SEROQUEL®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using SEROQUEL?

SEROQUEL contains the active ingredient quetiapine fumarate. SEROQUEL is used to correct chemical imbalances in the brain.

For more information, see Section 1. Why am I using SEROQUEL? in the full CMI.

2. What should I know before I use SEROQUEL?

Do not use if you have ever had an allergic reaction to quetiapine fumarate or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use SEROQUEL? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SEROQUEL and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use SEROQUEL?

- Your doctor will tell you how many tablets you will need to take each day and how long you need to take it.
- Swallow your SEROQUEL tablets whole with a full glass of water. You can take them with or without food.

More instructions can be found in Section 4. How do I use SEROQUEL? in the full CMI.

5. What should I know while using SEROQUEL?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using SEROQUEL. • Tell your doctor or mental health professional immediately, or go to the nearest hospital, if you have any suicidal thoughts or other mental/mood changes. • 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 it.
Things you should not do	• Do not stop using this medicine suddenly. • Do not use SEROQUEL to treat other complaints unless your doctor or pharmacist tells you to. • Do not give SEROQUEL to anyone else, even if they have the same symptoms or condition as yours.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how **SEROQUEL** affects you. It can make some people dizzy or sleepy.
Drinking alcohol	• Combining SEROQUEL and alcohol can make you more sleepy or dizzy.
Looking after your medicine	• Store below 30°C.

For more information, see Section 5. What should I know while using SEROQUEL? in the full CMI.

6. Are there any side effects?

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

Most common side effects include feeling sleepy, weight gain, increased appetite, feeling weak, dry mouth.

Serious side effects include falling, feeling dizzy or faint on standing up, flat and red skin lesions or substantial hemorrhages under the skin (purpura), difficulty in speaking, difficulty in swallowing, rapid heart beat.

Very Serious side effects include long lasting and painful erection, fainting (particularly in children). For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

SEROQUEL®

Active ingredient(s): ***Quetiapine fumarate***

Consumer Medicine Information (CMI)

This leaflet provides important information about using SEROQUEL. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using SEROQUEL.**

Where to find information in this leaflet:

1. Why am I using SEROQUEL?
2. What should I know before I use SEROQUEL?
3. What if I am taking other medicines?
4. How do I use SEROQUEL?
5. What should I know while using SEROQUEL?
6. Are there any side effects?
7. Product details

1. Why am I using SEROQUEL?

SEROQUEL contains the active ingredient quetiapine fumarate. SEROQUEL belongs to a group of medicines called antipsychotics.

SEROQUEL helps to correct chemical imbalances in the brain. It is used to treat conditions such as:

- Schizophrenia, an illness with disturbances in thinking, feelings and behaviour
- Bipolar disorder, 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 of energy, lose their appetite and have trouble sleeping.
- SEROQUEL is available only with a doctor's prescription.

2. What should I know before I use SEROQUEL?

Warnings

Do not use SEROQUEL if:

- you are allergic to quetiapine fumarate, or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skins or you may feel faint.

  Always check the ingredients to make sure you can use this medicine.
- it is beyond expiry date which is printed on the pack.
- the packaging is torn or shows signs of tampering.
- You are pregnant or breastfeeding unless your doctor says so. Ask your doctor about the risks and benefits involved.

Do not give SEROQUEL to children or adolescents unless recommended by your doctor.

The effects of SEROQUEL have only been studied in children aged between 10 and 17 years with mania and in children aged between 13 and 17 years with schizophrenia. There is not enough information on its effects in children to recommend its use in other age groups or for other conditions.

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. In clinical studies with 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 has been reported.

If it has expired or is damaged, return it to your pharmacist for disposal

If you are not sure whether you should start taking SEROQUEL, talk to your doctor or pharmacist.

