



## 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:

- What Quel XR is and what it is used for
- Before you take Quel XR
- How to take Quel XR
- Possible side effects
- How to store Quel XR
- Further information

### What Quel XR is and what it is used for

#### Pharmacotherapeutic group:

Quel XR contains a substance called quetiapine. This belongs to a group of medicines called anti-psychotics, ATC: N05AH04.

#### Therapeutic indications:

- Quel XR can be used to treat several illnesses, such as:
  - **Bipolar depression and major depressive episodes in major depressive disorder**, 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.

When Quel XR is being taken to treat major depressive episodes in major depressive disorder, it will be taken in addition to another drug being used to treat this illness. Your doctor may continue to prescribe Quel XR even when you are feeling better.

### What you need to know before you take Quel XR

#### Do not take Quel XR:

- If you are allergic (hypersensitive) to quetiapine or any of the other ingredients of Quel XR
- 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 Quel XR if the above applies to you. If

you are not sure, talk to your doctor or pharmacist before taking Quel XR.  
**Take special care with Quel XR**  
Talk to your doctor or pharmacist before taking Quel XR 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 Quel XR.
- 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, Quel XR should not be taken because a group of medicines that Quel XR belongs to may increase the risk of stroke, or in some cases the risk of death, in elderly people with dementia.
- 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.

Tell your doctor immediately if you experience any of the following after taking Quel XR:

- 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 Quel XR 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 behavior 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 behavior.

**Weight gain:** Weight gain has been seen in patients taking Quel XR. You and your doctor should check your weight regularly.

**Children and Adolescents:** Quel XR is not for use in children and adolescents below 18 years of age.

#### Taking other medicines

Tell your doctor if you are taking or have recently taken any other medicines.

**Do not take Quel XR 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.
- Medicines (called anti-cholinergics) that affect the way nerve cells function in order to treat certain medical conditions.

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

If you have any further questions about this you should speak to your doctor.

#### Quel XR with food, drink and alcohol

Quel XR can be affected by food and you should therefore take your tablets at least one hour before a meal or prior to bedtime.

- Be careful how much alcohol you drink. This is because the combined effect of Quel XR and alcohol can make

you sleepy.

- Do not drink grapefruit juice while you are taking Quel XR. 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 planning to have a baby ask your doctor for advice before taking Quel XR. You should not take Quel XR during pregnancy unless this has been discussed with your doctor. Quel XR 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 used Quel XR 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:** Do not drive or use any tools or machines until you know how the tablets affect you because your tablets may make you feel sleepy.

**Effect on Urine Drug Screens:** If you are having a urine drug screen, taking Quel XR 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.

#### Important information about some of the ingredients of Quel XR

Quel XR contains lactose which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

#### How to take Quel XR

Always take Quel XR 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. The maintenance dose (daily dose) will depend on your illness and needs but usually between 150 mg and 800 mg.

- You will take your tablets once a day.
- Do not split, chew or crush the tablets.
- Swallow your tablets whole with a drink of water.
- Take your tablets without food (at least one hour before a meal or at bedtime, your doctor will tell you when).
- Do not drink grapefruit juice while you are taking Quel XR. 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 people:

If you are elderly your doctor may change your dose.

#### Use in children and adolescents:

Quel XR should not be used by children and adolescents aged under 18 years.

#### If you take more Quel XR than you should

If you take more Quel XR than prescribed by your doc-

tor, you may feel sleepy, feel dizzy and experience abnormal heart beats. Contact your doctor or nearest hospital straight away. Take the Quel XR tablets with you.

#### If you forget to take a dose of Quel XR:

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 Quel XR

If you suddenly stop taking Quel XR, you may be unable to sleep (insomnia), or you may feel sick (nausea), or you may experience headache, diarrhea, 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.

#### Possible side effects:

Like all medicines, Quel XR can cause side effects, although not everybody gets them.

#### Very common side effects (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 Quel XR) (may lead to falls).
- Discontinuation symptoms (symptoms which occur when you stop taking Quel XR) 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.
- Abnormal muscle movements. These include difficulty starting muscle movements, shaking, feeling restless or muscle stiffness without pain.
- Changes in the amount of certain fats (triglycerides and total cholesterol).

#### Common side effects (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 more hungry.
- Feeling irritated.
- Disturbance in speech and language.
- Thoughts of suicide and worsening of your depression.
- Shortness of breath.
- Vomiting (mainly in the elderly).
- Fever.
- Changes in the amount of thyroid hormones in your blood.

#### Decreases 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 side effects (may affect up to 1 in 100 people):**
  - Fits or seizures
  - Allergic reactions that may include raised lumps (wheals), swelling of the skin and swelling around the mouth.
  - Unpleasant sensation in the legs (also called restless legs syndrome).
  - Difficulty swallowing
  - Uncontrollable movements, mainly of your face or tongue.
  - Sexual dysfunction.
  - Diabets.
  - 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.
  - Difficulty in passing urine.
  - Fainting (may lead to falls).
  - Stuffy nose.
  - Decrease in the amount of red blood cells.
  - Decrease in the amount of sodium in the blood.
  - Worsening of pre-existing diabetes.

#### Rare side effects (may affect up to 1 in 1,000 people):

- A combination of high temperature (fever), sweating, stiff muscles, feeling very drowsy or faint (a disorder called "neuroleptic malignant syndrome").
- Yellowing of the skin and eyes (jaundice).
- Inflammation of the liver (hepatitis).
- A long-lasting and painful erection (priapism).
- Swelling of breasts and unexpected production of breast milk (galactorrhoea).
- Menstrual disorder.
- 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. If you notice any of these symptoms seek medical advice immediately.
- Walking, talking, eating or other activities while you are asleep.
- Body temperature decreased (hypothermia).
- Inflammation of the pancreas.
- A condition (called "metabolic syndrome") where you may have a combination of 3 or more of the following: an increase in the 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.
- Combination of fever, flu-like symptoms, sore throat, or any other infection with very low white blood cell count,

