

PART III: CONSUMER INFORMATION

Fr SEROQUEL®

quetiapine fumarate immediate-release tablets

This leaflet is part III of a three-part "Product Monograph" published when SEROQUEL was approved for sale in Canada and is designed specifically for Consumers/Care givers. This leaflet is a summary and will not tell you everything about SEROQUEL. Contact your doctor or pharmacist if you have any questions about the drug.

Before taking SEROQUEL, read this leaflet carefully. Keep this leaflet until you have taken all of your SEROQUEL tablets.

ABOUT THIS MEDICATION

What the medication is used for:

SEROQUEL (quetiapine fumarate immediate release) (pronounced SER-O-KWELL) is used to:

- Treat the symptoms of schizophrenia, such as hallucinations (hearing or seeing things which are not there), fixed false beliefs, unusual suspiciousness, or emotional withdrawal. Patients may also feel depressed, anxious or tense.
- Treat the symptoms of mania associated with bipolar disorder, such as racing thoughts, irritability, aggressiveness, agitation, impulsive behaviour or excessively elevated mood.
- Treat the symptoms of depression associated with bipolar disorder, such as sadness, feeling guilty, lack of energy, loss of appetite and/or sleep disturbance.

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.

Your doctor may have prescribed SEROQUEL for another reason. Ask your doctor if you have any questions about why SEROQUEL has been prescribed for you.

SEROQUEL is not a cure for your condition but it can help manage your symptoms and help you feel better.

What it does:

SEROQUEL is a medication that belongs to a class of medicines called "atypical antipsychotics".

Illnesses that affect the brain, such as schizophrenia and bipolar disorder, may be due to certain chemicals in the brain being out of balance. These imbalances may cause

some of the symptoms you may be experiencing. Doctors and scientists are not sure what causes these imbalances to occur. SEROQUEL is thought to work by regulating the imbalance of chemicals in the brain.

When it should not be used:

Do not take SEROQUEL if you have had an allergic reaction to SEROQUEL or any of the ingredients listed in the "nonmedicinal ingredients" section of this leaflet.

What the medicinal ingredient is:

SEROQUEL tablets contain the active ingredient quetiapine fumarate.

What the nonmedicinal ingredients are:

The inactive ingredients in SEROQUEL tablets are: calcium hydrogen phosphate dihydrate, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, red ferric oxide (25 mg tablets only), sodium starch glycolate, titanium dioxide, and yellow ferric oxide (25 mg and 100 mg tablets only).

What dosage forms it comes in:

SEROQUEL comes in four tablet strengths: 25 mg (round, peach colour), 100 mg (round, yellow colour), 200 mg (round, white colour) and 300 mg (capsule-shaped, white colour). The word "SEROQUEL" and the strength are written on each tablet. These words are easy to read on the tablets and if you see them you know you are taking the right medicine.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Studies with various medications of the group to which SEROQUEL belongs, including SEROQUEL, when used in elderly patients with dementia have been associated with an increased rate of death. SEROQUEL is not indicated in elderly patients with dementia.

Before starting SEROQUEL, be sure to tell your doctor:

- If you have had an allergic reaction to any medicine which you have taken previously to treat your condition, or if you think you might be sensitive or allergic to any of the ingredients in SEROQUEL.
- About any other medications - prescription, non-prescription or alternative - that you are taking or plan to take. Certain medications can seriously affect the way other medications work.
- If you are pregnant or plan to become pregnant while taking SEROQUEL.
- If you are breast-feeding or are planning on breast-feeding while taking SEROQUEL. You should not breast-feed while taking SEROQUEL.
- If you drink alcohol or use street drugs.
- If you have any health problems.
- If you have low or high blood pressure or have had a stroke.

- If you or a family member have a history of any problems with the way your heart beats or have a history of heart disease or heart problems or if you are taking any medicines that may have an impact on the way your heart beats.
- If you have a history of seizures (fit).
- If you have diabetes, a family history of diabetes or high blood sugar during pregnancy.
- If you have a history of liver or kidney problems.
- If you know that you had a low white blood cell count in the past which may or may not have been caused by other medicines.
- If you exercise vigorously or work in hot or sunny places.

