Package leaflet: Information for the patient

Quetiapine 25 mg film-coated tablets
Quetiapine 100 mg film-coated tablets
Quetiapine 150 mg film-coated tablets
Quetiapine 200 mg film-coated tablets
Quetiapine 300 mg film-coated tablets
quetiapine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Quetiapine is and what it is used for
2. What you need to know before you take Quetiapine
3. How to take Quetiapine
4. Possible side effects
5. How to store Quetiapine
6. Contents of the pack and other information.

1. What Quetiapine is and what it is used for

Quetiapine contains a substance called quetiapine. This belongs to a group of medicines called anti-psychotics. Quetiapine can be used to treat several illnesses, such as:
- Bipolar depression: where you feel sad. You may find that you feel depressed, feel guilty, lack energy, lose your appetite or can't sleep.
- Mania: where you may feel very excited, elated, agitated, enthusiastic or hyperactive or have poor judgment including being aggressive or disruptive.
- Schizophrenia: where you may hear or feel things that are not there, believe things that are not true or feel unusually suspicious, anxious, confused, guilty, tense or depressed.

Your doctor may continue to prescribe Quetiapine even when you are feeling better.

2. What you need to know before you take Quetiapine

Do not take Quetiapine:
- if you are allergic to quetiapine or any of the other ingredients of this medicine (listed in section 6).
- if you are taking any of the following medicines:
- some medicines for HIV
- azole medicines (for fungal infections)
- erythromycin or clarithromycin (for infections)
- nefazodone (for depression)

Do not take Quetiapine if the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Quetiapine.

Warnings and precautions
Talk to your doctor or pharmacist before taking Quetiapine if:

- You, or someone in your family, have or have had any heart problems, for example heart rhythm problems, weakening of the heart muscle or inflammation of the heart, or if you are taking any medicines that may have an impact on the way your heart beats.
- You have low blood pressure.
- You have had a stroke, especially if you are elderly.
- You have problems with your liver.
- You have ever had a fit (seizure).
- You have diabetes or have a risk of getting diabetes. If you do, your doctor may check your blood sugar levels while you are taking Quetiapine.
- You know that you have had low levels of white blood cells in the past (which may or may not have been caused by other medicines).
- You are an elderly person with dementia (loss of brain function). If you are, Quetiapine should not be taken because the group of medicines that Quetiapine belongs to may increase the risk of stroke, or in some cases the risk of death, in elderly people with dementia.
- You are an elderly person with Parkinson's disease/parkinsonism.
- You or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots.
- You have or have had a condition where you stop breathing for short periods during your normal nightly sleep (called "sleep apnoea") and are taking medicines that slow down the normal activity of the brain ("depressants").
- You have or have had a condition where you can't completely empty your bladder (urinary retention), have an enlarged prostate, a blockage in your intestines, or increased pressure inside your eye. These conditions are sometimes caused by medicines (called "anti-cholinergics") that affect the way nerve cells function in order to treat certain medical conditions.
- You have a history of problems with alcohol or drug use.
- If you have depression or other conditions that are treated with antidepressants. The use of these medicines together with Quetiapine can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Quetiapine").

Tell your doctor immediately if you experience any of the following after taking Quetiapine:
- Have a fast and irregular heartbeat, even when you are at rest, palpitations, breathing problems, chest pain or unexplained tiredness. Your doctor will need to check your heart and if necessary, refer you to a cardiologist immediately**.**
- A combination of fever, severe muscle stiffness, sweating or a lowered level of consciousness (a disorder called "neuroleptic malignant syndrome"). Immediate medical treatment may be needed.
- Uncontrollable movements, mainly of your face or tongue.
- Dizziness or a severe sense of feeling sleepy. This could increase the risk of accidental injury (fall) in elderly patients.
- Fits (seizures).
- A long-lasting and painful erection (priapism).

These conditions can be caused by this type of medicine.

