

PACKAGE LEAFLET: INFORMATION FOR THE USER

Seroquel[®] 25 mg, 100 mg, 200 mg and 300mg Film-coated Tablets Quetiapine

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.

In this leaflet:

1. What Seroquel is and what it is used for
2. Before you take Seroquel
3. How to take Seroquel
4. Possible side effects
5. How to store Seroquel
6. Further information

1. WHAT SEROQUEL IS AND WHAT IT IS USED FOR

Seroquel contains a substance called quetiapine. It belongs to a group of medicines called antipsychotics. Seroquel can be used to treat several illnesses such as:

- Bipolar depression: 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.

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

2. BEFORE YOU TAKE SEROQUEL

Do not take Seroquel if;

You are allergic (hypersensitive) to quetiapine or any of the other ingredients of Seroquel (See section 6: Further information).
You are taking any of the following medicines:

- Some medicines for HIV
- Azole medicines (for fungal infections)
- erythromycin or clarithromycin (for infections)
- nefazadone (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.

Take special care with Seroquel

Before you take your medicine, tell your doctor if;

- You or someone in your family have or have had any heart problems, for example heart rhythm problems 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 Seroquel.
- 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, 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 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.

Thoughts of suicide and worsening of your depression

If you are depressed you may sometimes have thought of harming or killing yourself. These maybe 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 has been seen in patients taking Seroquel. You and your doctor should check your weight regularly.

Taking other medicines

Please tell your doctor 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 prescription and herbal medicines.

Do not take Seroquel 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 (another anti-psychotic medicine),
- 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).

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

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 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. You should not take Seroquel during pregnancy unless this has been discussed with your doctor. Seroquel should not be taken if you are breast-feeding.

The following symptoms 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.

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 that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

Effect on Urine Drug Screens

If you are having a urine drug screen, taking Seroquel 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

Always take Seroquel exactly as your doctor has told you. You should check with you 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, at bedtime or twice a day, depending on your illness.
- Swallow your tablets whole with a drink of water.
- You can take your tablets with or without food.
- Do not drink grapefruit juice while you are taking Seroquel. 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

Children and adolescents

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

If you take more Seroquel than you should

If you take more Seroquel 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 tablets with you.

If you forget to take a dose of Seroquel

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), 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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Seroquel 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 (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.
- Feeling like your heart is pounding, racing or has skipped beats.
- Stuffy nose.
- Constipation, upset stomach (indigestion).
- Feeling weak, fainting (may lead to falls).
- 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 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 and language.
- Thoughts of suicide and worsening of your depression.
- Shortness of breath.
- Vomiting (mainly in the elderly).
- Fever

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.
- Unpleasant sensations in the legs (also called restless legs syndrome).
- Difficulty swallowing.
- Uncontrollable movements, mainly of your face or tongue.
- Sexual dysfunction
- Worsening of pre-existing diabetes.
- Change in electrical activity of the heart seen on ECG (QT prolongation).

Rare (affects less than 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.

Very rare (affects less than 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).
- Inappropriate secretion of a hormone that controls urine volume.
- Breakdown of muscle fibres and pain in muscles (rhabdomyolysis).

Not known (cannot be estimated from the available data)

- Skin rash with irregular red spots (erythema multiforme).
- Serious, sudden allergic reactions with symptoms such as fever and blisters on the skin and peeling of the skin (toxic epidermal necrolysis).

The class of medicines to which Seroquel 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 a 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.

Children and adolescents

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

The following side effect has only been seen 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.

5. HOW TO STORE SEROQUEL

- Keep your tablets out of reach and sight of children
- Do not use Seroquel after the expiry date, which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.
- Do not store above 30°C (Note: for the 200mg product only, store the tablets in the original package).
- 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.

6. FURTHER INFORMATION

What Seroquel Tablets contain

Seroquel 25mg Film-coated Tablets: Each tablet contains 25mg quetiapine (as fumarate).

Seroquel 100mg Film-coated Tablets: Each tablet contains 100mg quetiapine (as fumarate).

Seroquel 200mg Film-coated Tablets: Each tablet contains 200mg quetiapine (as fumarate).

Seroquel 300mg Film-coated Tablets: Each tablet contains 300mg quetiapine (as fumarate).

They also contain the following excipients:

Seroquel 25mg: Calcium hydrogen phosphate dihydrate, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, macrogol, povidone, sodium starch glycolate, titanium dioxide (E171), ferric oxide (E172).

Seroquel 100mg: Calcium hydrogen phosphate dihydrate, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, macrogol, povidone, sodium starch glycolate, titanium dioxide (E171), ferric oxide (E172).

Seroquel 200mg: Calcium hydrogen phosphate dihydrate, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, macrogol, povidone, sodium starch glycolate, titanium dioxide (E171).

Seroquel 300mg: Calcium hydrogen phosphate dihydrate, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose (E460), macrogol 400, povidone, sodium starch glycollate Type A, titanium dioxide (E171).

Seroquel 25mg are peach round tablets with “Seroquel 25” imprinted on one side.

Seroquel 100mg are yellow round tablets with “Seroquel 100” imprinted on one side.

Seroquel 200mg are white round tablets with “Seroquel 200” imprinted on one side.

Seroquel 300mg are white biconvex tablets with “Seroquel” imprinted on one side and “300” on the other.

Pack size: Seroquel are available in blister packs of 60 tablets contained in an outer cardboard carton.

Parallel Product Authorisation Numbers:

Seroquel 25mg Film-coated Tablets: PPA 465/153/1

Seroquel 100mg Film-coated Tablets: PPA 465/153/2

Seroquel 200mg Film-coated Tablets: PPA 465/153/3

Seroquel 300mg Film-coated Tablets: PPA 465/153/4

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PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath.

MANUFACTURER

AstraZeneca UK Ltd., Macclesfield, Chesire, UK **or** AstraZeneca NV, Destelbergen, Belgium **or** AstraZeneca, Reims, France **or** AstraZeneca Farmaceutica Spain S.A., Porriño, Pontevedra, Spain **or** AstraZeneca GmbH, Plankstadt, Germany **or** Biofabri S.L, C/ A Relva, s/n, 36400 O Porriño (Pontevedra), Spain.

Seroquel is a registered trademark of the AstraZeneca Group

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

COUNTRY	TRADE NAME
Austria	Seroquel
Belgium	Seroquel
Bulgaria	Seroquel
Czech Republic	Seroquel
Cyprus	Seroquel
Denmark	Seroquel
Estonia	Seroquel
Finland	Seroquel
Germany	Seroquel
Greece	Seroquel
Hungary	Seroquel
Iceland	Seroquel
Ireland	Seroquel
Italy	Seroquel
Latvia	Seroquel
Lithuania	Seroquel
Luxembourg	Seroquel
Malta	Seroquel
Netherlands	Seroquel
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