

MEDICATION GUIDE

SEROQUEL (SER-oh-kwell)

(quetiapine fumarate)

Tablets

Read this Medication Guide before you start taking SEROQUEL and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or treatment.

What is the most important information I should know about SEROQUEL?

Serious side effects may happen when you take SEROQUEL, including

- **Risk of death in the elderly with dementia:** Medicines like SEROQUEL can raise the risk of death in elderly people who have lost touch with reality due to confusion and memory loss (dementia). SEROQUEL is not approved for treating psychosis in the elderly with dementia.
- **Risk of suicidal thoughts or actions:** Antidepressant medicines, depression and other serious mental illnesses, and suicidal thoughts or actions:
 1. Antidepressant medicines may increase suicidal thoughts or actions in some children, teenagers, and young adults within the first few months of treatment.
 2. Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. Some people may have a particularly high risk of having suicidal thoughts or actions. These include people who have (or have a family history of) depression, bipolar illness (also called manic-depressive illness), or suicidal thoughts or actions.
 3. **How can I watch for and try to prevent suicidal thoughts and actions in myself or a family member?**
 - Pay close attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings. This is very important when an antidepressant medicine is started or when the dose is changed.
 - Call the healthcare provider right away to report new or sudden changes in mood, behavior, thoughts, or feelings.

- Keep all follow-up visits with the healthcare provider as scheduled. Call the healthcare provider between visits as needed, especially if you have concerns about symptoms.

Call a healthcare provider right away if you or your family member has any of the following symptoms, especially if they are new, worse, or worry you:

- thoughts about suicide or dying
- attempts to commit suicide
- new or worse depression
- new or worse anxiety
- feeling very agitated or restless
- panic attacks
- trouble sleeping (insomnia)
- new or worse irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- other unusual changes in behavior or mood

What else do I need to know about antidepressant medicines?

- **Never stop an antidepressant medicine without first talking to your healthcare provider.** Stopping an antidepressant medicine suddenly can cause other symptoms.
- **Antidepressants are medicines used to treat depression and other illnesses.** It is important to discuss all the risks of treating depression and also the risks of not treating it. Patients and their families or other caregivers should discuss all treatment choices with the healthcare provider, not just the use of antidepressants.
- **Antidepressant medicines have other side effects.** Talk to the healthcare provider about the side effects of the medicine prescribed for you or your family member.
- **Antidepressant medicines can interact with other medicines.** Know all of the medicines that you or your family member take. Keep a list of all medicines to show the healthcare provider. Do not start new medicines without first checking with your healthcare provider.

- **Not all antidepressant medicines prescribed for children are FDA approved for use in children.** Talk to your child's healthcare provider for more information.

What is SEROQUEL?

- SEROQUEL is a prescription medicine used to treat schizophrenia in people age 13 or older.
- SEROQUEL is a prescription medicine used to treat bipolar disorder, including:
 - depressive episodes associated with bipolar disorder in adults
 - manic episodes associated with bipolar I disorder alone or with lithium or divalproex in adults
 - long-term treatment of bipolar I disorder with lithium or divalproex in adults
- SEROQUEL is used to treat manic episodes associated with bipolar I disorder in children ages 10 to 17 years.

SEROQUEL has not been studied in patients younger than 10 years of age.

What should I tell my healthcare provider before taking SEROQUEL?

Before taking SEROQUEL, tell your healthcare provider if you have or have had:

- diabetes or high blood sugar in you or your family: your healthcare provider should check your blood sugar before you start SEROQUEL and also during therapy
- high levels of total cholesterol, triglycerides or LDL-cholesterol or low levels of HDL-cholesterol
- low or high blood pressure
- low white blood cell count
- cataracts
- seizures
- abnormal thyroid tests
- high prolactin levels
- heart problems
- liver problems
- any other medical condition
- pregnancy or plans to become pregnant. It is not known if SEROQUEL will harm your unborn baby

- breast-feeding or plans to breast-feed. SEROQUEL can pass into your breast milk. You and your healthcare provider should decide if you will take SEROQUEL or breast-feed. You should not do both.