Tell your doctor as soon as possible if you have:
- A fever, flu-like symptoms, sore throat, or any other infection, as this could be a result of a very low white blood cell count, which may require your medicine to be stopped and/or treatment to be given.
- Constipation along with persistent abdominal pain, or constipation which has not responded to treatment, as this may lead to a more serious blockage of the bowel.

Thoughts of suicide and worsening of your depression
If you are depressed, you may sometimes have thoughts of harming or killing yourself. These may be increased when first starting treatment, since these medicines all take time to work, usually about two weeks but sometimes longer. These thoughts may also be increased if you suddenly stop taking your medication. You may be more likely to think like this if you are a young adult. Information from

clinical trials has shown an increased risk of suicidal thoughts and/or suicidal behaviour in young adults aged less than 25 years with depression.

If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away. You may find it helpful to tell a relative or close friend** that you are depressed, and ask them to read this leaflet. You might ask them to tell you if they think your depression is getting worse, or if they are worried about changes in your behaviour.

Severe cutaneous adverse reactions (SCARs)
Severe cutaneous adverse reactions (SCARs) which can be life threatening or fatal have been reported very rarely with treatment of this medicine. These are commonly manifested by:

- Stevens-Johnson syndrome (SJS), a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals
- Toxic Epidermal Necrolysis (TEN), a more severe form causing extensive peeling of the skin
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) consists of flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes)
- Acute Generalized Exanthematous Pustulosis (AGEP), small blisters filled with pus
- Erythema Multiforme (EM), skin rash with itchy-red irregular spots

Stop using Quetiapine if you develop these symptoms and contact your doctor or seek medical attention immediately.

Weight gain
Weight gain has been seen in patients taking quetiapine. You and your doctor should check your weight regularly.

Children and adolescents
Quetiapine is not for use in children and adolescents below 18 years of age.

Other medicines and Quetiapine
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take Quetiapine if you are taking any of the following medicines:
- Some medicines for HIV.
- Azole medicines (for fungal infections).
- Erythromycin or clarithromycin (for infections).
- Nefazodone (for depression).

Tell your doctor if you are taking any of the following medicines:
- Epilepsy medicines (like phenytoin or carbamazepine).
- High blood pressure medicines.
- Barbiturates (for difficulty sleeping).
- Thioridazine or lithium (other anti-psychotic medicines).
- Medicines that have an impact on the way your heart beats, for example, drugs that can cause an imbalance in electrolytes (low levels of potassium or magnesium) such as diuretics (water pills) or certain antibiotics (drugs to treat infections).
- Medicines that can cause constipation.
- Anti-depressants. These medicines may interact with Quetiapine and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C (serotonin syndrome). Contact your doctor when experiencing such symptoms.

Before you stop taking any of your medicines, please talk to your doctor first.

Quetiapine with food, drink and alcohol
Be careful how much alcohol you drink. This is because the combined effect of quetiapine and alcohol can make you sleepy.

Do not drink grapefruit juice while you are taking Quetiapine. It can affect the way the medicine works.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. You should not take Quetiapine during pregnancy unless this has been discussed with your doctor. Quetiapine should not be taken if you are breast-feeding.

The following symptoms, which can represent withdrawal, may occur in newborn babies of mothers that have taken 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.

Driving and using machines
Your tablets may make you feel sleepy. Do not drive or use any tools or machines until you know how the tablets affect you.

Quetiapine contains lactose and sodium
Quetiapine contains **lactose** which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Effect on urine drug screens
If you are having a urine drug screen, taking Quetiapine may cause positive results for methadone or certain drugs for depression called tricyclic antidepressants (TCAs) when some test methods are used, even though you may not be taking methadone or TCAs. If this happens, a more specific test can be performed.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Quetiapine

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will decide on your starting dose. The maintenance dose (daily dose) will depend on your illness and needs but will usually be between 150 mg and 800 mg.

