

# Seroquel<sup>®</sup>

## quetiapine fumarate, 25 mg, 100 mg and 200 mg tablets

### CONSUMER MEDICINE INFORMATION

#### What is in this leaflet

This leaflet answers some of the common questions people ask about **Seroquel**. It does not contain all the information that is known about **Seroquel**. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your doctor will have weighed the risks of you taking **Seroquel** against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.** You may need to read it again.

#### What Seroquel is used for

**Seroquel** is used to treat schizophrenia and bipolar disorder. Schizophrenia is an illness with disturbances in thinking, feelings and behaviour. Bipolar disorder is an illness in which there are sustained mood swings either up (mania) or down (depression). During mania patients experience episodes of overactivity, elation or irritability. During depression, patients may feel depressed or guilty, lack energy, lose their appetite and have trouble sleeping.

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

**Seroquel** belongs to a group of medicines called anti-psychotics, which improve the symptoms of certain types of mental illness. Your doctor will help you understand the benefits of taking **Seroquel** and why you are taking it. Ask your doctor for further information if you have any questions.

You may find it helpful to tell a friend or relative that you are suffering from these symptoms, and ask them to read this leaflet. You might ask them to tell you if they think your symptoms are getting worse, or if they are worried about any other changes in your behaviour.

**Seroquel** is not addictive.

This medicine is available only with a doctor's prescription.

#### Before you use Seroquel

***When you must not use it.***

**Do not use Seroquel if you have an allergy to Seroquel or to any ingredients listed at the end of this leaflet.** If you have an allergic reaction, you may get a skin rash, hayfever, difficulty breathing or feel faint.

**Seroquel is not approved for use below 18 years of age. There is limited information about use in children. Do not give Seroquel to children.**

**Seroquel**, as with other anti-psychotic medicines, is recommended for use with caution in the elderly and is not approved for treatment of dementia and behavioural disturbances. Clinical studies of this group of medicines for the treatment of dementia and behavioural disturbances in the elderly, have suggested an increased risk of cardiovascular adverse events including stroke, and increased mortality risk for elderly patients.

Do not use **Seroquel** after the use by (expiry date) printed on the pack. Do not take **Seroquel** if the packaging is torn or shows signs of tampering.

**Do not give this medicine to anyone else.**

**Before you start to take it****Tell your doctor if you have any allergies to:**

- other medicines
- any other substances, such as foods, dyes or preservatives.

**You must tell your doctor if you have any health problems or any of the following medical conditions:**

- high or low blood pressure
- family history of heart problems (including yourself)
- stroke
- problems with your circulation
- liver problems
- if you have ever had a seizure (fit)
- dementia or related behavioural disorders (especially in elderly patients)
- diabetes or high blood sugar. If you already have diabetes, you should be monitored for worsening of your diabetes.
- low white blood cell count
- sleep apnoea
- urinary retention (a condition where you can't completely empty your bladder)
- an enlarged prostate
- a blockage in your intestines
- increased pressure inside your eyes or glaucoma
- history of alcohol or drug abuse

If you have any of these it may not be correct for you to take **Seroquel**, or you may have to take a lower dose.

**Tell your doctor or mental health professional if you have any mental/mood changes or suicidal thoughts.** Depression and other mental illnesses can increase the risk of suicide. It is important to discuss all the risks of treating depression and mental illness as well as the risks of not treating it. You should discuss all treatment choices with your doctor, not just the use of antidepressants. Patients (and caregivers of patients) need to monitor for any worsening of their condition and/or the emergence of thoughts of suicide or suicidal behaviour or thoughts of harming themselves and to seek medical advice immediately if these symptoms present.

**Tell your doctor if you are pregnant, think you might be pregnant or are breast feeding.** The safety of **Seroquel** use during pregnancy is not yet known. It is not yet known how much **Seroquel** will pass through into breast milk.

Symptoms of withdrawal may occur in newborn babies of mothers that have used **Seroquel** during their pregnancy.

If you have not told your doctor any of the things above, please tell him/her before you start taking any **Seroquel**.

***Taking other medicines***

You need to take special care if you take other medicines at the same time as **Seroquel**.

**Tell your doctor if you are taking or about to stop taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.** Some medicines and **Seroquel** may interfere with each other, these include:

- medicines for anxiety or depression, mood swings, attention deficit hyperactivity disorder (ADHD) or other mood disorders.

- phenytoin or carbamazepine (medicines for epilepsy)
- medicines for high blood pressure (including diuretics or fluid tablets) or heart conditions
- some antibiotics such as rifampicin or erythromycin
- lorazepam – a medicine used to help you sleep
- ketoconazole (for fungal infections)
- thioridazine (an antipsychotic medicine)
- protease inhibitors (for Human Immunodeficiency Virus (HIV))
- medicines used to treat Parkinson's disease
- stimulants such as amphetamines
- glucocorticosteroids – medicines used to treat inflammation
- anticholinergics (medicines used to affect nerve cell function to treat certain medical conditions)
- medicines that can cause constipation.

