

Quetiapine 300 mg Film-coated Tablets (Quetiapine)

Ref: 186/003/150916/1/F

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking this medicine

- * 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- * If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

- 1 What Quetiapine Tablet is and what it is used for
- 2 Before you take Quetiapine Tablets
- 3 How to take Quetiapine Tablets
- 4 Possible side effects
- 5 How to store Quetiapine Tablets
- 6 Further information

1 What Quetiapine Tablet is and what it is used for

Quetiapine Tablets contains a substance called quetiapine. This belongs to a group of medicines called antipsychotics. These medicines help with conditions that cause symptoms such as:

- * You may see, hear or feel things that are not there, believe things that are not true or feel unusually suspicious, anxious, confused, guilty, tense or depressed.
- * You may feel very excited, elated, agitated, enthusiastic or hyperactive or have poor judgment including being aggressive or disruptive or aggressive behaviours.
- * Effects on your mood whereby you feel sad. You may find that you feel depressed, feel guilty, lack energy, lose your appetite and/or can't sleep.

Your doctor may continue to give you quetiapine tablets when you are feeling better to prevent your symptoms from returning.

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.

2 Before you take Quetiapine Tablets

Do not take Quetiapine Tablets if:

- * you are allergic (hypersensitive) to quetiapine or any of the ingredients of Quetiapine Tablets (see Section 6: Further information).
- * you are taking any of the following medicines:
 - protease inhibitors, such as nelfinavir (for HIV infection)
 - azole medicines (for fungal infections)
 - medicines for an infection (like erythromycin or clarithromycin)
 - nefazodone (for depression).

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

Take special care with Quetiapine Tablets:

Quetiapine should not be taken by elderly people with dementia (loss of brain function). This is 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.

Before you take your medicine, tell your doctor if:

- * You, or someone in your family have or had any heart problems, such as a very fast heart beat or prolonged QT on an ECG (heart tracing), 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 tablets.
- * 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 or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots.

Tell your doctor if you experience:

- * A combination of temperature (fever), severe muscle stiffness, feeling confused, 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.
- * A feeling of severe sleepiness. 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.

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. 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.

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

Taking other medicines:

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, because it may affect the way the medicines work. This includes medicines that you buy without a prescription and herbal medicines.

Do not take quetiapine tablets 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.
- * Rifampicin (for Tuberculosis)
- * Barbiturates (for difficulty sleeping).
- * Thioridazine (another anti-psychotic medicine).
- * Medicines that affect the heart, for example, drugs that can cause an imbalance in some of the chemicals in your blood such as diuretics (water pills) or certain antibiotics.

Before you stop taking any of your medicines, please talk to your doctor first. If you have a urine drug screen, taking Quetiapine could cause positive results for methadone or drugs for depression called tricyclic antidepressants (TCAs), even though you may not be taking methadone or TCAs. The result will need to be confirmed by a more specific test.

Taking Quetiapine tablets with food and drink

- * Quetiapine tables can be taken with or without food.
- * Be careful how much alcohol you drink. This is because the combined effect of quetiapine tables and alcohol can make you feel sleepy.
- * Do not drink grapefruit juice while you are taking quetiapine tablets. It can affect the way the medicine works.

Pregnancy and breast-feeding:

If you are pregnant, trying to get pregnant, or breast-feeding, talk to your doctor before taking quetiapine tablets. The following symptoms may occur in newborn babies of mothers that have used quetiapine tablets 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 may need to contact your doctor.

Driving and using machines

Taking quetiapine may make you feel sleepy. Do not drive or operate machinery until you know how this medicine affects you.

Hospital - If you go into hospital, tell the medical staff that you are taking quetiapine tablets.

Important information about some of the ingredients of Quetiapine tablets

Quetiapine tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3 How to take Quetiapine Tablets

Always take Quetiapine tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Your doctor will decide on your starting dose and may gradually increase it. After this the dose will usually be between 150 mg and 800 mg each day. This will depend on your type of illness and needs

Your doctor may start your treatment on a lower dose and increase the dose slowly if:

- You are elderly, or
- You have liver problems.

- * 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 tablets. It can affect the way the medicine works.
- * Do not stop taking your tablets even if you feel better, unless your doctor tells you.

Children and adolescents under 18 years

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

If you forget to take a dose of Quetiapine Tablets

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 dose.

If you take more Quetiapine Tablets than you should

If you take more Quetiapine tablets than prescribed by your doctor, you may experience sleepiness, dizziness and abnormal heart beats. Contact your doctor or nearest hospital straight away. Keep the Quetiapine tablets with you.

If you stop taking Quetiapine Tablets

If you suddenly stop taking Quetiapine tablets, 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 product, ask your doctor or pharmacist.