- You will take your tablets once a day, at bedtime or twice a day, depending on your illness.
- Swallow your tablets whole with a drink of water. You can take your tablets with or without food. Do not drink grapefruit juice while you are taking Quetiapine. It can affect the way the medicine works.
- Do not stop taking your tablets even if you feel better, unless your doctor tells you.

Liver problems:
If you have liver problems your doctor may change your dose.

Elderly:
If you are elderly your doctor may change your dose.

Use in children and adolescents
Quetiapine should not be used by children and adolescents aged under 18 years.

If you take more Quetiapine than you should
If you take more Quetiapine than prescribed by your doctor, you may feel sleepy, feel dizzy and experience abnormal heart beats, dry mouth, constipation, dilated pupils or blurred vision. Contact your doctor or nearest hospital straight away. Take the container and any remaining tablets with you.

If you forget to take a dose of Quetiapine
If you forget to take a dose, take it as soon as you remember. If it is almost time to take the next dose, wait until then. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Quetiapine
If you suddenly stop taking Quetiapine, you may be unable to sleep (insomnia), you may feel sick (nausea), or you may experience headache, diarrhoea, being sick (vomiting), dizziness or irritability. Your doctor may suggest you reduce the dose gradually before stopping treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Contact a doctor IMMEDIATELY if you experience any of the following side effects:
Very common (may affect more than 1 in 10 people):
- Abnormal muscle movements. These include difficulty starting muscle movements, shaking, feeling restless or muscle stiffness without pain

Common (may affect up to 1 in 10 people):
- Thoughts of self harm and suicide or worsening of your depression.

Uncommon (may affect up to 1 in 100 people):
- Diabetes mellitus: condition in which the body does not produce enough insulin or else the body tissues are not able to use the insulin present. This leads to hyperglycaemia (too much sugar in the blood). Symptoms may include excessive thirst, increased appetite with weight loss, feeling tired, drowsy, weak, depressed, irritable and generally unwell, and passing large amounts of urine
- Fits or seizures.
- Allergic reactions that may include raised lumps (weals), swelling of the skin and swelling around the mouth.
- Uncontrollable movements, mainly of your face or tongue.
- Change in electrical activity of the heart seen on ECG (QT prolongation), which can cause a very fast heart beat and fainting, and can cause serious problems with the heart.
- Difficulty in passing urine.
- Worsening of pre-existing diabetes.

Rare (may affect up to 1 in 1,000 people):
- A combination of high temperature (fever), sweating, stiff muscles, feeling very drowsy or faint, large increase in blood pressure or heartbeat (a disorder called “neuroleptic malignant syndrome”).
- Inflammation of pancreas which causes severe abdominal and back pain.
- Yellowing of the skin and eyes (Jaundice).
- Inflammation of the liver (Hepatitis).
- A long-lasting and painful erection (Priapism).

- Blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing.
- Combination of fever, flu-like symptoms, sore throat, or any other infection with very low white blood cell count, a condition called agranulocytosis.
- An obstruction of the bowel, causing severe constipation and a lack of wind (flatulence), with swelling or pain in the stomach.

Very rare (may affect up to 1 in 10,000 people):
- Severe allergic reaction (called anaphylaxis) that may include difficulty in breathing, dizziness and collapse.
- A severe rash, which may develop quickly. Symptoms may include redness, blistering or peeling of skin particularly around the mouth, nose, eyes and genitals (a condition known as Stevens-Johnson syndrome). See section 2
- Rapid swelling of the skin, usually around the eyes, lips and throat.
- Inappropriate secretion of ADH, a hormone that causes the body to retain water and dilute the blood, reducing the amount of sodium. This may lead to a lower than normal level of sodium in the blood, causing you to feel weak and confused with aching muscles.
- Breakdown of muscle fibres causing pain, tenderness and weakness in the muscles (rhabdomyolysis).

Not known (frequency cannot be estimated from the available data):
- A widespread redness of skin with blisters and peeling on much of the body surface (toxic epidermal necrolysis). See section 2
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). Widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome). See section 2. **Stop using Quetiapine if you develop these symptoms and contact your doctor or seek medical attention immediately**.
- Stroke with symptoms that include collapse, numbness or weakness of arms or legs, headache, dizziness, confusion, visual disturbance, difficulty swallowing or problems speaking, such as slurred speech and loss of speech.

