

## Quetiapine Therapy: Important Information for Patients

### What is quetiapine and what is it used for?

Quetiapine is an atypical (second generation) antipsychotic medication that can work well for people with treatment resistant depression when it is added onto an existing antidepressant medication.

Although you are most likely to be given antipsychotics if you are experiencing psychosis, they are also used to treat other mental health problems, usually at lower doses. Quetiapine extended-release tablets are currently licenced to treat major depressive disorder. These modified-release tablets have the letters 'XL' after the brand name and release quetiapine slowly and evenly throughout the course of the day (and are usually taken once daily, typically at bedtime).

It works to balance the chemical substances in your brain, for example, dopamine and serotonin levels.

### Checks needed before you start taking quetiapine

Not everyone can take quetiapine. Do not take quetiapine tablets if you:

- Are allergic to any of the ingredients of quetiapine tablets
- You are taking any of these 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)

It is important that your doctor knows about any medical conditions you have and any treatment you are already receiving when they are prescribing quetiapine. 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 interval on an ECG heart tracing (a rare heart problem that may cause irregular heartbeat, fainting, or sudden death)
- You have problems with your **liver, kidneys, prostate, pancreas or thyroid**
- You have ever had a fit (**seizure**)
- You have **diabetes** or have a risk of getting diabetes (e.g. high blood sugar or family history)
- You or someone else in your family has a history of **blood clots**
- You drink **alcohol** or have a history of alcohol or substance abuse
- You have **Alzheimer's disease, dementia or Parkinson's disease**
- You are in poor general health
- You have any problems with your **breathing**, or if you have any difficulties **swallowing**.

- You are dehydrated, have low blood volume, or will be exposed to very high temperatures
- You have a history of a **heart attack** or other **heart problems** (e.g. enlargement of the heart, heart failure, irregular heartbeat), stroke, blood vessel problems, high blood cholesterol or triglyceride levels, or high or low blood pressure
- You have **stomach** or **bowel** problems
- You have eye problems e.g. **cataracts**, or raised pressure in your eye (**glaucoma**)
- You have neuroleptic malignant syndrome (**NMS**)
- You have **gallstones**
- You have low blood **magnesium, potassium or white blood cell** levels
- You have had high blood **prolactin** levels
- You have history of certain types of **cancer** (e.g. breast, pancreas, pituitary, brain), or if you are at risk of breast cancer
- You have ever had yellowing of your skin or the whites of your eyes (**jaundice**) or a blood disorder
- You have a condition which causes muscle weakness, called **myasthenia gravis**
- You have a tumour on your adrenal gland (a condition called **phaeochromocytoma**)

You will usually have your weight checked and might also be asked to have some blood tests when you start taking quetiapine.

#### Additional precautions:

**Doctors should prescribe quetiapine with caution to older people:** This is because they may be prone to drops in blood pressure when standing up, leading to falls, and also to both high and low body temperature.

If you are older, your clinician will begin prescribing the medication at a lower dose and increase the dosing more gradually to make sure you are able to tolerate the medication and don't have these potential adverse effects.

**Pregnancy and contraception:** As a general rule, it is best not to take quetiapine while pregnant as it can harm the baby. If you are a woman who might become pregnant, it is important that you use contraception whilst taking quetiapine. You should not breastfeed while taking quetiapine.

#### How to take quetiapine

It could take some time for quetiapine to have its full effect on your mood. Treatment with quetiapine is usually long-term unless you experience an adverse effect. Continue to take quetiapine even if you feel well. Do not stop taking quetiapine without talking to your doctor first. It is important that you do not stop taking this medication suddenly as this can cause your illness to come back quickly and you may also get withdrawal symptoms such as nausea, vomiting, and

difficulty falling asleep or staying asleep. It is recommended to reduce the dose gradually and with the advice of your doctor.

Before you start the treatment, read the manufacturer's printed information leaflet from inside the medication pack. It will give you more information about quetiapine and it will also provide you with a full list of the side-effects which you may experience from taking it.

Doctors prescribe antipsychotics at the lowest effective dose to reduce your symptoms, and increase gradually if necessary. Your doctor will probably start you on a low dose of quetiapine and gradually increase your dose during the first week of your treatment. Ask your doctor or pharmacist if you have any questions about the amount of medication you should take each day.

Take quetiapine exactly as your doctor tells you to. Do not take more or less of it or take it more often than prescribed by your doctor. It is taken once or twice a day depending upon the type of tablet prescribed. The directions for taking the tablets will be printed on the label of the pack to remind you about what the doctor said to you.

