



- If you are breast-feeding or are planning on breast-feeding while taking SEROQUEL XR. You should not breast-feed while taking SEROQUEL XR.
- 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 XR and other drugs of this type, an increased risk of death has been reported in elderly patients with dementia and behavioural disturbances. SEROQUEL XR is not approved for this use.

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 XR 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 XR 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 XR. 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 XR, 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 XR.

Medications known to interact with SEROQUEL XR 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 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 XR 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 XR is not recommended for use in patients under 18 years old.

**USUAL DOSE:**

**Adult**

In order for SEROQUEL XR 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:**

***Schizophrenia and Bipolar Mania:***

The usual titration schedule is day 1: 300 mg, day 2: 600 mg and up to 800 mg from day 3 onwards taken once daily. The maximum dose is 800 mg per day.

***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 further increase the dose depending on your response and tolerability. The maximum dose is 600 mg per day.

***Major Depressive Disorder:***

The usual titration schedule is 50 mg on days 1 and 2 and 150 mg on day 3. Your doctor may adjust the dose upwards or downwards within the recommended dose range of 50-300 mg per day during the course of your treatment depending on your response and tolerability.

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 XR, or change the times of day you take SEROQUEL XR without talking to your doctor first.

If you stop taking SEROQUEL XR 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 XR, you must:

- Continue taking SEROQUEL XR 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 XR for you.

You may take SEROQUEL XR with or without food.

**Tablets should be swallowed whole. Do not split, crush or chew.**

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

**Switching from SEROQUEL tablets to SEROQUEL XR tablets:**

If you are currently being treated with divided doses of SEROQUEL (quetiapine, immediate-release formulation) your doctor may switch you to SEROQUEL XR at an equal total daily dose taken once daily.

**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 XR overdose or if you think you or anyone else are experiencing severe episodes of any of the side effects of SEROQUEL XR (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:**

SEROQUEL XR should be taken at the same time each day. If you miss a dose from the previous day, you should take your next regular dose of SEROQUEL XR the next day at the normal time.

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

- Take your SEROQUEL XR at the same time every day.
- Take SEROQUEL XR 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 XR 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 XR.
- Keep a written reminder to take your SEROQUEL XR 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 XR may produce side effects in some people.

Increases in blood glucose (sugar) and hyperglycaemia (high blood sugar) have been observed with SEROQUEL XR. Also, occasional cases of diabetes have been reported. Your doctor may take blood tests to check your blood sugar before starting SEROQUEL XR. 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 XR, 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 XR does not cause you to be drowsy.

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

Discontinuation symptoms which occur upon stopping SEROQUEL XR 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) and stuffy nose.

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 XR, 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 XR.

The following may also occur with SEROQUEL XR, 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 XR.
- 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 XR.
- Changes in the amount of fatty substances (lipid levels, such as triglycerides and cholesterol) in the blood.
- Increase in the amount of "creatinine 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.
- Changes in the amount of thyroid hormones in your blood. These changes usually do not affect how you feel.
- If you have high levels of prolactin and a condition called hypogonadism you may be at an 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 XR 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	
Common	Abnormal muscle movements, including difficulty starting muscle movements, shaking, restlessness or muscle stiffness without pain		√	
	New or worsening constipation	√		

**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	
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)		√	
	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 XR, contact your doctor or pharmacist.*

**HOW TO STORE IT**

Store SEROQUEL XR 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 XR or you find that it has passed its 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](http://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](http://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 XR. Other situations that cannot be predicted may arise. Nothing about this leaflet should stop you from calling your doctor or pharmacist with any questions or concerns you have about using SEROQUEL XR.

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](http://www.astrazeneca.ca), or by contacting the sponsor, AstraZeneca Canada Inc. at: Customer Inquiries – 1 (800) 668-6000,

Renseignements – 1 (800) 461-3787.

SEROQUEL XR<sup>®</sup> and the AstraZeneca logo are registered trademarks of the AstraZeneca group of companies.

©AstraZeneca 2007, 2009, 2011

This leaflet was prepared by AstraZeneca Canada Inc.,  
Mississauga, Ontario L4Y 1M4

Last revised: November 29, 2011