Other possible side effects:
Very common (may affect more than 1 in 10 people):
- Dizziness (may lead to falls), headache, dry mouth.
- Feeling sleepy (this may go away with time, as you keep taking quetiapine) (may lead to falls).
- Discontinuation symptoms (symptoms which occur when you stop taking quetiapine) include not being able to sleep (insomnia), feeling sick (nausea), headache, diarrhoea, being sick (vomiting), dizziness, and irritability. Gradual withdrawal over a period of at least 1 to 2 weeks is advisable.
- Putting on weight.
- Changes in the amount of certain fats (triglycerides and total cholesterol).

Common (may affect up to 1 in 10 people):
- Rapid heartbeat.
- Feeling like your heart is pounding, racing or has skipped beats.
- Constipation, upset stomach (indigestion).
- Feeling weak.
- Swelling of arms or legs.
- Low blood pressure when standing up. This may make you feel dizzy or faint (may lead to falls).
- Increased levels of sugar in the blood.
- Blurred vision.
- Abnormal dreams and nightmares.

- Feeling hungrier.
- Feeling irritated.
- Disturbance in speech and language.
- Shortness of breath.
- Vomiting (mainly in the elderly).
- Fever.
- Changes in the amount of thyroid hormones in your blood.
- Decreases in the number of certain types of blood cells.
- Increases in the amount of liver enzymes measured in the blood.
- Increases in the amount of the hormone prolactin in the blood. Increases in the hormone prolactin could in rare cases lead to the following:
- Men and women to have swelling of breasts and unexpectedly produce breast milk.
- Women to have no monthly period or irregular periods.

Uncommon (may affect up to 1 in 100 people):
- Unpleasant sensations in the legs (also called restless legs syndrome).
- Difficulty swallowing.
- Sexual dysfunction.
- A slower than normal heart rate which may occur when starting treatment and which may be associated with low blood pressure and fainting.
- Fainting (may lead to falls).
- Stuffy nose.
- Decrease in the amount of red blood cells.
- Decrease in the amount of sodium in the blood.
- Confusion.

Rare (may affect up to 1 in 1, 000 people):
- Swelling of breasts and unexpected production of breast milk (galactorrhoea).
- Menstrual disorder.
- Walking, talking, eating or other activities while you are asleep.
- Body temperature decreased (hypothermia).
- A condition (called "metabolic syndrome") where you may have a combination of 3 or more of the following: an increase in fat around your abdomen, a decrease in "good cholesterol" (HDL-C), an increase in a type of fat in your blood called triglycerides, high blood pressure and an increase in your blood sugar.
- Increased blood creatine phosphokinase (a substance from the muscles).

Not known (frequency cannot be estimated from the available data):
- Skin rash with irregular red spots (erythema multiforme).
- Symptoms of withdrawal may occur in newborn babies of mothers that have taken quetiapine during their pregnancy.
- Disorder of the heart muscle (cardiomyopathy).
- Inflammation of the heart muscle (myocarditis).
- Inflammation of blood vessels (Vasculitis), often with skin rash with small red or purple bumps.

The class of medicines to which quetiapine belongs can cause heart rhythm problems which can be serious and in severe cases may be fatal.

Some side effects are only seen when a blood test is taken. These include changes in the amount of certain fats (triglycerides and total cholesterol) or sugar in the blood, changes in the amount of thyroid hormones in your blood, increased liver enzymes, decreases in the number of certain types of blood cells, decrease in the amount of red blood cells, increased blood creatine phosphokinase (a substance in the muscles), decrease in the amount of sodium in the blood and increases in the amount of the hormone prolactin in the blood

Your doctor may ask you to have blood tests from time to time.