Quetiapine tablets come in different strengths and colours. If your dose is changed, your tablets may look different. If you are unsure about your tablets at any time, please ask your pharmacist for advice.

Swallow quetiapine extended-release tablets whole; do not split, chew, or crush them.

Take quetiapine at around the same time(s) every day. This will help you to remember to take it.

If you forget to take a dose, take it as soon as you remember unless it is nearly time for your next dose, in which case leave out the forgotten dose. Do not take two doses together to make up for a missed dose.

If you miss taking quetiapine for longer than 1 week, contact your doctor before you start to take it again. Your dose may need to be adjusted.

Quetiapine can make you drowsy. You should not drive or operate machinery and should take precautions to avoid falls until you know about how this medicine affects you.

#### *Storage and disposal of this medication*

Please follow the instructions given to you at your pharmacy. Keep all medicines out of the reach and sight of children. Store in a cool, dry place, away from direct heat and light. Do not keep out-of-date or unwanted medicines. Take them to your local pharmacy which will dispose of them for you. Medicines should not be disposed of via wastewater or household waste.

#### *Special dietary and lifestyle instructions whilst taking quetiapine*

Do not eat grapefruit or drink grapefruit juice while you are on quetiapine. This is because a chemical in grapefruit is likely to increase the amount of quetiapine in your bloodstream and make side-effects more likely.

You should know that you may gain weight while you are taking this medication. Talk to your doctor about ways to control weight gain, such as eating a healthy, balanced diet and exercising. You and your doctor should check your weight regularly while you are taking quetiapine.

Be sure to drink plenty of water every day while you are taking this medication.

Quetiapine may make it harder for your body to cool down when it gets very hot. In hot weather while you are taking quetiapine, you should avoid excessive exercise, stay inside as much as possible and dress lightly, stay out of the sun, and drink plenty of fluids. Avoid getting overheated or dehydrated in hot weather or while you are being active; heatstroke, dizziness, or fainting may occur.

If you drink alcohol, ask your doctor for advice. Alcohol is not recommended while taking quetiapine as it can increase the risk of side effects and make you drowsy.

Quetiapine may cause dizziness, light-headedness, and fainting when you get up too quickly from a lying position. This is more common when you first start taking quetiapine and when your dose is increased. To avoid this problem, get out of bed slowly, resting your feet on the floor for a few minutes before standing up.

Some medicines similar to quetiapine can cause the skin to become more sensitive to sunlight than normal. It may be advisable to use a sunscreen in bright sunlight until you know how your skin reacts.

Note: some formulations of quetiapine contain lactose.

### Medical tests after starting quetiapine

Lab tests, including full blood cell counts, blood sugar, cholesterol levels, liver function, thyroid function and heart traces (ECG, electrocardiograms) may be performed while you use quetiapine. You may also receive regular weight and blood pressure checks while you use quetiapine and for women the doctor may check that your menstrual periods are regular. These tests may be used to monitor your condition or check for side effects.

These checks may be more frequent at the start of your therapy, and after that, every 6-12 months. Be sure to keep all doctor and lab appointments. They are important because:

- Quetiapine can cause hypothyroidism, high liver enzymes, high cholesterol, and high triglycerides in some people.
- If you have diabetes you may need to check your blood glucose more frequently, as quetiapine may affect the levels of sugar in your blood. Your doctor will advise you about this and you may have to increase the medication you use for your diabetes.
- Even if you do not already have diabetes, you may experience hyperglycemia (increases in your blood sugar) while you are taking this medication. Tell your doctor immediately if you have any of the following symptoms while you are taking quetiapine:
  - wanting to drink a lot

- going for a wee a lot
- feeling more hungry
- feeling weak
- blurred vision

It is very important to call your doctor as soon as you have any of these symptoms, because high blood sugar can cause a serious condition called ketoacidosis. Ketoacidosis may become life-threatening if it is not treated at an early stage. Symptoms of ketoacidosis include: dry mouth, nausea and vomiting, shortness of breath, breath that smells fruity, and decreased consciousness.

### What happens if the levels of quetiapine in your blood are too high?

If you take more quetiapine tablets than prescribed by your doctor, speak to your doctor or other healthcare professional immediately. If this is not possible, ring the NHS non-emergency service on 111.