These medicines may affect the way **Seroquel** works. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

### Using Seroquel

Follow your doctor's instructions about when and how to take **Seroquel**. Please read the label on the container carefully. Ask your doctor or pharmacist if you are not sure about anything.

#### ***How to take it***

Your doctor will decide what dose of **Seroquel** you should take and how long you need to take it. This depends on your condition and whether or not you are taking any other medicines. **Seroquel** is usually started as a low dose that will be gradually increased by your doctor. Your doctor will recommend a dose especially for you. This will depend on various factors including your age, condition being treated, other medical conditions (e.g. liver problems), other medicines you are taking and how you may react to **Seroquel**. Your doctor will monitor your condition and may change your dose depending on how you respond to it. Your doctor will use the lowest dose for the least amount of time to keep you well.

#### ***When to take it***

**Seroquel** is taken once or twice a day depending on your condition. Your doctor will tell you how you should take it. Swallow **your Seroquel tablets whole with a full glass of water**. You can take them with or without food.

#### ***How long to take 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. **Do not stop taking Seroquel unless your doctor tells you to, even if you feel better.**

**Seroquel** tablets come in different sizes, and each size is a different colour.

#### ***If you forget to take it***

If it is almost time for your next dose (within 6 hours), skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally. **Do not double the dose to make up for the dose you have missed.** If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

### Overdose

**Telephone your doctor or the National Poisons and Hazardous Chemicals Information Centre Ph: 0800 POISON (0800 764 766) or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too much Seroquel, even if there are no signs of discomfort or poisoning.**

**While you are using Seroquel****Things you must do**

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking **Seroquel**. If you are about to be started on any new medicines, tell your doctor, dentist or pharmacist that you are taking **Seroquel**.

Tell your doctor or mental health professional immediately, or go to the nearest hospital, if you have any of the following suicidal thoughts or other mental/mood changes:

- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts of self-harm
- increase in aggressive behaviour, irritability or agitation
- worsening of depression.

Occasionally, the symptoms of depression may include thoughts of suicide or self-harm. These symptoms may continue or get worse during the early stages of treatment until the effect of the medicine becomes apparent. All mentions of suicide or violence must be taken seriously.

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.

**If you become pregnant while taking it, tell your doctor immediately.**

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking **Seroquel**. If you need to have any medical tests (including urine drug screening) while you are taking it, tell your doctor. **Seroquel** may affect the results of some tests.

**Be sure to keep all of your medical appointments so that your progress can be checked.** Your doctor will check your progress and may want to take some tests (e.g. blood tests, blood pressure, weight or height measurements) from time to time. These tests may help to prevent side effects.

**Things you must not do**

**Do not stop taking Seroquel, or change the dosage, even if you are feeling better, without checking with your doctor.** If you stop taking it suddenly, your condition may worsen or your chance of getting an unwanted side effect may increase. To prevent this, your doctor may gradually reduce the amount of **Seroquel** you take each day before stopping completely.

Do not give it to anyone else, even if their symptoms seem similar or they have the same condition as you.

Do not take **Seroquel** to treat any other complaints unless your doctor tells you to. Do not take any medicines that cause drowsiness while you are taking it, unless recommended by your doctor.

**Things to be careful of**

**Be careful driving or operating machinery until you know how Seroquel affects you.** It can make some people dizzy or sleepy. Make sure you know how you react to it before you do anything that could be dangerous if you are dizzy or sleepy. Children should be careful when riding bicycles or climbing trees.

**If it makes you feel light-headed, dizzy or faint, be careful when getting up from a sitting or lying position.** Standing up slowly, especially when you get up from bed or chairs, will help your body get

used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

**Be careful when drinking alcohol while you are taking it.** Combining **Seroquel** and alcohol can make you more sleepy or dizzy. Your doctor will suggest you avoid alcohol while you are being treated with **Seroquel**. Avoid getting over-heated or dehydrated - do not over-exercise. In hot weather stay inside in a cool place, stay out of the sun, do not wear too much or heavy clothing, drink plenty of water. Keep warm in cool weather. **Seroquel** may affect the way your body reacts to temperature changes.

**Avoid drinking large quantities of grapefruit juice.** This medicine may be affected by grapefruit juice.

Talk to your doctor or pharmacist about these things if you think they may bother you. **Do not stop taking your tablets, even if you are feeling well, unless your doctor tells you.**

#### Side effects

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Seroquel.** Side effects may be more likely to occur during long term treatment. Therefore, it is important that you tell your doctor as soon as possible if you notice anything that is making you feel unwell, even if you think the problems are not connected with this medicine. Your doctor may then decide to adjust your dose or use a different medicine. Ask your doctor or pharmacist to answer any questions you may have.

