

PACKAGE LEAFLET: INFORMATION FOR THE USER

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

1. What Tevaquel XL is and what it is used for

Tevaquel XL contains a substance called quetiapine. This belongs to a group of medicines called anti-psychotics. Tevaquel XL 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 Tevaquel 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 Tevaquel XL even when you feel better.

2. What you need to know before you take Tevaquel XL

Do not take Tevaquel 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)
 - Erythromycin or clarithromycin (for infections)
 - Nefazodone (for depression)

If you are not sure, talk to your doctor or pharmacist before taking Tevaquel XL.

Warnings and precautions

Talk to your doctor or pharmacist before taking Tevaquel XL:

- 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.
- if you have low blood pressure.
- if you have had a stroke, especially if you are elderly.
- if you have problems with your liver.
- if you have ever had a fit (seizure).
- if 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 Tevaquel XL.
- if 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).
- if you are an elderly person with dementia (loss of brain function). If you are, Tevaquel XL should not be taken because the group of medicines that Tevaquel XL belongs to may increase the risk of stroke, or in some cases the risk of death, in elderly people with dementia.
- if you are an elderly person with Parkinson's disease/parkinsonism.
- if 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.
- if 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").
- if 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
- if you have a history of alcohol or drug abuse.

Tell your doctor immediately if you experience any of the following after taking Tevaquel 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.
- 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.
- 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 Tevaquel XL 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 Tevaquel XL 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

Tevaquel XL is not for use in children and adolescents below 18 years of age.

Other medicines and Tevaquel XL

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

Do not take Tevaquel XL 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.

Tevaquel XL with food, drink and alcohol

- Tevaquel 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 Tevaquel XL and alcohol can make you sleepy.

- Do not drink grapefruit juice while you are taking Tevaquel 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 for advice before taking this medicine. You should not take Tevaquel XL during pregnancy unless this has been discussed with your doctor. Tevaquel XL 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 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.

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.

Effect on urine drug screens

If you are having a urine drug screen, taking Tevaquel 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.

Tevaquel XL contains sodium

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

3. How to take Tevaquel 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.

- 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 Tevaquel 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.

Elderly people

If you are elderly your doctor may change your dose.

Use in children and adolescents

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

If you take more Tevaquel XL than you should

If you take more Tevaquel 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. Keep the Tevaquel XL tablets with you.

If you forget to take a dose of Tevaquel 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 Tevaquel XL

If you suddenly stop taking Tevaquel 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.

If you get any of the following serious side effects, stop taking Tevaquel XL and go to your doctor or to the nearest hospital straight away:

Common side effects (may affect up to 1 in 10 people):

- **Thoughts of suicide** and worsening of your depression

Uncommon side effects (may affect up to 1 in 100 people)

- **Sudden fever**, especially with **sore throat** and other **flu-like symptoms**. These can be signs of an abnormal low concentration of white blood cells.
- Signs of **skin reactions** such as skin rash, hives, lumps, redness, itching, maybe with **swelling of the face**, eyelids, and lips. This could additionally lead to difficulty in breathing, dizziness or shock.
- **Fits or seizures**
- **Uncontrollable movements**, mainly of your face or tongue (tardive dyskinesia)
- Feeling your **heart is pounding or racing** together **with dizziness or fainting**. This can be signs of serious heart rhythm problems and in severe cases may be fatal.

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

- Severe **pain** and/or **swelling** and redness **in one of your legs**; sudden **severe pain in the chest** which may reach the left arm or sudden **breathlessness**. These can be signs of blood clots in the veins.
- **Severe upper stomach pain**, often radiating to the back, sometimes together **with nausea and vomiting**. This can be a sign of inflammation of the pancreas.
- **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.
- **Yellowing of the skin and eyes** (jaundice), dark coloured urine, especially together with unusual tiredness or fever (signs of a hepatitis).
- A long lasting and **painful erection**.
- A combination of **fever, sweating, stiff muscles**, feeling very drowsy or faint (a disorder called “neuroleptic malignant syndrome”).

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

- Severe rash, blisters, or red patches on the skin.
- A severe allergic reaction (called anaphylaxis) which 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) See section 2.
- Breakdown of muscle fibers and pain in muscles (rhabdomyolysis).