Symptoms of overdose may include the following:

- drowsiness
- severe dizziness / light headedness
- fainting
- fast or irregular heartbeat
- uncontrolled muscle movements, muscle pain, weakness or cramping
- seizures

### What side effects can quetiapine cause?

Experiences of taking quetiapine vary from person to person. It is not possible to predict how you will respond to quetiapine before you take it but not everyone taking this medication will get side effects. Many side effects go away with time, but some may last for longer.

If you get any medical problems or events that concern you, you should talk to your healthcare professional. See table below for known side effect of quetiapine. Please report any medical occurrences to a member of the study team even if they are not necessarily related to quetiapine.

Your doctor will need to: rule out anything else that might be causing that effect; adjust your dose; or prescribe additional medication to help you manage the side effects. It is also possible that changing your diet and the time of day when you take your dose could help.

All of the possible side effects will be listed in detail in the patient information sheet that comes with your medication. If you are not given one of these leaflets, ask your pharmacist for one.

Very common side effects (affecting more than 1 in 10 people) include:

- Feeling dizzy or light headed when you stand up
- Headache
- Feeling sleepy or drowsy

- Dry mouth
- Putting on weight

Common side effects (affecting less than 1 in 10 people) include:

- Indigestion, feeling or being sick (mainly in older people)
- Constipation
- Blurred vision
- Feeling more hungry
- Unusual dreams and nightmares
- Rapid heartbeat or feeling like your heart is pounding, racing or has skipped beats
- Swelling of feet, ankles, arms or legs
- Feeling irritable
- Shortness of breath
- Fever
- Feeling weak
- High blood sugar
- Disturbance in speech or language
- Thoughts of suicide and worsening of your depression or low mood
- Feeling restless or shaky, unusual or uncontrollable muscle movements

Tell your doctor immediately if you experience:

- A long-lasting and painful erection (priapism). This could happen even when you are not having sex. If this is not treated right away, it could lead to permanent sexual problems, such as impotence (rare – affects less than 1 in 1000 patients).
- 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 (rare – affects less than 1 in 1000 patients).
- Quetiapine may raise your blood sugar. High blood sugar may make you feel confused, drowsy, or thirsty. It can also make you flush, breathe faster, or have a fruit-like breath odour. Development of diabetes is uncommon (affects less than 1 in 1000).
- Uncontrollable movements, mainly of your face or tongue (uncommon – affects less than 1 in 100 patients).
- Rarely, quetiapine may lower the ability of your body to fight infection. Avoid contact with people who have colds or infections. Tell your doctor if you notice signs of infection, such as fever, sore throat, rash, or chills.
- Quetiapine may increase the amount of a certain hormone (prolactin) in your blood. Symptoms may include enlarged breasts, missed menstrual period, decreased sexual ability, or nipple discharge (rare, affects less than 1 in 1000 people)
- A feeling of severe sleepiness. This could increase the risk of accidental injury (fall) in elderly patients.

- Fits (seizures) – uncommon, affects less than 1 in 100 people.
- 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. 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.

### How does quetiapine interact with other drugs?

Quetiapine does not mix well with some other medicines. You should always check with your doctor or pharmacist before taking any drugs together, or closely following one another, in case they could interact with each other badly. This includes non-prescription, over-the counter-drugs, herbal and other complimentary medicines. Take special care to tell your doctor before you take quetiapine especially if you are taking the following medications:

- Epilepsy medicines (like phenytoin or carbamazepine)
- High blood pressure medicines
- Rifampicin (for tuberculosis)
- Barbiturates (to help people who have difficulty sleeping)
- Thioridazine (another anti-psychotic medicine)
- Medicines that affect the heart, like diuretics (water pills) or certain antibiotics. Check with your doctor or pharmacist if you are unsure if any of your medicines may increase the risk of this type of irregular heartbeat.
- Medicines that may harm the liver (e.g., acetaminophen, methotrexate, ketoconazole, isoniazid, certain medicines for HIV infection). Ask your doctor if you are unsure if any of your medicines might harm the liver

This may not be a complete list of all interactions that may occur. Ask your health care provider if quetiapine may interact with other medicines that you take. Check with your health care provider before you start, stop, or change the dose of any medicine.

### Who do I need to tell that I am taking quetiapine?

If you go into hospital, be sure to tell the medical staff you are taking quetiapine.

If you are having surgery, including dental surgery, tell your doctor or dentist that you are taking quetiapine. This is important because quetiapine may interfere with any anaesthetic you take.

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. Be sure your doctor and lab personnel know you are taking quetiapine.