**Tell your doctor if you notice any of the following and they worry you:**

- feeling sleepy
- weight gain, increased appetite
- feeling weak
- dry mouth
- runny or stuffy nose (particularly in children)
- indigestion, upset stomach, constipation, vomiting (mainly in elderly or children)
- swelling of your hands, feet or ankles
- blurred vision
- abnormal dreams, nightmares
- irritability
- shortness of breath, difficulty in breathing and/or tightness in the chest
- fast or irregular heartbeats (palpitations).

These side effects are usually mild. Some of these side effects may go away after a while.

**Tell your doctor as soon as possible if you notice the following:**

- falling, feeling dizzy or faint on standing up
- difficulty in speaking
- difficulty swallowing
- rapid heart beat
- symptoms of high blood sugar levels (including passing large amounts of urine, excessive thirst, increase in appetite with a loss of weight, feeling tired, drowsy, weak, depressed, irritable and generally unwell)
- breast enlargement, unusual secretion of breast milk
- difficulty in passing urine
- confusion

- rhabdomyolysis (breakdown of muscle fibres and pain in muscles)
- yellowish discolouration of the skin/palms or white of your eyes.

These are serious side effects. You may need medical attention.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- long lasting and painful erection
- fainting (particularly in children)
- signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal
- very marked drowsiness
- reduced consciousness
- abnormal muscle movements, including difficulty starting muscle movements, shaking, restlessness or muscle stiffness without pain
- worm-like movements of the tongue or other uncontrolled movements of the tongue, mouth, cheeks or jaw which may progress to the arms and legs
- a sudden increase in body temperature, with sweating, or a fast heart beat
- fits (seizures)
- severe allergic reaction (may include severe difficulty breathing, shock, swelling of the face, lips, tongue or other parts of the body, skin rash, hayfever, or you may feel faint)
- severe upper stomach pain, often with nausea and vomiting (particularly in patients with other risk factors such as gallstones, alcohol consumption and/or increased levels of certain fats within the blood) These are symptoms of pancreatitis.
- Combination of fever, very marked drowsiness, muscle stiffness, marked increase in blood pressure or heartbeats and reduced consciousness (a disorder called “neuroleptic malignant syndrome”)
- widespread skin rash that may include blistering (may be filled with pus) or peeling of the skin, flu like symptoms, fever, swelling of the face and/or swollen lymph nodes (painful, warm, or red lump under your skin - often under your chin, on your neck, groin, armpit or behind your ear), or itchy skin rash with pink-red irregular spots. These symptoms may also be associated with changes in your blood (eg white blood cell increase as sometimes seen in allergic reactions) or liver function. These are some of the symptoms of potentially life threatening conditions 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).
- combination of fever, flu-like symptoms, sore throat, or any other infection
- bowel obstruction.

These are very serious side effects. Stop using **Seroquel** if you develop these symptoms. You may need urgent medical attention or hospitalisation. Occasionally, **Seroquel** may be associated with changes in your liver function or blood (e.g. blood fat levels such as cholesterol or triglycerides, blood sugar levels, blood pressure, thyroid hormone levels, white blood cells). These can only be found when your doctor does tests from time to time to check your progress.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Tell your doctor or pharmacist if you have any side effects or if you notice anything else that is making you feel unwell.

**Important.** This leaflet alerts you to some of the situations when you should call your doctor. Other situations which cannot be predicted may arise. Nothing in this leaflet should stop you from calling your doctor or pharmacist with any questions or concerns you have about using **Seroquel**.

#### After using it

##### **Storage**

**Keep your Seroquel tablets in the blister pack until it is time to take them.** If you take the tablets out of the blister pack they may not keep well. **Keep your tablets in a cool, dry place where the temperature stays below 30°C. Do not store Seroquel tablets or any other medicine in the bathroom or near a sink.** Heat and dampness can destroy some medicines.

**Keep your tablets in a safe place where children cannot see or reach them.** A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

**Do not leave Seroquel tablets in the car on hot days.**

##### **Disposal**

**Ask your pharmacist what to do with any tablets you have left over if your doctor tells you to stop taking them, or you find that the expiry date has passed.**

#### Product description

**Seroquel** comes in three strengths, containing 25 mg, 100 mg or 200 mg of quetiapine fumarate. Each tablet strength is a different colour or shape:

- **Seroquel** 25 mg - peach coloured, round shaped tablet.
- **Seroquel** 100 mg - yellow coloured, round shaped tablet.
- **Seroquel** 200 mg - white coloured, round shaped tablet.

Each strength comes in a blister pack containing 60 tablets.

##### **Ingredients**

Each tablet contains the active ingredient quetiapine fumarate. Each tablet also contains:

- povidone
- calcium hydrogen phosphate
- microcrystalline cellulose
- sodium starch glycolate
- lactose monohydrate
- magnesium stearate
- hypromellose
- macrogol
- titanium dioxide (E Code 171)

in addition

**Seroquel** 25 mg contains iron oxide yellow C177492 (E 172) and iron oxide red C177491 (E 172)

**Seroquel** 100 mg contains iron oxide yellow C177492 (E 172)

#### Marketed by:

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