Tell the healthcare provider about all the medicines that you take or recently have taken including prescription medicines, nonprescription medicines, herbal supplements and vitamins.

SEROQUEL and other medicines may affect each other causing serious side effects. SEROQUEL may affect the way other medicines work, and other medicines may affect how SEROQUEL works.

Especially tell your healthcare provider if you take or plan to take medicines for:

- depression
- high blood pressure
- Parkinson's disease
- trouble sleeping
- abnormal heart beats or rhythm

Also tell your healthcare provider if you take or plan to take any of these medicines:

- phenytoin, divalproex or carbamazepine (for epilepsy)
- barbiturates (to help you sleep)
- rifampin (for tuberculosis)
- glucocorticoids (steroids for inflammation)
- thioridazine (an antipsychotic)
- ketoconazole, fluconazole or itraconazole (for fungal infections)
- erythromycin (an antibiotic)
- protease inhibitors (for HIV)

This is not a complete list of medicines that can affect or be affected by SEROQUEL. Your doctor can tell you if it is safe to take SEROQUEL with your other medicines. Do not start or stop any medicines while taking SEROQUEL without talking to your healthcare provider first. Know the medicines you take. Keep a list of your medicines to show your healthcare provider and pharmacist when you get a new medicine.

Tell your healthcare provider if you are having a urine drug screen because SEROQUEL may affect your test results. Tell those giving the test that you are taking SEROQUEL.

How should I take SEROQUEL?

- Take SEROQUEL exactly as your healthcare provider tells you to take it. Do not change the dose yourself.
- Take SEROQUEL by mouth, with or without food.
- If you feel you need to stop SEROQUEL, talk with your healthcare provider first.

If you suddenly stop taking SEROQUEL, you may experience side effects such as trouble sleeping or trouble staying asleep (insomnia), nausea, and vomiting.

- If you miss a dose, take it as soon as you remember. If it is close to the next dose, skip the missed dose. Just take the next dose at your regular time. Do not take 2 doses at the same time unless your healthcare provider tells you to. If you are not sure about your dosing, call your healthcare provider.
- If you take too much SEROQUEL, call your healthcare provider or poison control center at 1-800-222-1222 right away or go to the nearest hospital emergency room.

What should I avoid while taking SEROQUEL?

Do not drive, operate machinery, or do other dangerous activities until you know how SEROQUEL affects you. SEROQUEL may make you drowsy.

- Avoid getting overheated or dehydrated.
 - Do not over-exercise.
 - In hot weather, stay inside in a cool place if possible.
 - Stay out of the sun. Do not wear too much or heavy clothing.
 - Drink plenty of water.
- Do not drink alcohol while taking SEROQUEL. It may make some side effects of SEROQUEL worse.

What are possible side effects of SEROQUEL?

Serious side effects have been reported with SEROQUEL including:

Also, see “What is the most important information I should know about SEROQUEL?” at the beginning of this Medication Guide.

- **Neuroleptic malignant syndrome (NMS):** Tell your healthcare provider right away if you have some or all of the following

symptoms: high fever, stiff muscles, confusion, sweating, changes in pulse, heart rate, and blood pressure. These may be symptoms of a rare and serious condition that can lead to death. Stop SEROQUEL and call your healthcare provider right away.

- **High blood sugar (hyperglycemia):** Increases in blood sugar can happen in some people who take SEROQUEL. Extremely high blood sugar can lead to coma or death. If you have diabetes or risk factors for diabetes (such as being overweight or a family history of diabetes) your healthcare provider should check your blood sugar before you start SEROQUEL and during therapy.

