

Package leaflet: Information for the user

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

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

Setinin XL contains a substance called quetiapine prolonged-release. This belongs to a group of medicines called antipsychotics.

Setinin XL can be used to treat several illnesses, such as:

- Bipolar disorder 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 judgement 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 Setinin 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 Setinin XL even when you feel better.

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

Do not take Setinin 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).

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Setinin XL.

Tell your doctor 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 Setinin 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 elderly person with dementia (loss of brain function). If you are, Setinin XL should not be taken because the group of medicines that Setinin XL 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 a history of alcohol or drug abuse. 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 Setinin 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 and jaw.
- 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 Setinin 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.

Weight gain

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

Children and adolescents

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

Other medicines and Setinin XL

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

Do not take Setinin 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.

Setinin XL with food, drink and alcohol

- Setinin 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 Setinin XL and alcohol can make you sleepy.
- Do not drink grapefruit juice while you are taking Setinin 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 Setinin XL

during pregnancy unless this has been discussed with your doctor. Setinin 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.

Setinin XL contains lactose

Setinin XL contains lactose which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Effect on urine drug screens

If you are having a urine drug screen, taking Setinin 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 Setinin 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 should 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 Setinin 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

Setinin XL should not be used by children and adolescent aged under 18 years.

If you take more Setinin XL than you should

If you take more Setinin 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 Setinin XL tablets with you.

If you forget to take Setinin 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 Setinin XL

If you suddenly stop taking Setinin XL, 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 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 any of the following occurs, stop taking Setinin XL and contact a doctor or go to the nearest hospital straight away, as you may need urgent medical attention:

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.
- Uncontrollable movements, mainly of your tongue, mouth and jaw, but also of arms, legs, fingers and toes, facial grimacing and rapid eye blinking. These might be symptoms of a condition called ‘tardive dyskinesia’.

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

- A combination of high temperature (fever), sweating, stiff muscles, feeling very drowsy or faint, large increase in blood pressure and fast heartbeat (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).
- 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.
- Inflammation of the pancreas (pancreatitis). Symptoms can include severe pain in the abdomen and back, nausea and vomiting.

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

- 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)
- Abnormal muscle breakdown (rhabdomyolysis) with symptoms such as muscle pain, weakness and swelling which can lead to kidney problems (urine can become dark).

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

- Serious, sudden allergic reaction with symptoms such as fever and blisters on the skin and peeling of the skin (toxic epidermal necrolysis).
- Skin rash with irregular red spots (erythema multiforme)
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). Widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome). Stop using Setinin XL if you develop these symptoms and contact your doctor or seek medical attention immediately.

Other possible side effects:

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 Setinin XL) (may lead to falls).
- Discontinuation symptoms (symptoms which occur when you stop taking Setinin 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. Abnormal muscle movements. These include difficulty starting muscle movements, shaking, feeling restless or muscle stiffness without pain.
- Putting on weight.
- Changes in the amount of certain fats (triglycerides and total cholesterol).
- Decreased levels of a certain protein in red blood cells (haemoglobin).

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

- Rapid heartbeat.
- Feeling like your heart is pounding, racing or has skipped beats.
- Shortness of breath.
- Low blood pressure when standing up. This may make you feel dizzy or faint (may lead to falls).
- Constipation, upset stomach (indigestion).
- Vomiting (mainly in the elderly)
- Abnormal dreams and nightmares
- Thoughts of suicide and worsening of your depression
- Feeling more hungry
- Disturbance in speech and language
- 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.
- Blurred vision
- Feeling irritated
- Fever
- Increased levels of liver enzymes measured in the blood
- Changes in the amount of thyroid hormones in your blood
- Decrease in number of certain blood cells
- Increased levels of sugar in the blood
- Feeling weak
- Swelling of arms or legs.

