

SEROQUEL XR EXTENDED RELEASE TABLET

Quetiapine Fumarate (50mg, 200mg, 300mg, 400mg)

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What Seroquel XR is used for

Seroquel XR can be used to treat:

- Adults with schizophrenia, a disease with symptoms, such as hallucinations (for example unexplained voices), strange and frightening thoughts, changes in behaviour, feeling alone and confused.
- Adults with bipolar disorder, either in a moderate to severe manic or in a major depressive state. In a manic state people may find they are more talkative and have racing thoughts or ideas whereby they feel 'high' or excited. They may also feel unusually irritable, sad and guilty, lack energy, lose their appetite and/or can't sleep. Whereas depressed adults who do not feel high or excited, these individuals have prolonged periods of feeling sad, lack energy, are often tearful, and have changes in sleep or appetite.
- Seroquel XR can be used to prevent relapse in individuals with schizophrenia whose condition has been stabilized.
- Seroquel XR can be used to prevent relapse in individuals with bipolar disorder whose moderate to severe manic or major depressive episodes were successfully treated with quetiapine.
- Seroquel XR can be used to treat recurrent major depressive disorder in individuals for whom other antidepressant treatments are

not suitable (either because they do not work well or because of side effects).

Your doctor may continue to give you Seroquel XR even when you are feeling better to prevent your symptoms from returning.

How Seroquel XR works Seroquel XR contains quetiapine fumarate. Seroquel XR belongs to a group of medicines called antipsychotics. It helps to correct chemical imbalances in the brain.

Before you use Seroquel XR

- When you must not use it Do not take Seroquel XR if you have ever had an allergic reaction to Seroquel XR or to any of its ingredients (see section Product Description).

Do not take Seroquel XR if you are taking any of the following medicines:

- HIV-protease inhibitor for Human Immunodeficiency Virus (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.

- Before you start to use it Take special care with Seroquel XR. If you go into hospital let the medical staff know you are taking Seroquel XR. Tell your doctor:

- if you have any health problems
- if you are at risk for lung inflammation that occurs after you inhale foreign matter
- if you have rare hereditary sugar intolerance problems
- if you have low blood pressure or have had a stroke
- if you or a family member have a history of any problems with the way your heart beats or have a history of heart disease or heart problems or if you are taking any medicines that may have an impact on the way your heart beats

- if you have problems with your liver
- if you know that you had a low white blood cell count in the past which may or may not have been caused by other medicines
- if you have ever had a seizure (fit).
- if you are an elderly person with dementia (loss of brain function). It has been reported that elderly individuals with dementia-related psychosis are at an increased risk of death compared to people who do not receive antipsychotic medicines.
- if you have diabetes, or you are at risk for diabetes (e.g. family history of diabetes, high blood sugar during pregnancy, obesity) (see also Things to be careful of)
- if you have a history of alcohol or drug abuse
- 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 had a condition where you cannot 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 "anticholinergics") that affect the way nerve cells function in order to treat medical conditions
- 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 also Taking other medicines)

Pregnancy and breast feeding

Tell your doctor if you are pregnant, think that you may be pregnant or are planning to become pregnant.

The following *extrapyramidal* and/or *withdrawal symptoms* may occur in newborn babies, of mothers that have used Seroquel XR in the last trimester (last three months of their pregnancy): agitation, muscle stiffness and/or weakness, shaking, sleepiness, breathing

problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

Avoid this medicine if you are breast-feeding. This is because the medicine may pass into the mother's milk.

Ask your doctor for advice before taking any medicine if you are pregnant or breast-feeding.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, or about to stop taking, any other medicines including those, which you may have bought without prescription particularly:

- medicines listed under *When you must not use it*
- grapefruit juice
- antidepressants. 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
- thioridazine, for mental illness
- medicines for epilepsy (such as phenytoin or carbamazepine)
- medicines for high blood pressure
- medicines (called "anticholinergics") that affect the way nerve cells function in order to treat certain medical conditions
- medicines that cause constipation
- barbiturates (for sleeplessness)

Please note that these statements may also apply to products used some time ago.

How to use Seroquel XR

- How much to use

Follow your doctor's instructions about when and how to take your tablets. Please READ THE LABEL on the container. This will also tell you how many tablets to take and when you should take them. Ask your doctor, nurse or pharmacist if you are not sure.

Seroquel XR is usually started as a low dose that will be monitored and gradually increased by your doctor. For maintenance dose, your doctor may adjust your daily dose of Seroquel XR between 50 mg and 800 mg depending on your disease, age, and individual treatment and needs.

If you have liver disease, or you are elderly, your doctor may start you on a lower dose and increase it more gradually.

Seroquel XR is not approved for children or adolescents under 18 years of age.

- When to use it

You will take your tablets once a day. Take your tablets without food (at least one hour before a meal or at bedtime, your doctor will tell you when). Swallow your tablets whole with a drink of water. Do not split, chew or crush the tablets.

- How long to use it

Continue taking the tablets for as long as your doctor tells you. Seroquel XR helps control your condition, but does not cure it. Therefore, you must take it every day.

