

QUETAPEL



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

What is in this leaflet

This leaflet answers some of the common questions people ask about **Quetapel**. It does not contain all the information that is known about **Quetapel**.

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 mania associated with bipolar disorder. Schizophrenia and bipolar disorder are mental illnesses with disturbances in thinking, feelings and behaviour.

How Quetapel works

Quetapel belongs to a group of medicines called anti-psychotics, which improve the symptoms of certain types of mental illness and emotional conditions.

Your doctor will help you understand the benefits of taking **Quetapel** and why you are taking it. Ask your doctor for further information if you have any questions.

Before you take Quetapel

You must tell your doctor if:

You have any of the following medical conditions:

- heart problems and/or low blood pressure
- stroke
- problems with your circulation
- liver problems
- if you have ever had a seizure (fit)
- diabetes or high blood sugar

Tell your doctor if you know that you had a low white blood cell count in the past.

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.

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

Tell your doctor if you are pregnant or intend to become pregnant. The safety of Quetapel use during pregnancy is not yet known. Your doctor will discuss the risks and benefits of using Quetapel if you are pregnant.

Tell your doctor if you are breast-feeding or planning to breast-feed. It is not yet known how much **Quetapel** will pass through into breast milk.

If you have not told your doctor any of the things above or of any other medical conditions, please tell him/her before you start taking any **Quetapel**.

When you must not take it

Do not use Quetapel if you have an allergy to Quetapel or to any ingredients listed at the end of this leaflet.

If you have an allergic reaction, you may get a skin rash, hayfever, difficulty breathing or feel faint.

Do not give Quetapel to children. There is no information about its use in children.

Do not use Quetapel after the use by (expiry date) printed on the pack. It may have no effect at all, or an unexpected effect if you take it after the expiry date.

Do not take Quetapel if the packaging is torn or shows signs of tampering.

Do not give this medicine to anyone else.

Taking other medicines

You need to take special care if you take other medicines at the same time as **Quetapel**.

Tell your doctor if you are taking or about to stop taking any other medicines, including:

- medicines for anxiety or depression
- medicines for epilepsy
- medicines for high blood pressure
- rifampicin (for tuberculosis)
- barbiturates (for sleeplessness)
- ketoconazole (for fungal infections)
- erythromycin (an antibiotic)
- thioridazine (an antipsychotic)
- protease inhibitors (for Human Immunodeficiency Virus (HIV))
- any other medicines that you buy at the chemist, supermarket or health food shop.

These medicines may affect the way **Quetapel** works. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

How to take Quetapel

Follow your doctor's instructions about when and how to take **Quetapel**. Please read the label on the container carefully. Ask your doctor or pharmacist if you are not sure about anything.

How to take it

Your doctor will decide what dose of **Quetapel** you should take.

Quetapel is taken twice a day. The total dose is usually between 300mg and 450mg a day. Some people may need more or less than this. Your dose will depend on your response.

If you are elderly, or have liver problems, your doctor will adjust your dose to suit you.

Swallow your Quetapel tablets whole with a full glass of water. You can take them before or after food.

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

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 double the dose to make up for the dose you have missed. If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

Overdose

Telephone your doctor or the National Poisons and Hazardous Chemicals Information Centre Ph: 0800 POISON (0800 764 766) or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too much Quetapel, even if there are no signs of discomfort or poisoning.

While you are taking Quetapel

If you go into hospital, please let the medical staff know that you are taking Quetapel.

Do not stop taking your tablets because you are feeling better, unless advised by your doctor.

Be careful driving or operating machinery until you know how Quetapel affects you. **Quetapel** may cause dizziness or sleepiness in some people. Make sure you know how you react to **Quetapel** before you do anything else that could be dangerous if you are dizzy or sleepy. If you drink alcohol, dizziness or sleepiness may be worse.

If you are unsure about any of these points or have further questions, please ask your doctor or pharmacist.

Side effects

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

All medicines can have 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 described below.

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

- very marked drowsiness
- reduced consciousness
- priapism (long-lasting and painful erection)
- fits (seizures)

a sudden increase in body temperature, with sweating, or a fast heartbeat

These are rare but very serious side effects. If you have them, you may have had a serious reaction to **Quetapel**. You may need urgent medical attention or hospitalisation.

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

feeling sleepy
feeling dizzy or faint

These things usually happen when you first take Quetapel and usually go away after a while.

Other side effects can include:

feeling weak
constipation
dry mouth
stuffy nose
indigestion
swelling of arms or legs
rapid heart rate
weight gain
fainting

These are all mild side effects of **Quetapel**.

Occasionally, **Quetapel** may be associated with changes in your liver or blood which may require your doctor to do certain blood tests.

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

Tell your doctor or pharmacist if you have any side effects or if you notice anything else that is making you feel unwell. Your doctor may wish to alter your treatment.

Important. This leaflet alerts you to some of the situations when you should call your doctor. Other situations which cannot be predicted, may arise. Nothing in this leaflet should stop you from calling your doctor or pharmacist with any questions or concerns you have about using **Quetapel**.

After taking it

Storage

Keep your Quetapel tablets in the foil pack until it is time to take them. If you take the tablets out of the box or foil 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 tablets or any other medicine in the bathroom or near a sink. Heat and dampness can destroy some medicines.

Keep your tablets in a safe place where children cannot see or reach them. A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

Do not leave Quetapel tablets in the car on hot days.

Disposal

If your doctor tells you to stop taking the tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What Quetapel 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: 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 Code 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 Poyorbate, Iron Oxide Yellow CI77492 (E 172) & Iron Oxide Black CI77499.

Quetapel 200 mg & 300 mg contain Polysorbate.

Marketed by:

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23 October 2007 (Based on datasheet 23 October 2007)