Check with your doctor if you:

- have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.
- have or have had any medical conditions, especially the following:
  - heart or blood vessel problems or a family history of heart or blood vessel problems including high or low blood pressure, stroke, problems with your circulation or any condition that affects blood flow to the brain, problems with the way your heart beats or a history of heart attack
  - liver problems
  - diabetes (or a family history of diabetes). Patients with diabetes or who have a higher chance of diabetes should have their blood sugar checked before and during treatment with SEROQUEL.
  - increased cholesterol levels
  - inflammation of pancreas
  - difficulty swallowing
  - epilepsy (seizures or fits)
  - dementia or related behavioural disorders (especially in elderly patients)
  - low white blood cell count
  - sleep apnoea - a condition where you stop breathing for short periods during your normal nightly sleep

- 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
- 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 "What if I am taking other medicines?).

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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

It is not known if it is safe for you to take it while you are pregnant.

Neonates exposed to antipsychotic drugs (including quetiapine) may experience agitation, hypertonia (high level muscle tone), hypotonia (decreased muscle tone), tremor, somnolence, respiratory distress and feeding disorder following delivery (extrapyramidal neurological disturbances and/or withdrawal symptoms). These complications have varied in severity; while in some cases symptoms have been self-limited, in other cases neonates have required additional medical treatment or monitoring.

However, if you need to take it during your pregnancy, the doctor will discuss the risks and benefits of taking it with you.

It is recommended that you do not breastfeed while taking it, as it may pass into breast milk.

Before your doctor starts you on SEROQUEL your doctor may want to take some tests (eg blood tests, blood pressure, weight or height measurements). These tests may help to prevent side effects.

Tell your doctor if you are lactose intolerant.

SEROQUEL tablets contain lactose.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with SEROQUEL and affect how it works.

Some medicines and SEROQUEL may interfere with each other. These include:

- medicines used to treat anxiety, depression, mood swings, attention deficit hyperactivity disorder (ADHD) or other mood disorders
- lorazepam - a medicine used to help you sleep
- medicines for high blood pressure (including diuretics or fluid tablets) or heart conditions
- thioridazine - an antipsychotic medicine
- medicines used to treat Parkinson's disease
- stimulants such as amphetamines
- medicines that have anti-cholinergic (muscarinic) effects

These medicines may be affected by SEROQUEL, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Anti-depressants 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.

Medicines that may increase the effect of SEROQUEL include:

- some antibiotics such as erythromycin
- medicines used for fungal infections such as ketoconazole
- medicines for Human Immunodeficiency Virus (HIV)

Medicines that may reduce the effect of SEROQUEL include:

- phenytoin or carbamazepine - medicines for epilepsy
- some antibiotics such as rifampicin
- glucocorticoids - medicines used to treat inflammation

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking SEROQUEL.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SEROQUEL.

4. How do I use SEROQUEL?

How much to take / use

- Your doctor will tell you how many tablets you will need to take each day 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 (eg 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.
- Follow the instructions provided and use SEROQUEL until your doctor tells you to stop.

When to take / use SEROQUEL

- SEROQUEL is taken once or twice a day depending on your condition. Your doctor will tell you how you should take it.
- You can take them with or without food.

How to use SEROQUEL

- Swallow your SEROQUEL tablets whole with a full glass 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.
- Do not stop taking it unless your doctor tells you to - even if you feel better.

If you forget to use SEROQUEL

SEROQUEL should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember.

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 take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you use too much SEROQUEL

If you think that you have used too much SEROQUEL, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too many SEROQUEL tablets you may feel drowsy, sleepy, dizzy or have fast heart beats.

Patients with pre-existing severe cardiovascular disease may be at an increased risk of the effects of overdose.

There were cases reported of QT prolongation (abnormal electrocardiogram) with overdose.

There have been very rare reports of overdose of quetiapine alone resulting in death or coma.

5. What should I know while using SEROQUEL?

Things you should do

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking it.

If you are about to be started on any new medicines, tell your doctor, dentist or pharmacist that you are taking it.

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.

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 it.

If you need to have any medical tests (including urine drug screening) while you are taking it, tell your doctor.

It may affect the results of some tests.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

Your doctor will check your progress and may want to take some tests (eg blood tests, blood pressure, weight or height measurements) from time to time. These tests may help to prevent side effects.

Call your doctor straight away if your:

- condition worsens or does not improve.