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PATIENT INFORMATION LEAFLET (continued)

4 Possible side effects

Like all medicines, Quetiapine tablets can cause side effects, although not everybody gets them.

If any of the following happen, stop taking Quetiapine tablets and contact a doctor or go to the nearest hospital straight away, as you may need urgent medical attention:

- * Thoughts of suicide and worsening of your depression

Uncommon (affects less than 1 in 100 patients):

- * 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 (Tardive dyskinesia).

Rare (affects less than 1 in 1,000 patients):

- * 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.
- * 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”).
- * Jaundice (yellowing of the skin and eyes).
- * Hepatitis (inflammation of the liver).
- * Priapism (a long-lasting and painful erection).

Very rare (affects less than 1 in 10,000 patients):

- * Rapid swelling of the skin, usually around the eyes, lips and throat (angioedema).
- * 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 the skin, with possible blisters in the mouth or nose.

Other possible side effects:

Very common (affects more than 1 in 10 patients):

- * Dizziness (may lead to falls), headache, dry mouth, anemia
- * Feeling sleepy (this may go away with time, as you keep taking Quetiapine Tablets) (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. They usually go away after 1 week from your last dose
- * Putting on weight.

Common (affects less than 1 in 10 patients):

- * 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 led to falls)
- * High blood sugar
- * Blurred vision
- * Abnormal muscle movements. These include difficulty starting muscle movements, shaking, feeling restless or muscle stiffness without pain
- * Abnormal dreams and nightmares
- * Feeling more hungry
- * Feeling irritated
- * Disturbance in speech or language.
- * Shortness of breath.
- * Vomiting (mainly in the elderly).
- * Fever
- * Syncope
- * Rhinitis

Uncommon (affects 1 in 100 patients):

- * Fainting (may lead to falls).
- * Unpleasant sensations in the legs and/or restless legs (also called restless legs syndrome).
- * Difficulty swallowing.
- * Sexual dysfunction
- * Stuffy nose
- * Development of diabetes
- * Change in electrical activity of the heart seen on ECG (QT prolongation)
- * A slower than normal heart rate which may occur when starting treatment and which may be associated with low blood pressure and fainting.

Rare (affects less than 1 to 1,000 patients):

- * Menstrual disorder
- * Walking, talking, eating or other activities while you are asleep
- * Body temperature decreased (hypothermia)
- * Swelling of breasts and unexpected production of breast milk (galactorrhoea).
- * Inflammation of the pancreas, which causes severe pain in the abdomen and back.

Very rare (affect less than 1 in 10,000 patients):

- * High blood sugar or worsening of pre-existing diabetes.
- * Inappropriate secretion of a hormone that controls urine volume.
- * Breakdown of muscle fibres and pain in muscles (rhabdomyolysis).

Not known (can not be estimated from the available data):

- * Skin rash with irregular red spots (erythema multiforme)

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

Ref: 186/003/150916/1/B

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, decreases in the number of certain types of blood cells (including red blood cells), decreases in the amount of sodium in the blood, changes in the amount of thyroid hormones in the blood, increased liver enzymes, increased blood creatine phosphokinase (a substance in the muscles) and 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.
- Therefore, your doctor may ask you to have blood tests from time to time. If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Children and adolescents:

The same side effects that may occur in adults can also be present in children and adolescents.

The following side effects are only observed in children and adolescents:

Very common (affect more than 1 in 10 patients):

- * Increase in blood pressure

The following adverse events were observed more frequently in children and adolescents:

Very common (affect more than 1 in 10 patients):

- * Increase in the amount of hormone call prolactin in the blood. Increasing amount of hormone call prolactin in rare cases can lead to the following:
 - Swelling of the breasts and unexpected lactation in boys and girls.
 - The absence or irregularity of menstruation in girls.
- * Increased appetite.
- * Abnormal muscle movement. These may include difficulty in getting motion muscles, tremors, restlessness or muscle stiffness without pain.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Quetiapine Tablets

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

This medicinal product does not require any special storage condition.

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

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Further information

What Quetiapine Tablets contains:

The active ingredient is quetiapine hemifumarate. Each film-coated tablet contains 300 mg quetiapine (as quetiapine hemifumarate).

The other ingredients are:

Core tablets: lactose monohydrate, cellulose microcrystalline, povidone K30, magnesium stearate (E470b), sodium starch glycolate (Type A), di basic calcium phosphate dihydrate.

Film-coating contains: hypromellose E-5, macrogol 400 titanium dioxide.

What Quetiapine Tablets look like and contents of the pack.

300mg tablets are white to off white, capsule shaped, biconvex, film-coated tablet, with ‘300’ debossed on one side and plain on other side, PVC/Aluminium foil blisters in pack sizes of 60 tablets per carton.

The Parallel Product Authorisation Holder is:

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