Uncommon (may affect up to 1 in 100 people):

- Unpleasant sensations in the legs (also called restless legs syndrome).
- Difficulty swallowing.
- Change in electrical activity of the heart seen on ECG (QT prolongation)
- Diabetes
- Sexual dysfunction.
- Decreased number of red blood cells (anaemia) or platelets in the blood (thrombocytopenia),
- Decrease in the amount of sodium in the blood (hyponatraemia)
- A slower than normal heart rate which may occur when starting treatment and which may be associated with low blood pressure and fainting.
- Stuffy nose
- Fainting (may lead to falls)
- Difficulty in passing urine
- Worsening of pre-existing diabetes
- Decreases in the number of certain types of blood cells (neutrophils)

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

- Swelling of breasts and unexpected production of breast milk (galactorrhoea).
- Menstrual disorder.
- 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.
- Walking, talking, eating or other activities while you are asleep.
- Body temperature decreases.
- Combination of fever, flu-like symptoms, sore throat or any other infection with very low white blood cell count, a condition called agranulocytosis.
- Bowel obstruction
- Increased blood creatine phosphokinase (a substance from the muscles)

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

- Inappropriate secretion of a hormone that controls urine volume can cause low sodium levels in your blood. That can lead to symptoms such as headache, nausea, confusion and weakness.

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

- Symptoms of withdrawal may occur in newborn babies of mothers that have used quetiapine during their pregnancy.

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

Additional 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 than in adults or have only been seen 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
- Abnormal muscle movements. These include difficulty starting muscle movements, shaking, feeling restless or muscle stiffness without pain.
- Increase in blood pressure

Common (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, pharmacist or nurse. 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 Setinin 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.

Store below 25°C.

Do not use this medicine if you notice the tablets are broken or crumbled.

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 Setinin XL contains

- The active substance is quetiapine prolonged-release. Setinin XL prolonged-release tablets contain 50 mg, 200 mg, 300 mg or 400 mg of quetiapine prolonged-release (as quetiapine fumarate).
- The other ingredients are:
 - Tablet core:* Lactose monohydrate, cellulose (microcrystalline), magnesium oxide, light, carrageenan lambda, povidone (K-30), magnesium stearate.
 - Tablet coating:* Carrageenan lambda, titanium dioxide (E171), macrogol 400, ferric oxide yellow (E172) <[50 mg, 200 mg and 300 mg tablets]>, ferric oxide red (E172) <[50 mg tablets only]>.
 - Printing ink:* Opacode S-1-17823 black ink, containing shellac glaze, iron oxide black (E172), propylene glycol.

What Setinin XL looks like and contents of the pack

Setinin XL prolonged-release tablets are capsule shaped and biconvex.

50 mg tablets are light pink to pink coloured, with dimensions of 12.4 mm x 6.4 mm and printed with '305' on one side with black ink; 200 mg tablets are yellow coloured, with dimensions of 14.3 mm x 7.2 mm and printed with '243' on one side with black ink; 300 mg tablets are pale yellow coloured, with dimensions of 17.9 mm x 7.0 mm and printed with '244' on one side with black ink. 400 mg tablets are white to off-white coloured, with dimensions of 22.1 mm x 8.9 mm and printed with '245' on one side with black ink.

Pack sizes:

Blister packs: 10, 60 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Actavis Group PTC ehf.
Reykjavíkurvegi 76-78
220 Hafnarfjörður
Iceland

Manufacturer

Balkanpharma-Dupnitsa AD
3, Samokovsko shosse Str.,
2600 Dupnitsa
Bulgaria

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

Portugal	Quetiapina Aurovitas
Denmark	Quetiapin Actavis
Ireland	Setinin XL 50 / 200 / 300 / 400 mg Prolonged-release Tablets
Italy	Quetiapina Aurobindo Pharma Italia
Norway	Quetiapin Actavis
Romania	Setinin 50 / 200 / 300 / 400 mg comprimate cu eliberare prelungită
Spain	Quetiapina Aurovitas 50 / 200 / 300 /400 mg comprimidos de liberación prolongada EFG
United Kingdom	Tenprolide XL 50 / 200 / 300 / 400 mg Prolonged-release Tablets

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