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

- Skin rash with irregular red spots (erythema multiforme). See section 2.
- Rapid appearance of areas of red skin studded with small pustules (small blisters filled with white/yellow fluid called as Acute Generalized Exanthematous Pustulosis (AGEP). See section 2.
- Serious, sudden allergic reaction with symptoms such as fever and blisters on the skin and peeling of the skin (toxic epidermal necrolysis) See section 2.
- 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) See section 2.
- Disorder of the heart muscle (cardiomyopathy)
- Inflammation of the heart muscle (myocarditis)
- Stroke

Other possible side effects

Do not be concerned if you see a tablet in your stools after taking Tevaquel XL. As the tablet travels the length of your gastrointestinal tract, quetiapine is slowly released. The shape of the tablet remains undissolved and is eliminated in your stools. Therefore, even though you may see a tablet in your stools, your dose of quetiapine has been absorbed.

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 Tevaquel XL) (may lead to falls).
- Discontinuation symptoms (symptoms which occur when you stop taking Tevaquel 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.
- Decreased level of haemoglobin (protein in red blood cells that carry oxygen)
- 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.
- Shortness of breath.
- Vomiting (mainly in the elderly).
- Fever.
- Changes in the amount of thyroid hormones in your blood.
- Changes 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 side effects (may affect up to 1 in 100 people)

- Unpleasant sensations in the legs (also called restless legs syndrome).
- Difficulty swallowing.
- Sexual dysfunction.
- Diabetes.
- 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 sodium in the blood.
- Worsening of pre-existing diabetes
- Confusion

Rare side effects (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).

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

- Inappropriate secretion of a hormone that controls urine volume.

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

- Symptoms of withdrawal may occur in newborn babies of mothers that have used Tevaquel XL during their pregnancy.
- Inflammation of blood vessels (Vasculitis), often with skin rash with small red or purple bumps

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. 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.

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 side effects (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 side effects (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 HPRA Pharmacovigilance website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tevaquel XL

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

Do not use Tevaquel XL after the expiry date which is stated on the container and blister after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture.

Tevaquel XL does not require any special temperature storage conditions.

<For tablet container only>

After first opening of the container, the product should be used within 60 days.

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 Tevaquel XL contains

- The active substance is quetiapine. Tevaquel XL tablets contain 50 mg, 150 mg, 200 mg, 300 mg or 400 mg of quetiapine (as quetiapine fumarate).
- The other ingredients are:

Tablet core: hypromellose, cellulose microcrystalline, sodium citrate anhydrous, magnesium stearate.

Tablet coating: titanium dioxide (E171), hypromellose, macrogol/PEG 400, polysorbate 80. The 50 mg, 200 mg and 300 mg tablets contain Iron Oxide Yellow (E172) and Iron Oxide Red (E172). The 50 mg and 300 mg tablets also contain Iron Oxide Black (E172).

What Tevaquel XL looks like and contents of the pack

- Tevaquel XL 50 mg prolonged-release tablets
Brown, biconvex, oblong film-coated tablets with debossing "Q50" on one side

- Tevaquel XL 150 mg prolonged-release tablets
White, biconvex, oblong film-coated tablets with debossing “Q150” on one side
- Tevaquel XL 200 mg prolonged-release tablets
Yellow, biconvex, oblong film-coated tablets with debossing “Q200” on one side
- Tevaquel XL 300 mg prolonged-release tablets
Light yellow, biconvex, oblong film-coated tablets with debossing “Q300” on one side
- Tevaquel XL 400 mg prolonged-release tablets
White, biconvex oblong film-coated tablets with debossing “Q400” on one side

Packs of 10, 20, 30, 50, 50x1 (perforated unit dose blister) (hospital pack), 56 (calendar pack), 60, 90 and 100 tablets are registered for all strengths. Not all pack sizes may be available.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Austria	Quetiapin ratiopharm
Belgium	Tevaquel XL
Bulgaria	TEVAQUEL XL XR / BG
Czech Republic	Tevaquel XL Retard
Germany	Quetiapin-ratiopharm

Denmark	Tevaquel XL
Estonia	Tevaquel XL
Greece	QUETIAPINE/TEVA XR
Spain	Quetiapina Teva EFG
Finland	Quetiapin ratiopharm
Hungary	Quetiapin XR Teva
Ireland	Tevaquel XL
Italy	Quetiapina Teva Italia
Lithuania	Tevaquel XL
Latvia	Tevaquel XL
Luxembourg	Quetiapin-ratiopharm Retard tabletten
The Netherlands	Quetiapine Retard
Norway	Quetiapin ratiopharm
Poland	Kwetax XR
Portugal	Quetiapina Teva
Romania	Quetiapina Teva
Slovenia	Loquen SR
Slovakia	Quetiapin Teva
United Kingdom	SONDATE XL

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