In clinical studies with SEROQUEL and other drugs of this type, an increased risk of death has been reported in elderly patients with dementia and behavioural disturbances. SEROQUEL is not approved for this use.

Pancreatitis (inflammation of the pancreas) has been reported in some patients. Many of these patients also had factors which are known to be associated with pancreatitis such as increased triglyceride (a fatty substance in the blood) levels, gallstones and alcohol consumption.

If you already have diabetes, you should be monitored for worsening of your diabetes.

Do not drive or operate machinery until you know your response to this medication, as SEROQUEL can cause drowsiness.

Thoughts of suicide and worsening of your depression or other mental illnesses:

If you are depressed and/or have other mental illnesses 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.

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 or have other mental illnesses, and ask them to read this leaflet. You might ask them to tell you if they think your depression or mental illness is getting worse, or if they are worried about changes in your behaviour.

Effects on Newborns:

In some cases, babies born to a mother taking SEROQUEL during pregnancy have experienced symptoms that are severe and require the newborn to be hospitalized. Sometimes, the symptoms may resolve on their own. Be prepared to seek immediate emergency medical attention for your newborn if they have difficulty breathing, are overly

sleepy, have muscle stiffness, or floppy muscles (like a rag doll), are shaking, or are having difficulty feeding.

INTERACTIONS WITH THIS MEDICATION

Because certain medications can seriously affect the way other medications work, it is important to tell all doctors, dentists, and pharmacists who are treating you that you are taking SEROQUEL. As well, be sure to tell them about any other medications – prescription, non-prescription or alternative – that you are taking or plan to take.

You should not drink alcohol while taking SEROQUEL, as the combination could increase the effects of the alcohol.

You should tell your doctor if you are taking or about to stop taking medications for anxiety, depression, epilepsy (such as phenytoin or carbamazepine), high blood pressure, or to help you sleep.

Dopamine agonists, e.g. levodopa (antiparkinsonian agent), may decrease the effect of SEROQUEL.

Medications known to interact with SEROQUEL include carbamazepine (anticonvulsant), phenytoin (anticonvulsant), ketoconazole (antifungal), and protease inhibitors (for treating Human Immunodeficiency Virus).

You should tell your doctor if you are taking erythromycin (antibiotic), clarithromycin (antibiotic), nefazodone, thioridazine (antipsychotic), diltiazem or verapamil (blood pressure medications). You should also tell your doctor if you are taking medicines that have an impact on the way and how slow 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).

Effect on Urine Drug Screens:

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 these drugs. Confirmation of the results by more specific tests is recommended.

PROPER USE OF THIS MEDICATION

SEROQUEL is not recommended for use in patients under 18 years old.

USUAL DOSE:

Adults

In order for SEROQUEL to help you feel better, it is very important to take it every day exactly as your doctor tells you to. Take the exact number of tablets your doctor has prescribed at the right time every day.

Recommended Dose:

Your dose will be titrated based on your clinical response and tolerability.

Schizophrenia:

The usual starting dose is 25 mg, twice daily. The recommended dose range is 50 to 800 mg/day, taken twice daily.

Bipolar Mania:

The usual starting dose is 50 mg, twice daily. The recommended dose range is 100 to 800 mg/day, taken twice daily.

Bipolar Depression:

The usual titration schedule is day 1: 50 mg, day 2: 100 mg, day 3: 200 mg, and day 4 and onwards: 300 mg taken once daily. Your doctor may increase the dose to 400 mg on day 5 and up to 600 mg per day from day 8 onwards depending on your response and tolerability. The maximum dose is 600 mg per day.

It takes time to feel better and you should expect some symptoms to improve slowly over the first few weeks of treatment. Do not stop taking SEROQUEL, or change the times of day you take SEROQUEL, without talking to your doctor first.

