

PACKAGE LEAFLET: INFORMATION FOR THE USER

Quettor XL 50 mg prolonged-release tablets
Quettor XL 200 mg prolonged-release tablets
Quettor XL 300 mg prolonged-release tablets
Quettor XL 400 mg prolonged-release 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 Quettor XL is and what it is used for
2. What you need to know before you take Quettor XL
3. How to take Quettor XL
4. Possible side effects
5. How to store Quettor XL
6. Contents of the pack and other information

1. WHAT QUETTOR XL IS AND WHAT IT IS USED FOR

Quettor XL contains a substance called quetiapine. This belongs to a group of medicines called antipsychotics. Quettor XL can be used to treat several illnesses, such as

- Bipolar depression and major depressive episodes in major depressive disorder: where you feel sad or 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 Quettor XL 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 Quettor XL even when you are feeling better.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE QUETTOR XL

Do not take Quettor XL

- 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)
 - medicines for an infection (like **erythromycin** or **clarithromycin**)
 - **nefazodone** (for depression).

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Quettor XL, if

- You, or someone in your family, have or have had any heart problems, for example heart rhythm problems 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 an older person.
- 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 Quettor XL.
- 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 older person with dementia (loss of brain function). If you are, Quettor XL should not be taken because the group of medicines that Quettor XL belongs to may increase the risk of stroke, or in some cases the risk of death, in older 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.

Tell your doctor immediately if you experience any of the following after taking Quettor XL:

- 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 older patients.
- Fits (seizures).
- A long-lasting and painful erection (Priapism).

These conditions can be caused by this type of medicine.

Inform your doctor immediately when you have any of the following symptoms:

- Fever, flu-like symptoms, sore throat or other infection, as the cause of this may be a very reduced number of white blood cells. It may be necessary to discontinue Quettor XL and/or treat the symptoms.
- Constipation with persistent stomach pain or constipation that does not respond to treatment. This may cause a severe intestinal obstruction.

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.

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

Other medicines and Quettor XL

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

Do not take Quettor XL if you are taking any of the following medicines:

- o Some medicines for HIV.
- o Azole medicines (for fungal infections).
- o Erythromycin or clarithromycin (for infections).
- o Nefazodone (for depression).

Tell your doctor if you are taking any of the following medicines:

- o Epilepsy medicines (like phenytoin or carbamazepine).
- o High blood pressure medicines.
- o Barbiturates (for difficulty sleeping).
- o Thioridazine or Lithium (other anti-psychotic medicines).
- o 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).
- o Medicines that can cause constipation.

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

Quettor XL with food, drink and alcohol

- Quettor XL 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 Quettor XL and alcohol can make you sleepy.
- **Do not drink grapefruit juice** while you are taking Quettor XL. 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 Quettor XL during pregnancy unless this has been discussed with your doctor

The following symptoms may occur in newborn babies, of mothers that have used 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 may need to contact your doctor. Quettor XL should not be taken if you are breast-feeding.

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.

Quettor XL contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicinal product.

Effect on Urine Drug Screens

If you are having a urine drug screen, taking Quettor XL 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.

3. HOW TO TAKE QUETTOR XL

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.

Method of administration

- 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 Quettor XL. 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.

Older people

If you are an older person your doctor may change your dose.

Children and adolescents under 18 years

Quettor XL should not be used by children and adolescents aged under 18 years.

If you take more Quettor XL than you should

If you take more Quettor XL than prescribed by your doctor, you may feel sleepy, feel dizzy and experience abnormal heart beats. Contact your doctor or nearest hospital straight away. Take the Quettor XL tablets with you.

If you forget to take Quettor XL

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 Quettor XL

If you suddenly stop taking Quettor XL, you may be unable to sleep (insomnia), or 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.

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 Quettor XL) (may lead to falls).
- Discontinuation symptoms (symptoms which occur when you stop taking Quettor XL) 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.

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 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.

Uncommon (may affect up to 1 in 100 people)

- Fits or seizures.
- Allergic reactions that may include raised lumps (weals), swelling of the skin and swelling around the mouth.
- Unpleasant sensations in the legs (also called restless legs syndrome).
- Difficulty swallowing.
- Uncontrollable movements, mainly of your face or tongue.
- Sexual dysfunction.
- Development of diabetes.
- Change in the 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 urination
- Fainting (may lead to falls).
- Stuffy nose.

