

# SEROQUEL<sup>®</sup>

Quetiapine fumarate

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## 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 for**

Seroquel belongs to a group of medicines called antipsychotics, which improve the symptoms of certain types of mental illness.

Seroquel is used to treat schizophrenia and acute mania associated with Bipolar 1 Disorder. Schizophrenia and Bipolar 1 Disorder are mental illnesses with disturbances in thinking, feelings and behaviour.

Your doctor will have explained why you are being treated with Seroquel and told you what dose to take.

**Follow all directions given to you by your doctor carefully.**

They may differ from the information contained in this leaflet.

Your doctor may prescribe this medicine for another use. Ask your doctor if you want more information.

Seroquel is not addictive.

### **Before you use Seroquel**

#### ***When you must not use it***

**Do not take Seroquel if you have an allergy to Seroquel or to any of the other ingredients of Seroquel listed at the end of this leaflet.**

**Do not use Seroquel if you are pregnant or breastfeeding unless your doctor says so. Ask your doctor about the risks and benefits involved.**

We do not know if it is safe for you to take it while you are pregnant.

It is recommended that you do not breastfeed while taking Seroquel, as it is not known whether Seroquel passes into breast milk.

**Seroquel is not approved for use in children.**

There is no experience of its use in children.

**Do not use Seroquel after the use by (expiry) date printed on the pack.**

It may have no effect at all or an unexpected effect if you take it after the expiry date.

**Do not use Seroquel if the packaging is torn or shows signs of tampering.**

**Do not use it to treat any other complaints unless your doctor tells you to.**

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

#### ***Before you start to use it***

**You must tell your doctor if:**

- 1. you have any allergies to:**
  - any other medicines, foods, dyes or preservatives
  - any other substances

If you have an allergic reaction, you may get a skin rash, hayfever, difficulty breathing, swelling of the face, lips tongue or other parts of the body, or you may feel faint.

- 2. you have any of these medical conditions**
  - heart problems
  - problems with your circulation
  - liver problems
  - diabetes (or a family history of diabetes)
  - if you have ever had a fit (seizure)
  - any condition that affects blood flow to the brain
  - dementia or related behavioural disorders (especially in elderly patients)

It may not be safe for you to take Seroquel if you have any of these conditions. Your doctor will keep these conditions in mind if you are given Seroquel.

## **Taking other medicines**

### **Tell your doctor if you are taking any other medicines, including**

- medicines for anxiety or depression
- medicines for epilepsy
- medicines for high blood pressure
- rifampicin
- ketoconazole
- erythromycin
- thioridazine
- any medicines that you buy at the chemist, supermarket or health food shop.

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.

If you have not told your doctor about any of these things, tell them before you take any Seroquel.

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## **Taking Seroquel**

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### **How much to take**

Your doctor will decide what dose of Seroquel you should take and how long you need to take it.

**Follow the dosage directions carefully.**

The total daily dose is slowly increased depending on your condition and the usual dose may be between 150 mg and 800 mg a day. Some people may need a different dose. Your dose will depend on your response.

If you are elderly, or have liver problems, your doctor will adjust your dose to suit you.

Seroquel is taken twice a day.

**Swallow your Seroquel tablets whole with a full glass of water.** You can take them with or without food.

## **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, the Poisons Information Centre (13 11 26) or go to casualty 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.**

If you take too many Seroquel tablets you will probably feel drowsy, sleepy, dizzy and have fast heart beats.

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## **While you are using it**

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### **Things you must do**

**If you go into hospital tell the staff you are taking Seroquel.**

**Take your Seroquel regularly.** If you do not take it regularly your condition will not be well controlled.

### **Things you must not do**

**Do not stop taking Seroquel even if you feel well.**

Discuss any changes of the dose of Seroquel with your doctor.

If you stop taking Seroquel abruptly you may experience nausea, vomiting or insomnia.

## **Things to be careful of**

**Be careful driving or operating machinery until you know how Seroquel affects you.**

Seroquel can make some people dizzy or sleepy. Make sure you know how you react to Seroquel before you do anything that could be dangerous if you are dizzy or sleepy.

**Be careful when drinking alcohol while you are using Seroquel.**

It may make you dizzy or sleepy.

Please talk to your doctor or pharmacist about these things if you think they may bother you.

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## **Side effects**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Seroquel.**

Seroquel helps most people with schizophrenia and mania, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**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
- feeling dizzy or faint
- small increase in weight

These things usually happen when you first take Seroquel and usually go away after a while.

Other side effects can include:

- feeling weak
- constipation
- dry mouth
- runny or stuffy nose
- indigestion
- fainting

These are all mild side effects of Seroquel.

**If any of the following happen, stop taking Seroquel and tell your doctor immediately or go to casualty at your nearest hospital.**

- Abnormal muscle movements, including difficulty starting muscle movements, shaking, restlessness or muscle stiffness without pain.
- uncontrolled movements of the tongue, mouth, cheeks or jaw
- a sudden increase in body temperature, with sweating, or a fast heart beat
- very fast breathing
- muscle stiffness
- fits (seizures)

These are very serious side effects. If you have them, you may have had a serious reaction to Seroquel. You may need urgent medical attention or hospitalisation.

All of these side effects are rare.

Occasionally, Seroquel may be associated with changes in your liver or blood, which may require your doctor to do certain blood tests.

**Tell your doctor if you notice anything else that is making you feel unwell.**

Some people may get other side effects while taking Seroquel.

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## After using it

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### Storage

**Keep your Seroquel tablets in the blister pack until it is time to take them.**

If you take Seroquel out of the blister pack it will not keep well.

**Keep it in a cool dry place where the temperature stays below 30°C.**

**Do not store it or any other medicine in the bathroom or near a sink.**

Heat and dampness can destroy some medicines.

**Keep it where young children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

**Do not leave it in the car on hot days.**

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## Disposal

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**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.**

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## Product description

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### What Seroquel looks like

The following Seroquel tablets are round, film coated:

- 25 mg - peach coloured
- 100 mg - yellow coloured
- 200 mg - white coloured

The following Seroquel tablet is capsule shaped, film coated:

- 300 mg - white coloured.

The pack sizes for each strength are

- Seroquel 25 mg - 60 tablets.
- Seroquel 100 mg - 90 tablets.
- Seroquel 200 mg - 60 tablets
- Seroquel 300 mg – 60 tablets.

## Ingredients

Each Seroquel tablet contains quetiapine fumarate as the active ingredient equivalent to quetiapine 25 mg, 100 mg, 200 mg or 300 mg

plus,

Povidone  
Calcium hydrogen phosphate  
Microcrystalline cellulose (E 460)  
Sodium starch glycolate  
Lactose  
Magnesium stearate (E572)  
Hypromellose  
Macrogol 400  
Titanium dioxide (E 171)

in addition

Seroquel 25 mg contains iron oxide yellow CI77492 (E 172) iron oxide red CI77491 (E 172)

Seroquel 100 mg contains iron oxide yellow CI77492 (E 172).

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## Supplier

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AstraZeneca Pty Ltd  
ABN 54 009 682 311  
Alma Road  
**NORTH RYDE NSW 2113**

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Seroquel 25 mg: 58112  
Seroquel 100 mg: 58113  
Seroquel 200 mg: 58114  
Seroquel 300 mg: 78361