If you stop taking SEROQUEL abruptly you may experience withdrawal symptoms such as insomnia (inability to sleep), nausea, and vomiting.

To make sure you are getting the most benefit from SEROQUEL, you must:

- Continue taking SEROQUEL everyday and
- Keep your doctor well informed of how you are feeling, both good and bad.

By doing these two things, you and your doctor together will be able to make sure that you are getting the best dose of SEROQUEL for you.

You may take SEROQUEL with or without food.

Do not give SEROQUEL to anyone else. Your doctor has prescribed SEROQUEL for you only.

OVERDOSE:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

In case of SEROQUEL overdose or if you think you, or anyone else, are experiencing severe episodes of any of the side effects of SEROQUEL (especially drowsiness, including also rapid heart beat, lightheadedness and/or

dizziness, especially when standing up quickly or getting out of bed), call your doctor or poison control centre or go to the nearest hospital emergency room right away. Make sure to bring your medication bottle with you.

MISSED DOSE:

If you miss a dose by only a few hours, take it as soon as possible. If most of the day has passed since your missed dose, skip that dose and wait until your next scheduled dose. Never take two doses at once.

Here are some tips that can help you remember to take each dose of SEROQUEL:

- Take your SEROQUEL at the same time every day.
- Take SEROQUEL during daily events which will help you remember to take your medicine as well, e.g., mealtime or bedtime.
- Use a pill container that will separate your SEROQUEL doses by the day of the week.
- Use a calendar to note the day and time after you have taken each dose to help you keep track of when you need to take your SEROQUEL.
- Keep a written reminder to take your SEROQUEL that can be easily seen, e.g., on a mirror or on the refrigerator.
- Have a family member or friend remind you to take your medication.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like any medication, SEROQUEL may produce side effects in some people.

Increases in blood glucose (sugar) and hyperglycaemia (high blood sugar) have been observed with SEROQUEL. Also, occasional cases of diabetes have been reported. Your doctor may take blood tests to check your blood sugar before starting SEROQUEL. They may continue to monitor your blood sugar for as long as you are being treated.

Light-headedness and dizziness (symptoms of postural hypotension) and drowsiness are among the most common side effects you may experience while taking SEROQUEL, particularly during the first week of treatment or after an increase in dose. The dizziness and drowsiness are usually mild and should go away with time. To help prevent these feelings, be careful to move slowly when you are getting up from a sitting or lying position. Dizziness and drowsiness may lead to falls.

Low blood pressure in standing position is common, which may result in dizziness or feeling faint (may lead to falls).

As feelings of drowsiness are also common at the start of treatment, or when your dose is increased, if you have to drive, operate machinery or do anything else that requires you to be fully alert, use extra caution until you are sure SEROQUEL does not cause you to be drowsy.

Dry mouth and weight gain have also been reported very commonly in patients taking SEROQUEL. Your doctor may take your body weight before starting SEROQUEL and continue to monitor it for as long as you are being treated.

Discontinuation symptoms which occur upon stopping SEROQUEL have been reported very commonly and include insomnia (inability to sleep), nausea, headache, diarrhea, vomiting, dizziness, and irritability. Gradual withdrawal over a period of at least one to 2 weeks is advisable.

Other common side effects may include: headache, rapid heart beat, feeling like your heart is pounding, racing or has skipped beats, shortness of breath, constipation, indigestion, feeling weak, swelling of arms and legs, fever, upset stomach or abdominal pain, vomiting (mainly in the elderly), blurred vision, abnormal dreams and nightmares, irritability, feeling more hungry, disturbance in speech and language, and changes in laboratory tests for liver and thyroid functions.

There have been uncommon cases of difficulty swallowing, fainting (may lead to falls), stuffy nose and a slower than normal heart rate which may occur when starting treatment and which may be associated with low blood pressure and fainting.

There have also been reports, in a small number of patients, of changes to the lens of the eye. Although it is not known whether or not these changes are caused by SEROQUEL, your doctor may advise you that a specific type of eye exam is recommended in order to maximize safe use of this drug.