Rare (may affect up to 1 in 1000 people)

- A combination of high temperature (fever), sweating, stiff muscles, feeling very drowsy or faint (a disease 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 a type of 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.
- A combination of fever, flu-like symptoms, sore throat or other infection with a very reduced number of white blood cells (a disease called "agranulocytosis").
- Intestinal obstruction.

Very rare (may affect up to 1 in 10,000 people)

- Severe rash, blisters or red patches on the skin.
- A severe allergic reaction (called anaphylaxis) that may cause difficulty in breathing or shock.
- Rapid swelling of the skin, usually around the eyes, lips and throat (angioedema).
- A serious blistering condition of the skin, mouth, eyes and genitals ("Stevens-Johnson syndrome")
- Inappropriate secretion of a hormone that controls urine volume.
- Breakdown of muscle fibres and pain in muscles (rhabdomyolysis).
- Worsening of pre-existing diabetes.

Not known (frequency cannot be estimated from the available data):

- Skin rash with irregular red spots (erythema multiforme).
- Serious, sudden allergic reaction with symptoms such as fever and blisters on the skin and peeling of the skin (toxic epidermal necrolysis)
- Withdrawal symptoms can occur in newborn babies whose mothers have taken Quettor XL during pregnancy.

The class of medicines to which Quettor XL belongs can cause heart rhythm problems, which can be serious and in severe cases 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.

- Men and women to have swelling of breasts and unexpectedly produce breast milk.
- Women to have no monthly period or irregular periods.

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

Children and adolescents

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

The following side effects have been seen more often or only in children and adolescents:

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
- Increase in blood pressure.

Common (may affect up to 1 in 10 people)

- 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 www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE QUETTOR XL

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 and blister after EXP. The expiry date refers to the last day of that month.

For Quettor XL 50 mg:

Do not store above 30°C.

For Quettor XL 200/300/400 mg:

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater. 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 Quettor XL contains

- The active substance is Quetiapine.
- Each tablet contains either 50 mg, 200 mg, 300 mg or 400 mg of quetiapine (as quetiapine fumarate).
- The other ingredients are:

Core

Lactose monohydrate, microcrystalline cellulose, light magnesium oxide, carrageenan, povidone K 30, magnesium stearate

Film-coating

Carrageenan, titanium dioxide (E 171), macrogol 400.

The 50 mg tablets contain additionally: Ferric oxide yellow (E 172) and Ferric oxide red (E 172).

The 200 and 300 mg tablets contain additionally: Ferric oxide yellow (E 172).

Printing:

Opacode S-1-17823 black ink (contains propylene glycol, iron oxide black (E172), shellac glaze)

What Quettor XL looks like and contents of the pack

Quettor XL 50 mg: Light pink to pink colored, capsule shaped, biconvex, prolonged-release tablets, printed with '305' with black ink.

Quettor XL 200 mg: Yellow colored, capsule shaped, biconvex, prolonged-release tablets, printed with '243' with black ink.

Quettor XL 300 mg: Pale yellow colored, capsule shaped, biconvex, prolonged-release tablets, printed with '244' with black ink.

Quettor XL 400 mg: White to off-white, capsule shaped, biconvex, prolonged-release tablets, printed with '245' with black ink.

Pack sizes: 10, 50, 60, 100 prolonged-release tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

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This medicinal product is authorised in the Member States of the EEA under the following names:

Germany: Quetiapin Heumann retard 50/200/300/400 mg Retardtabletten

Lithuania: Quetiapine Torrent 50/200/300/400 mg, paiginto atpalaidavimo tabletet

Romania: Q mind 50/200/300/400 mg comprimate filmate cu eliberare prelungita

United Kingdom: Quettor XL 50/200/300/400 mg, prolonged-release tablets

This leaflet was last revised in 04/2014.

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REMARK : Folding Length 38 mm				
SUBSTRATE :				
Activities	Department	Name	Signature	Date
Prepared By	Pkg.Dev			
Reviewed By	Pkg.Dev			
Reviewed By	RA			
Approved By	CQA			

■ Colour Black



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