

PATIENT INFORMATION LEAFLET

Seroquel 25mg, 100mg, 200mg, 300mg tablet

Quetiapine fumarate

Please read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What Seroquel is used for

Seroquel can be used to treat several illnesses, such as:

- 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.
- Mania: where you may feel very excited, elated, agitated, enthusiastic or hyperactive or have poor judgment including being aggressive or disruptive.
- Bipolar depression: where you may feel sad all the time or you may find that you feel depressed, feel guilty, lack energy, lose your appetite or can't sleep.

Your doctor may continue to prescribe Seroquel even when you are feeling better.

How Seroquel works

Seroquel contains a medicine called quetiapine. This belongs to a group of medicines called anti-psychotics.

Before you take Seroquel

When you must not take it

- You are allergic (hypersensitive) to quetiapine or any of the other ingredients of Seroquel.
- you are taking any of the following medicines:
 - protease inhibitors, such as nelfinavir (for HIV infection)
 - azole medicines (for fungal infections)
 - medicines for an infection (like erythromycin or clarithromycin)
 - nefazodone (for depression).

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

Before you start to take it

Before you take your medicine, tell your doctor if:

- You, or someone in your family, have or have had any heart problems such as a very fast heart beat or prolonged QT on an ECG (heart tracing), 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.
- You have problems with your liver.
- You have ever had a fit (seizure).
- 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 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.
- You are an elderly person with dementia. If you are, Seroquel should not be taken because the group of medicines that Seroquel 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.

Tell your doctor immediately if you experience:

- 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 feeling very drowsy. 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.

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

Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines because it may affect the way the medicines work. This includes medicines that you buy without a prescription and herbal medicines.

In particular, tell your doctor if you are taking any of the following medicines:

- Epilepsy medicines (like phenytoin or carbamazepine).
- High blood pressure medicines.
- Rifampicin (for tuberculosis).
- Barbiturates (for difficulty sleeping).

- Thioridazine (another anti-psychotic medicine).
- Medicines that affect the heart, for example, drugs that can cause an imbalance in some of the chemicals in your blood such as diuretics (water pills) or certain antibiotics.

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

If you have a urine drug screen, taking Seroquel could cause positive results for methadone or drugs for depression called tricyclic antidepressants (TCAs), even though you may not be taking methadone or TCAs. The result will need to be confirmed by a more specific test.

How to take Seroquel

How much to take

Always take Seroquel exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Your doctor will decide on your starting dose and may gradually increase it. When you are on your regular dose you will usually be taking between 150 mg and 800 mg each day. It will depend on your illness and needs.

Seroquel tablets come in 4 different strengths and each strength is a different colour or shape. Even though the dose might stay the same, it might be supplied as different strength tablets.

So don't be surprised if the colour of your tablets changes from time to time.

Liver problems

If you have liver problems your doctor may give you a lower dose.

Elderly people

If you are elderly your doctor may give you a lower dose.

Children and adolescents under 18 years

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

When to take it

You will take your tablets once a day, at bedtime or twice a day, depending on your illness. Swallow your tablets whole with a drink of water.

How long to take it

Do not stop taking your tablets even if you feel better, unless your doctor tells you.

If you forget to take it

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 dose.

If you stop taking Seroquel

If you suddenly stop taking Seroquel, 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 product, ask your doctor or pharmacist.

If you take too much (overdose)

If you take more Seroquel than prescribed by your doctor, you may feel sleepy, feel faint or dizzy and have palpitations (a pounding heart beat). Contact your doctor or nearest hospital straight away. Take the Seroquel tablets with you.

While you are using Seroquel

Things you must do

Follow your doctor/psychiatrist advice and continue taking the medication

Things you must not do

Do not drive or use any tools or machines until you know how the tablets affect you.

Things to be careful of

Taking Seroquel with food and drink

Seroquel can be taken with or without food.

Be careful how much alcohol you drink. This is because the combined effect of Seroquel and alcohol can make you feel sleepy.

Do not drink grapefruit juice while you are taking Seroquel. It can affect the way the medicine works.

Pregnancy and breast-feeding

If you are pregnant, trying to get pregnant, or breast-feeding, talk to your doctor before taking Seroquel.

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.

Hospital - If you go into hospital, tell the medical staff that you are taking Seroquel.

Important information about some of the ingredients of Seroquel

Seroquel contains lactose which is a type of sugar. If you have been told by your doctor or pharmacist that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine.

Side effects

Like all medicines, Seroquel can cause side effects, although not everybody gets them.