In rare cases, there have been reports of decreased body temperature (hypothermia) and walking, talking, eating or other activities while asleep.

In very rare cases, this type of medicine can interfere with your body's ability to control body temperature. Therefore, take care to avoid becoming overheated or dehydrated (for example with vigorous exercise, or exposure to extreme heat) while taking SEROQUEL.

The following may also occur with SEROQUEL, and may be seen in routine blood testing:

- Decrease in the amount of white blood cells. These changes will normally disappear when stopping the treatment of SEROQUEL.
- Decrease in the amount of red blood cells. These are the cells that transport oxygen throughout the body.
- Increase in the amount of eosinophils. These are a type of white blood cell sometimes seen in allergic reactions.
- Decrease in platelets (thrombocytopenia), which are cells that help you stop bleeding if you get a cut.
- Increase in the amount of liver enzymes. These changes will normally disappear when continuing the treatment of SEROQUEL.

- Changes in the amount of fatty substances (lipid levels, such as triglycerides and cholesterol) in the blood.
- Increase in the amount of 'creatin phosphokinase', a substance in the muscles.
- Increase in the amount of sugar (glucose) in the blood.
- Increase in the amount of hormone prolactin in the blood. Rarely (<0.1% - ≥0.01%) this may lead to swelling of breasts and unexpected production of breast milk in women and in some men, and changes in the regularity of monthly period.
- If you have high levels of prolactin and a condition called hypogonadism you may be at increased risk of breaking a bone due to osteoporosis. This may occur in both men and women.

One of the most important things for you to do to minimize the risks from side effects, while helping SEROQUEL work for you, is to contact your doctor or pharmacist if you notice any symptom that worries you, even if you think it is not connected with this medicine or is not listed here.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor right away		Stop taking drug and seek immediate emergency assistance
		Only if severe	In all cases	
Very Common	Abnormal muscle movements, including difficulty starting muscle movements, shaking, restlessness or muscle stiffness without pain		√	
	New or worsening constipation	√		
Uncommon	Involuntary movements, mainly of your face or tongue (Tardive dyskinesia)		√	
	Symptoms of allergic reactions such as, skin lumps, bumps or swelling			√
	Restless legs (unpleasant sensations in the legs)		√	

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Symptom / effect	Talk with your doctor right away		Stop taking drug and seek immediate emergency assistance
	Only if severe	In all cases	
Seizure (i.e. loss of consciousness with uncontrollable shaking "fit")			√
Rare	Long-lasting (greater than 4 hours in duration) and painful erection of the penis		√
	Combination of high fever, muscle stiffness, marked increase in blood pressure and/or heartbeats, and reduced consciousness (called neuroleptic malignant syndrome)		√
Very Rare	Anaphylaxis (severe form of allergic reaction; symptoms may include swelling of the mouth, face, lips or tongue, may include severe difficulty breathing and shock)		√

This is not a complete list of side effects. For any unexpected effects while taking SEROQUEL, contact your doctor or pharmacist.

HOW TO STORE IT

Store SEROQUEL at room temperature (between 15 - 30°C) and well out of the reach of children.

The expiry date of this medicine is printed on the package label. Do not use the medicine after this date.

If your doctor tells you to stop taking SEROQUEL or you find that they have passed their expiry date, please return any left over medicine to your pharmacist.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

Important Note: This leaflet alerts you to some of the times you should call your doctor while you are taking SEROQUEL. Other situations that cannot be predicted may arise. Nothing about this leaflet should stop you from calling your doctor or pharmacists with any questions or concerns you have about using SEROQUEL.

This CONSUMER INFORMATION Leaflet provides you with the most current information at the time of printing. For the most current information, the Consumer Information Leaflet plus the full Product Monograph, prepared for health professionals can be found at: www.astrazeneca.ca, or by contacting the sponsor, AstraZeneca Canada Inc. at: Customer Inquiries – 1 (800) 668-6000, Renseignements – 1 (800) 461-3787.

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