- If you forget to use it

If you miss a dose, take the dose as soon as you remember. Then take the next dose at the usual time. Do not take a double dose.

- If you use too much (overdose)

If you take more than your normal dose, contact a doctor or the nearest hospital, immediately. Symptoms of an overdose may include: drowsiness and sedation, rapid heartbeat and low blood pressure.

While you are using it

- Things you must do

If you have the impression that the effect of Seroquel XR is too strong or too weak, talk to your doctor or pharmacist. If you become pregnant while taking it, tell your doctor immediately.

- Things you must not do

Do not stop taking your tablets even if you are feeling better, unless your doctor tells you. If your doctor decides that you need to stop taking Seroquel XR, he/she will reduce the dose gradually over a period of at least one to two weeks.

If you stop taking Seroquel XR abruptly you may experience nausea, vomiting or insomnia (sleeping difficulty), headache, diarrhoea, dizziness and irritability.

- Things to be careful of

Driving and using machines

Your tablets may make you feel sleepy. This may disappear while you continue taking your tablets. Even so, you should not drive or use machinery until you know how these tablets affect you.

Effect on Urine Drug Screens If you are having a urine drug screen, taking Seroquel XR may cause positive results for methadone or certain medicines for depression called tricyclic antidepressants (TCAs) when some test methods are used, even though you may not be taking methadone or TCAs. Confirmation of the results by more specific tests is recommended.

Diabetes

If you suffer from a high level of sugar in the blood (diabetes) your doctor may regularly check your level of sugar in the blood.

Pancreatitis Pancreatitis

(inflammation of the pancreas) has been reported in some individuals. Many of these individuals also had factors which are known to be associated with pancreatitis such as increased triglyceride levels (a fatty substance in the blood), gallstones, and alcohol consumption.

Thoughts of suicide and worsening of your depression or other mental illnesses

If you are depressed and/or have other mental illnesses 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 first few weeks but

sometimes longer. You may be more likely to think like this if:

- You have previously had thoughts about killing or harming yourself.
- You are a child, teenager or young adult. Information from clinical trials has shown an increased risk of suicidal thoughts and/or suicidal behaviour in children, teenagers, or young adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

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 or have other mental illnesses, and ask them to read this leaflet. You might ask them to tell you if they think your depression or mental illness is getting worse, or if they are worried about changes in your behaviour.

Severe cutaneous adverse reactions (SCARs)

Severe skin related adverse reactions including Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), Acute Generalized Exanthematous Pustulosis (AGEP), Erythema Multiforme (EM) and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) which can be life threatening, have been reported with the use of this medicine. These serious skin reactions may present with one or more combination of the following symptoms: widespread blistering (may be filled with pus) or peeling of the skin, flu like symptoms, blood abnormalities (increase in a type of white blood cells), swollen glands (enlarged lymph nodes) or itchy skin rash with pink-red irregular spots.

Stop using Seroquel XR if you develop these symptoms and contact your doctor or seek medical attention immediately.

Side effects

Like all medicines Seroquel XR can have side effects. Tell your doctor if any of the following side effects bothers you. Contact your doctor immediately or go to the nearest

hospital if any of the following events happen to you.

- A combination of fever, very marked drowsiness, muscle stiffness, marked increase in blood pressure or heartbeats and reduced consciousness (a disorder called “neuroleptic malignant syndrome”)
- Fits (seizures)
- Priapism (long-lasting and painful erection)
- Involuntary movements, mainly of your face or tongue (Tardive dyskinesia)

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 Seroquel 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.

Side effects that are very common (more than 10 of every 100 individuals are likely to have them):

- Dizziness (may lead to falls)
 - Feeling sleepy (this may go away whilst you continue taking your tablets) (may lead to falls)
 - Dry mouth
 - Headache
 - Weight gain
 - You may have abnormal muscle movements, including difficulty starting muscle movements, shaking, restlessness or muscle stiffness without pain.
- Discontinuation symptoms (i.e., symptoms which occur upon stopping Seroquel XR) include vomiting, dizziness, nausea, headache, diarrhoea, insomnia and irritability. Gradual withdrawal over a period of at least 1 to 2 weeks is advisable).

Side effects that are common (1 to 10 of every 100 individuals are likely to have them):

- Rapid heart beat
- Feeling like your heart is pounding, racing or has skipped beats
- Constipation
- Indigestion

- Feeling weak
- Swelling of arms or legs
- Low blood pressure in standing position, which may result in dizziness or feeling faint (may lead to falls)
- Blurred vision
- Abnormal dreams and nightmares
- Irritability
- Increased appetite
- Disturbance in speech
- Shortness of breath
- Vomiting (mainly in the elderly)
- Fever

Side effects that are uncommon (less than 1 of every 100 individuals are likely to have them):

- Allergic reactions that may include weals and swelling of the skin
- Fits (seizures)
- Restless legs syndrome (unpleasant leg sensations and an intense urge to move the legs)
- Difficulty swallowing
- Fainting (may lead to falls)
- Runny or stuffy nose (inflammation of nose mucous membrane)
- A slower than normal heart rate which may occur when starting treatment and which may be associated with low blood pressure and fainting.
- Urinary retention (difficulty or inability to pass urine)
- Sleep apnoea (trouble breathing during sleep)
- Confusion