Remind any doctor, dentist or pharmacist you visit that you are using SEROQUEL.

Things you should not do

- Do not stop using this medicine suddenly.
- **Do not stop taking it, 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 it 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

- **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 if you have any concerns.
- **Talk to your doctor or pharmacist about these things if you think they may bother you.**

Driving or using machines

Be careful before you drive or use any machines or tools 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

Be careful when drinking alcohol while you are taking it.

Combining SEROQUEL and alcohol can make you more sleepy or dizzy. Your doctor may suggest you avoid alcohol while you are being treated with it.

Looking after your medicine

- Store below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

If your doctor tells you to stop taking it or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• feeling sleepy • weight gain, increased appetite • feeling weak • dry mouth	**Speak to your doctor if you have any of these less serious side**

• 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 • confusion • shortness of breath, difficulty in breathing and/or tightness in the chest • fast or irregular heartbeats (palpitations) • muscle pain or swelling or weakness • headache • insomnia • diarrhoea These side effects are usually mild. Some of these side effects may go away after a while.	**effects and they worry you.**

Serious side effects

Serious side effects	What to do
• falling, feeling dizzy or faint on standing up • flat and red skin lesions or substantial hemorrhages under the skin (purpura) • difficulty in speaking • difficulty swallowing • rapid heart beat • symptoms of high sugar levels in the blood (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 • cutaneous vasculitis, with skin symptoms such as lesions, including palpable purpura (discoloration of skin, raised and can be felt), petechiae (tiny spots of bleeding under the skin), urticaria, ulcers, livedo reticularis (a type of skin disorder), and nodules.	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Very Serious side effects

Very Serious side effects	What to do
• 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 disorder called tardive dyskinesia) • a sudden increase in body temperature, with sweating, or a fast heart beat • fits (seizures) • widespread skin rash that may include blistering or peeling of the skin, often accompanied by 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). 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 called Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS). • 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.	**These are very serious side effects. Stop using SEROQUEL if you develop these symptoms. You may need urgent medical attention or hospitalization.**

• Combination of fever, very marked drowsiness, muscle stiffness, marked increase in blood pressure or heartbeats and reduced consciousness (a disorder called "neuroleptic malignant syndrome").	

Occasionally, SEROQUEL may be associated with changes in your liver function or blood (eg 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.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What SEROQUEL contains

Active ingredient	Quetiapine fumarate
Other ingredients	• Povidone • Calcium hydrogen phosphate dihydrate • Microcrystalline cellulose (E460) • Sodium starch glycollate • Lactose monohydrate • Magnesium stearate (E572) • Hypromellose • Macrogol 400 • Titanium dioxide (E171) • Iron oxide red CI77491 (E172 - 25 mg only) • Iron oxide yellow CI77492 (E172 - 100 mg only).

Do not take this medicine if you are allergic to any of these ingredients.

SEROQUEL tablets do not contain gluten or sucrose.

What SEROQUEL looks like

SEROQUEL tablets are film-coated.

Tablet shape and colouring is as follows:

- 25 mg: Peach, round, biconvex tablet, intagliated with either 'SEROQUEL' and '25' or 'Q' and '25' on one side, and plain on the other side.
- 100 mg: Yellow, round, biconvex tablet, intagliated with either 'SEROQUEL' and '100' or 'Q' and '100' on one side, and plain on the other side.
- 200 mg: White, round, biconvex tablet, intagliated with either 'SEROQUEL' and '200' or 'Q' and '200' on one side, and plain on the other side.
- 300 mg: White, capsule-shaped tablet, intagliated with either 'SEROQUEL' or 'Q' on one side and '300' on the other side.

SEROQUEL 25 mg, 200 mg and 300 mg come in packs of 60 tablets. SEROQUEL 100 mg comes in packs of 90 tablets.

SEROQUEL Australian Registration Numbers:

SEROQUEL 25 mg: AUST R 58112
SEROQUEL 100 mg: AUST R 58113
SEROQUEL 200 mg: AUST R 58114
SEROQUEL 300 mg: AUST R 78361

Who distributes SEROQUEL

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