

SEROQUEL TABLET

Quetiapine Fumarate (25mg, 100mg, 200mg, 300mg)

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What Seroquel is used for Seroquel can be used to treat schizophrenia in people 13 years of age or older with symptoms, such as hallucinations (for example unexplained voices), strange and frightening thoughts, changes in behaviour, feeling alone and confused.

Seroquel can also be used to treat adults with Bipolar Disorder, either in a manic or in a depressed 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. In a depressed state individuals with this condition may feel sad or depressed, feel guilty, lack energy, lose their appetite and/or can't sleep.

Seroquel can also be used to treat manic episodes associated with bipolar disorder in children ages 10 to 17 years old.

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

How Seroquel works

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

Before you use Seroquel

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

Do not take Seroquel 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.

- Before you start to use it Take special care with Seroquel. If you go into hospital let the medical staff know you are taking Seroquel. 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 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 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 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 "anti-cholinergics") that affect the way nerve cells function in order to treat certain medical conditions.
- medicines that caused constipation
- barbiturates (for sleeplessness)

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

How to use Seroquel

- 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 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 between 150 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 is not approved for children or adolescents under 18 years of age with Bipolar Depression and children with schizophrenia.

- When to use it

You will take your tablets once a day, at bedtime or twice a day, or three times a day where needed depending on your illness. Try to take the tablets at the same time each day.

It does not matter if you take Seroquel before or after your food. Swallow your tablets whole with a drink of water.

- How long to use it

Continue taking the tablets for as long as your doctor tells you. SEROQUEL 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 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, he/she will reduce the dose gradually over a period of at least one to two weeks.

If you stop taking Seroquel 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 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 if you develop these symptoms and contact your doctor or seek medical attention immediately.

Side effects

Like all medicines Seroquel can have side effects. The same side effect that occur in adults may also occur in children and adolescents. 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 include vomiting, dizziness, nausea, headache, diarrhoea, insomnia, and irritability. Gradual withdrawal over a period of at least 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.

- 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, 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.
- 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.
- 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 the 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

- Storage
 - Keep your Seroquel 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 tablets come in four strengths:

 - *25 mg tablet*: round, 6 mm, peach coloured, biconvex, film-coated.
 - *100 mg tablet*: round, 8.5 mm, yellow coloured, biconvex, film-coated.
 - *200 mg tablet*: round, 11 mm, white, biconvex, film-coated.

Seroquel 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 povidone, calcium hydrogen phosphate, microcrystalline cellulose, sodium starch glycollate Type A, lactose monohydrate, magnesium stearate, hypromellose, macrogol, titanium dioxide (E171), ferric oxide, yellow (E172) (25 mg, 100 mg, 150 mg and 400 mg tablets), ferric oxide, red (E172) (25 mg tablets)

- MAL numbers:

25mg: MAL20000261ACZ
100mg: MAL20000262ACZ
200mg: MAL20000263ACZ

Manufacturer

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