Side effects in children and adolescents:
The same side effects that may occur in adults may also occur in children and adolescents.

The following side effects have been seen more often in children and adolescents or have not been seen in adults:

Very common (may affect more than 1 in 10 people):
- Increase in the amount of a hormone called prolactin, in the blood. Increases in the hormone prolactin could in rare cases lead to the following:
- Boys and girls to have swelling of breasts and unexpectedly produce breast milk
- Girls to have no monthly period or irregular periods.
- Increased appetite.
- Vomiting.
- Abnormal muscle movements. These include difficulty starting muscle movements, shaking, feeling restless or muscle stiffness without pain.
- Increase in blood pressure.

Common (may affect up to 1 in 10 people):
- Feeling weak, fainting (may lead to falls).
- Stuffy nose.
- Feeling irritated.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly via the Yellow Card Scheme via the website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Quetiapine

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after 'EXp'. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Quetiapine film-coated tablets contain
- The active substance is quetiapine fumarate.
- Each 25 mg/100 mg/150 mg/200 mg/300 mg film-coated tablet contains 25 mg/100 mg/150 mg/200 mg/300 mg quetiapine (as quetiapine fumarate).
- The other ingredients are: lactose monohydrate (see section 2 "Quetiapine contains lactose and sodium"), microcrystalline cellulose, povidone 30, magnesium stearate, sodium starch glycolate (Type A) (see section 2 "Quetiapine contains lactose and sodium) calcium hydrogen phosphate dihydrate.

The tablet coating contains:

25 mg tablets: hypromellose, titanium dioxide (E171), macrogol 400 and iron oxide red (E172).
100 mg tablets: hypromellose, titanium dioxide (E171), macrogol 6000, iron oxide yellow (E172) and talc.
150 mg tablets: hypromellose, titanium dioxide (E171), macrogol 400, iron oxide yellow (E172), iron oxide black (E172) and polysorbate 80.
200 mg and 300 mg tablets: hypromellose, titanium dioxide (E171), macrogol 400 and polysorbate 80.

What Quetiapine Film-coated Tablets look like and contents of the pack
Quetiapine tablets are film-coated tablets.

25 mg tablets:
The tablets are round, peach coloured, biconvex and engraved "Q" on one side.
The tablets are available in blister packs with 1, 3, 6, 7, 10, 14, 20, 28, 30, 50, 56, 60, 84, 90, 98, 100, 6x1 tablets and in bottles with 60, 84, 90, 98, 100, 250, 500, 1000 tablets

100 mg tablets:
The tablets are round, yellow, biconvex, and engraved "Q" over "100" on one side.
The tablets are available in blister packs with 1, 3, 6, 7, 10, 14, 20, 28, 30, 50, 56, 60, 84, 90, 98, 100, 60x1 tablets and in bottles with 60, 84, 90, 98, 100, 250, 500, 1000 tablets.

150 mg tablets:
The 150 mg tablet is round, pale yellow and engraved "Q" over "150" on one side.
The tablets are available in blister packs with 1, 3, 6, 7, 10, 14, 20, 28, 30, 50, 56, 60, 84, 90, 98, 100 tablets and in bottles with 60, 84, 90, 98, 100, 250, 500, 1000 tablets.

200 mg tablets:
The 200 mg tablet is round, white and engraved "Q" over "200" on one side.
The tablets are available in blister packs with 1, 3, 6, 7, 10, 14, 20, 28, 30, 50, 56, 60, 84, 90, 98, 100, 60x1 tablets and in bottles with 60, 84, 90, 98, 100, 250, 500, 1000 tablets

300 mg tablets:
The 300 mg tablet is capsule shaped, white and engraved "Q" breakline "300" on one side. The tablet can be divided into equal doses.
The tablets are available in blister packs with 1, 3, 6, 7, 10, 14, 20, 28, 30, 50, 56, 60, 84, 90, 98, 100, 60x1 tablets and in bottles with 60, 84, 90, 98, 100, 250, 500, 1000 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder:
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