Package leaflet: Information for the user

Seroquel® XR 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 Seroquel XR is and what it is used for
2. What you need to know before you take Seroquel XR
3. How to take Seroquel XR
4. Possible side effects
5. How to store Seroquel XR
6. Contents of the pack and other information

1. What Seroquel XR is and what it is used for

Seroquel XR contains a substance called quetiapine. This belongs to a group of medicines called anti-psychotics. Seroquel XR can be used to treat several illnesses, such as:
- Bipolar depression and major depressive episodes in major depressive disorder: where you may 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 Seroquel 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 Seroquel XR even when you are feeling better.

2. What you need to know before you take Seroquel XR

Do not take Seroquel XR:
- 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 Seroquel XR.

Warnings and precautions
Talk to your doctor or pharmacist before taking Seroquel 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.
- 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 Seroquel XR.
- 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, Seroquel XR should not be taken because the group of medicines that Seroquel XR 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.
- if you have depression or other conditions that are treated with antidepressants. The use of these medicines together with Seroquel XR can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Seroquel XR").

<u>Tell your doctor immediately if you experience any of the following after taking Seroquel XR:</u>
- 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).
- 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.

These conditions can be caused by this type of medicine.

<u>Tell your doctor as soon as possible if you have:</u>
- 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 Seroquel 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 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 Seroquel XR if you develop these symptoms and contact your doctor or seek medical attention immediately.

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

Children and adolescents
Seroquel XR is not for use in children and adolescents below 18 years of age.

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

Do not take Seroquel 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.
- Anti-depressants. These medicines may interact with Seroquel XR and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C (serotonin syndrome). Contact your doctor when experiencing such symptoms.

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

Seroquel XR with food, drink and alcohol
- Seroquel 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 Seroquel XR and alcohol can make you sleepy.
- Do not drink grapefruit juice while you are taking Seroquel 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 this medicine. You should not take Seroquel XR during pregnancy unless this has been discussed with your doctor. Seroquel 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 Seroquel 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.

Seroquel XR contains lactose
Seroquel 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.

Seroquel XR contains sodium
Seroquel XR 400 mg prolonged-release tablets contain 27 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 1.35% of the recommended maximum daily dietary intake of sodium for an adult.

Effect on Urine Drug Screens
If you are having a urine drug screen, taking Seroquel 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.

3. How to take Seroquel XR

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

If you take more Seroquel XR than you should
If you take more Seroquel XR 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 Seroquel XR tablets with you.

If you forget to take Seroquel 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 Seroquel XR
If you suddenly stop taking Seroquel XR, 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 any of the following side effects get serious, or if you notice side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 Seroquel) (may lead to falls).
- Discontinuation symptoms (symptoms which occur when you stop taking Seroquel) 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: 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 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: 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.
- Diabetes.
- 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.
- Confusion.

Rare: 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 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, 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
- 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.
- Inappropriate secretion of a hormone that controls urine volume.
- 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.
- Symptoms of withdrawal may occur in newborn babies of mothers that have used Seroquel XR during their pregnancy.
- Stroke.
- Disorder of the heart muscle (cardiomyopathy).
- Inflammation of the heart muscle (myocarditis).
- Inflammation of blood vessels (vasculitis), often with skin rash with small red or purple bumps.

The class of medicines to which Seroquel XR 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 or have not been seen in adults:

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via
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 Seroquel XR

- 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.
- This medicine does not require any special storage conditions.
- 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 Seroquel XR contains
- The active substance is quetiapine. Seroquel XR tablets contain 400 mg of quetiapine (as quetiapine fumarate).
- The other ingredients are:
  Tablet core: microcrystalline cellulose, sodium citrate, lactose monohydrate, magnesium stearate, hypromellose.
  Tablet coating: hypromellose, macrogol, titanium dioxide (E171).

What Seroquel XR looks like and contents of the pack
Prolonged-release tablets are capsule shaped and marked with XR and the strength. 400 mg tablets are white coloured.
Pack size of 60 tablets.

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder:
PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

Manufacturer
Klocke Pharma-Service GmbH, Straßburger Str. 77, 77767 Appenweier, Germany.

Parallel Product Authorisation Numbers:
Seroquel XR 400 mg prolonged-release tablets- PPA0465/438/007

Seroquel is a registered trademark of Cheplapharm Arzneimittel GmbH.

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

COUNTRY	TRADE NAME
Austria	Seroquel XR
Belgium	Seroquel XR
Croatia	Seroquel XR
Cyprus	Seroquel XR
Denmark	Seroquel Prolong
Estonia	Seroquel XR
Finland	Seroquel Prolong
France	Xeroquel LP
Germany	Seroquel Prolong® 50 mg Retardtabletten
	Seroquel Prolong® 150 mg Retardtabletten
	Seroquel Prolong® 200 mg Retardtabletten
	Seroquel Prolong® 300 mg Retardtabletten
	Seroquel Prolong® 400 mg Retardtabletten
Greece	Seroquel XR
Hungary	Seroquel XR
Iceland	Seroquel Prolong
Ireland	Seroquel XR
Italy	Seroquel compresse a rilascio prolungato
Latvia	Seroquel XR
Lithuania	Seroquel XR
Luxembourg	Seroquel XR
Netherlands	Seroquel XR
	Quetiapine XR AstraZeneca
Norway	Seroquel Depot
Portugal	Seroquel SR
Slovakia	Seroquel XR
Slovenia	Seroquel SR
Spain	Seroquel Prolong
Sweden	Seroquel Depot
United Kingdom	Seroquel XL

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