Call your healthcare provider if you have any of these symptoms of high blood sugar while taking SEROQUEL:

- feel very thirsty
 - need to urinate more than usual
 - feel very hungry
 - feel weak or tired
 - feel sick to your stomach
 - feel confused, or your breath smells fruity
- **High cholesterol and triglyceride levels in the blood (fat in the blood):** Increases in total cholesterol, triglycerides and LDL (bad) cholesterol and decreases in HDL (good) cholesterol have been reported in clinical trials with SEROQUEL. You may not have any symptoms, so your healthcare provider should do blood tests to check your cholesterol and triglyceride levels before you start taking SEROQUEL and during therapy.
 - **Increase in weight (weight gain):** Weight gain has been seen in patients who take SEROQUEL so you and your healthcare provider should check your weight regularly.
 - **Tardive dyskinesia:** Tell your healthcare provider about any movements you cannot control in your face, tongue, or other body parts. These may be signs of a serious condition. Tardive dyskinesia may not go away, even if you stop taking SEROQUEL. Tardive dyskinesia may also start after you stop taking SEROQUEL.

- **Orthostatic hypotension (decreased blood pressure):** lightheadedness or fainting caused by a sudden change in heart rate and blood pressure when rising too quickly from a sitting or lying position.
- **Increases in blood pressure:** reported in children and teenagers. Your healthcare provider should check blood pressure in children and adolescents before starting SEROQUEL and during therapy.
- **Low white blood cell count**
- **Cataracts**
- **Seizures**
- **Abnormal thyroid tests:** Your healthcare provider may do blood tests to check your thyroid hormone level.
- **Increases in prolactin levels:** Your healthcare provider may do blood tests to check your prolactin levels.
- **Increases in liver enzymes:** Your healthcare provider may do blood tests to check your liver enzyme levels.
- **Long lasting and painful erection**
- **Difficulty swallowing**

Common possible side effects with SEROQUEL include:

Adults

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|------------------|---|
| • drowsiness | • sore throat |
| • dry mouth | • sluggishness |
| • dizziness | • upset stomach |
| • weakness | • weight gain |
| • abdominal pain | • a sudden drop in blood pressure upon standing |
| • constipation | • abnormal liver tests |

Children and Adolescents:

- | | |
|---------------|----------------------|
| • drowsiness | • dizziness |
| • fatigue | • increased appetite |
| • nausea | • vomiting |
| • dry mouth | • rapid heart beat |
| • weight gain | |

These are not all the possible side effects of SEROQUEL. For more information, ask your healthcare provider or pharmacist.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store SEROQUEL?

- Store SEROQUEL at room temperature, between 59°F to 86°F (15°C to 30°C).
- Keep SEROQUEL and all medicines out of the reach of children.

General information about SEROQUEL

Do not take SEROQUEL unless your healthcare provider has prescribed it for you for your condition. Do not share SEROQUEL with other people, even if they have the same condition. It may harm them.

This Medication Guide provides a summary of important information about SEROQUEL. For more information about SEROQUEL, talk with your healthcare provider or pharmacist or call 1-800-236-9933. You can ask your healthcare provider for information about SEROQUEL that is written for health professionals.

What are the ingredients in SEROQUEL?

Active ingredient: quetiapine fumarate

Inactive ingredients: povidone, dibasic dicalcium phosphate dihydrate, microcrystalline cellulose, sodium starch glycolate, lactose monohydrate, magnesium stearate, hypromellose, polyethylene glycol, and titanium dioxide. The 25 mg tablets contain red and yellow ferric oxide. The 100 mg and 400 mg tablets contain only yellow ferric oxide.

The symptoms of Schizophrenia include:

- Having lost touch with reality (psychosis)
- Seeing things that are not there or hearing voices (hallucinations)
- Believing things that are not true (delusions)
- Being suspicious (paranoia).

The symptoms of Bipolar Disorder include:

- General symptoms of bipolar disorder include extreme mood swings, along with other specific symptoms and behaviors. These mood swings, or "episodes," include manic (highs) and depressive (lows).
- Common symptoms of a manic episode include feeling extremely happy, being very irritable, restless, talking too fast and too much, and having more energy and needing less sleep than usual.
- Common symptoms of a depressive episode include feelings of sadness or emptiness, increased tearfulness, a loss of interest in activities you once enjoyed, loss of energy, difficulty concentrating or making decisions, feelings of worthlessness or guilt, changes in sleep or appetite.
- Thoughts of death or suicide.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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