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

Uncommon (affects less than 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 face or tongue (Tardive dyskinesia).

Rare (affects less than 1 in 1,000 people):

- A combination of high temperature (fever), sweating, stiff muscles, feeling very drowsy or faint, large increase in blood pressure or heartbeat (a disorder called "neuroleptic malignant syndrome").
- Jaundice (yellowing of the skin and eyes).

- Hepatitis (inflammation of the liver).
- Priapism (a long-lasting and painful erection).
- 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.

Very rare (affects less than 1 in 10,000 people):

- Severe allergic reaction that may include difficulty in breathing, dizziness and collapse.
- Rapid swelling of the skin, usually around the eyes, lips and throat.

Other possible side effects:

Very common (affects 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.

Common (affects less than 1 in 10 people):

- Rapid heartbeat or fainting.
- Feeling like your heart is pounding, racing or has skipped beats.
- Stuffy nose.
- Indigestion or constipation.
- Feeling weak (may lead to falls).
- Swelling of arms or legs.
- High blood sugar.
- Low blood pressure when standing. This may make you feel dizzy or faint (may lead to falls).
- Blurred vision.
- Abnormal muscle movements. These include difficulty starting muscle movements, shaking, feeling restless or muscle stiffness without pain.
- Abnormal dreams and nightmares.
- Feeling more hungry.
- Feeling irritated.
- Disturbance in speech or language.
- Shortness of breath.
- Vomiting (mainly in the elderly).
- Fever.

Uncommon (affects less than 1 in 100 people):

- Restless legs.
- Difficulty swallowing.
- Sexual dysfunction.

Rare (affects less than 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).

Very rare (affects less than 1 in 10,000 people):

- Worsening of pre-existing diabetes.
- A severe rash, blisters or red patches on the skin.
- Inappropriate secretion of a hormone that controls urine volume.
- Breakdown of muscle fibres and pain in muscles (rhabdomyolysis).

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, decreases in the number of certain types of blood cells, decreases in the amount of sodium in the blood, changes in the amount of thyroid hormones in the blood, increased blood creatine phosphokinase (a substance in the muscles) 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 the 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.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Children and adolescents

The same side effects that may occur in adults may also occur in children and adolescents.

The following side effect has been seen only in children and adolescents:

Very Common (affects more than 1 in 10 people):

- Increase in blood pressure.

The following side effects have been seen more often in children and adolescents:

Very Common (affects 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.
- Abnormal muscle movements. These include difficulty starting muscle movements, shaking, feeling restless or muscle stiffness without pain.

Storage and Disposal of Seroquel

Keep your Seroquel tablets in the original pack and do not store above 30°C.

Keep your Seroquel tablets in a safe place, where children cannot see or reach them.

Do not take your tablets after the expiry date which is stated on the container. The expiry date refers to the last day of that month.

Product description

- 25 mg tablet: round, 6 mm, peach coloured, biconvex, film-coated tablet containing quetiapine fumarate delivering a dose of 25 mg of quetiapine free base.
- 100 mg tablet: round, 8.5 mm, yellow coloured, biconvex, film-coated tablet containing quetiapine fumarate delivering a dose of 100 mg of quetiapine free base.

- 200 mg tablet: round, 11 mm, white, biconvex, film-coated tablet containing quetiapine fumarate delivering a dose of 200 mg of quetiapine free base.
- 300 mg tablet: capsule shaped, 19 mm x 7.62 mm, white, film-coated tablet containing quetiapine fumarate delivering a dose of 300 mg of quetiapine free base.

The following packs are available:

25 mg film-coated tablets (coloured peach) 60 tablet pack;
100 mg film-coated tablets (coloured yellow) 60 tablet pack;
200 mg film-coated tablets (coloured white) 60 tablet pack; and
300 mg film-coated tablets (coloured white) 60 tablet pack.

Ingredients

- Seroquel tablets contain 25 milligrams (mg), 100 mg, 200 mg or 300 mg of quetiapine fumarate. Quetiapine fumarate is the active medicine.
- The other ingredients are calcium hydrogen phosphate dihydrate, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, sodium starch glycollate and titanium dioxide. The 25 mg and 100 mg tablets also contain ferric oxide.

Malaysian registration numbers:

Seroquel 25mg: MAL20000261A
Seroquel 100mg: MAL20000263A
Seroquel 200mg: MAL20000264A
Seroquel 300mg: MAL06041484A

Manufacturer

AstraZeneca UK Limited, Macclesfield, Cheshire, United Kingdom

Date of revision

The text was revised in September 2011

CNS.000-340-262.2.0