Side effects that are rare (less than 1 of every 1000 individuals are likely to have them):

- Combination of fever, very marked drowsiness, muscle stiffness, marked increase in heartbeats or blood pressure and reduced consciousness (a disorder called “neuroleptic malignant syndrome”)
- Men and women to have swelling of breasts and unexpectedly produce breast milk.
- Priapism (long-lasting and painful erection)
- Walking, talking, eating or other activities while you are asleep
- Body temperature decreased (hypothermia)
- Inflammation of the liver (with or without jaundice)

Side effects that are very rare (less than 1 of every 10000 individuals are likely to have them):

- Anaphylaxis (severe form of allergic reaction; may include severe difficulty breathing and shock)

Side effects that are of unknown frequency (cannot be estimated from the available data):

- Combination of widespread rash, high body temperature, blood abnormalities (liver enzyme elevations, increase in a type of white blood cells sometimes seen in allergic reactions) and enlarged lymph nodes (a condition called “drug reaction with eosinophilia and systemic symptoms”) may occur.
- 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)) and a severe form of skin rash with itchy pink-red irregular spots (a condition known as Erythema multiforme (EM)) may occur.
- Formation of a gum like sticky mass of tablets in the stomach may occur only when you take more Seroquel XR than you should. Please contact your doctor immediately as it may require endoscopy for removal of the sticky mass.
- 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

If you have any of the above side effects contact your doctor.

The following side effects can also occur with Seroquel XR, and may be seen when a blood test is taken:

- Decrease in the amount of white blood cells. These changes will normally disappear when stopping the treatment of Seroquel XR.
- Decrease in the amount of red blood cells. These are the cells that transport oxygen throughout the body.

- Increase in the amount of eosinophils. These are a type of white blood cell sometimes seen in allergic reactions.
- ‘Thrombocytopenia’, a decrease in platelets, which are cells that help you stop bleeding if you get a cut
- Increase in the amount of liver enzymes. These changes will normally disappear when continuing the treatment of Seroquel XR.
- Changes in the amount of fatty substances (lipid levels such as triglycerides and cholesterol) in the blood.
- Increase in the amount of ‘creatinine phosphokinase’, a substance in the muscles.
- Increase in blood sugar level and/or symptoms of high blood sugar (e.g. increased thirst, increased hunger, and frequent urination).
- Increase in the amount of hormone prolactin in the blood. Rarely this may lead to:
 - Men and women to have swelling of breasts and unexpectedly produce breast milk.
 - Women to have no monthly period or irregular periods.
- Changes in the amount of thyroid hormones in your blood. These changes usually do not affect how you feel.

Children and adolescents (10 to 17 years of age)

Side effects that have occurred in clinical trials of Seroquel in children and adolescents (10 to 17 years of age). Tell your doctor if any of the following side effects bothers you:

Side effects that are very common (more than 10 of every 100 individuals are likely to have them): •

- Increase in blood pressure
- Increase in the amount of the hormone prolactin in the blood. Rarely this may lead to:
 - 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

Side effects that are common (1 to 10 of every 100 individuals are likely to have them):

- Runny or stuffy nose (inflammation of nose mucous membrane)
- Fainting (may lead to falls)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist as soon as possible.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03- 78835490, or visiting the website npra.gov.my [Consumers  Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Seroquel XR

- Storage

- Keep your Seroquel XR tablets out of the reach and sight of children. Your tablets could harm them.
- Do not store above 30°C.

- Disposal

- Medicines should not be disposed of via wastewater or household waste.
- Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.
- Do not take your tablets after the expiry date on the container. Return all out of date tablets to your pharmacist.

Product Description

- What it looks like

Seroquel XR tablets come in four strengths:

- **50 mg:** Peach, film-coated, capsule shaped, biconvex, intagliated tablet with ‘XR50’ on 1 side and plain on the other.
- **200 mg:** Yellow, film-coated, capsule shaped, biconvex, intagliated tablet with ‘XR200’ on 1 side and plain on the other.
- **300 mg:** Pale yellow, film-coated, capsule shaped, biconvex, intagliated tablet with ‘XR300’ on 1 side and plain on the other.

- 400 mg: White, film-coated, capsule shaped, biconvex, intagliated tablet with 'XR400' on 1 side and plain on the other.

Seroquel XR tablets come in blister packs containing 60 tablets in strips of 10 tablets.

- Ingredients

- Active ingredient(s) The active substance is quetiapine.

- Inactive ingredients The other ingredients are hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, sodium citrate, titanium dioxide (E171). The 50 mg, 200 mg and 300 mg tablets also contain iron oxide (E172).

-MAL numbers:

50mg: MAL09011462ACRZ
200mg: MAL09011463ACRZ
300mg: MAL09011464ACRZ
400mg: MAL09011465ACRZ

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Date of revision

10/03/2025

Serial Number

NPRA (R1/5) 06012022/011