medicines used to treat Parkinson's disease
- medicines for epilepsy
- medicines for high blood pressure or heart conditions,

including diuretics or fluid tablets

- rifampicin for tuberculosis
- barbiturates for sleeplessness
- thioridazine (an antipsychotic)
- glucocorticosteroids – medicines used to treat inflammation
- benzodiazapines – medicines used to treat anxiety or epilepsy
- medicines that have anti-cholinergic (muscarinic) effects, e.g. some medicines used to relieve stomach cramps or spasms or some medicines to manage symptoms of overactive bladder

These medicines may be affected by Quetapel 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 Quetapel.

How to take Quetapel

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 on the pack, ask your doctor or pharmacist for help.

Do not halve Quetapel 25 mg, 100 mg, 150 mg or 200 mg tablets.

Quetapel 300 mg tablets may be halved if necessary.

How much to take

Your doctor will decide what dose of Quetapel you should take. Quetapel is usually started as a low dose that will be gradually increased by your doctor.

Your dose depends on your condition and other factors including your age, other medical conditions (e.g. liver problems), other

medicines you are taking and how you may react to Quetapel.

Your doctor will monitor your condition and may change your dose depending on how you respond.

How to take it

Swallow your Quetapel tablets whole with a full glass of water.

The different strengths of Quetapel tablets come in different sizes and colours. Therefore don't be surprised if the colour of your tablet differs from time to time.

When to take it

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

Take your medicine at about the same time(s) each day.

Taking it at the same time(s) 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 with or without 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 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 your medicine as you would normally.

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

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 National Poisons Information Centre (0800 POISON or 0800 764 766) 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 Quetapel. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include drowsiness, a fast heart beat and low blood pressure.

While you are taking Quetapel

Things you must do

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

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 while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Tell your doctor immediately if you have any distressing thoughts (thoughts of suicide or self-harm) while you are taking Quetapel.

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

Your doctor may do some blood tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take Quetapel 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 it suddenly, your condition may worsen or you may have unwanted side effects such as trouble sleeping, nausea and vomiting. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Things to be careful of

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

This medicine may cause dizziness or sleepiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Avoid drinking alcohol while you are taking this medicine.

If you drink alcohol, the symptoms of dizziness or sleepiness may be worse.

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, Quetapel may affect the way your body reacts to temperature changes.

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.

Side effects

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

This medicine helps most people, but it may have unwanted side effects in a few people. 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.

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, increased appetite
- feeling weak
- dry mouth
- runny or stuffy nose (particularly in children)
- indigestion, upset stomach, constipation, vomiting (mainly in the elderly or children)
- swelling of hands, feet or ankles
- blurred vision
- abnormal dreams, nightmares
- irritability
- shortness of breath, difficulty in breathing and/or tightness in the chest
- feeling dizzy or faint
- difficulty or inability to pass urine

These side effects are usually mild and short-lived.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital as you may need medical attention:

- falling, feeling faint or dizzy on standing up
- difficulty in speaking
- difficulty in swallowing
- very marked drowsiness
- reduced consciousness

- symptoms of high blood sugar levels (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)
- unusual secretion of breast milk
- priapism (long-lasting and painful erection)
- fits (seizures)
- uncontrollable twitching or jerking movements tongue, mouth, cheeks or jaw which may progress to the arms and legs
- a sudden increase in body temperature, with sweating, or a fast heartbeat
- chest pain and difficulty in breathing
- severe skin reaction
- swelling, pain and redness in the leg
- yellowing of the eyes and/or skin, or dark coloured urine

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

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 side effects (for example, changes in blood sugar, thyroid or cholesterol levels) can only be found when your doctor does tests from time to time to check your progress.

After taking Quetapel

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 tablets in a cool dry place where the temperature stays below 25°C.

Do not store Quetapel 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

25 mg: Peach coloured, round, biconvex, film-coated tablets, 5mm in diameter and engraved Q on one side.

100 mg: Yellow coloured, round, biconvex, film-coated tablets, 8.5mm in diameter and engraved Q over 100 on one side.

150 mg (not currently marketed): Pale yellow coloured, round, biconvex, film-coated tablets, 10mm in diameter and engraved Q over 150 on one side.

200 mg: White coloured, round, biconvex, film-coated tablets, 11mm in diameter and engraved Q over 200 on one side.

300 mg: White coloured, capsule-shaped (19.0mm x 7.5mm), film coated tablets, engraved Q breakline 300 on one side. The opposing side is plain except for the breakline.

Each strength comes in a blister pack containing 90 tablets.

Ingredients

Each tablet contains the active ingredient quetiapine fumarate. Each tablet also contains:

- povidone
- calcium hydrogen phosphate dihydrate
- microcrystalline cellulose
- sodium starch glycolate
- lactose monohydrate
- magnesium stearate
- hypromellose
- macrogol

- titanium dioxide (E 171)

In addition:

Quetapel 25 mg contains Iron Oxide Red CI77491 (E 172).

Quetapel 100 mg contains Iron Oxide Yellow CI77492 (E 172) & Talc.

Quetapel 150 mg contains Polysorbate, Iron Oxide Yellow CI77492 (E 172) & Iron Oxide Black CI77499.

Quetapel 200 mg & 300 mg contain Polysorbate.

This medicine does not contain gluten.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: (09) 579 2792

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3 October 2018 (Based on data sheet dated 3 October 2018)