

MEDICATION GUIDE

SEROQUEL XR (SER-oh-kwell)

(quetiapine fumarate)

Extended-Release Tablets

Read this Medication Guide before you start taking SEROQUEL XR 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 XR?

SEROQUEL XR may cause serious side effects, including:

1. risk of death in the elderly with dementia: Medicines like SEROQUEL XR can increase the risk of death in elderly people who have memory loss (dementia). SEROQUEL XR is not for treating psychosis in the elderly with dementia.

2. risk of suicidal thoughts or actions (antidepressant medicines, depression and other serious mental illnesses, and suicidal thoughts or actions).

• Talk to your, or your family member's, healthcare provider about:

- o all risks and benefits of treatment with antidepressant medicines
- o all treatment choices for depression or other serious mental illness

- **Antidepressant medicines may increase suicidal thoughts or actions in some children, teenagers, and young adults within the first few months of treatment.**

- **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.

• How can I watch for and try to prevent suicidal thoughts and actions in myself or a family member?

- o 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.
- o Call the healthcare provider right away to report new or sudden changes in mood, behavior, thoughts, or feelings.
- o 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 XR?

SEROQUEL XR is a prescription medicine used to treat:

- schizophrenia in people 13 years of age or older
- bipolar disorder in adults, including:
 - o depressive episodes associated with bipolar disorder
 - o manic episodes associated with bipolar I disorder alone or with lithium or divalproex
 - o long-term treatment of bipolar I disorder with lithium or divalproex
- manic episodes associated with bipolar I disorder in children ages 10 to 17 years old.
- major depressive disorder as add-on treatment with antidepressant medicines when your healthcare provider determines that 1 antidepressant alone is not enough to treat your depression.

It is not known if SEROQUEL XR is safe and effective in children under 10 years of age.

Who should not take SEROQUEL XR?

Do not take SEROQUEL XR if you are allergic to quetiapine fumarate or any of the ingredients in SEROQUEL XR. See the end of this Medication Guide for a complete list of ingredients in SEROQUEL XR.

What should I tell my healthcare provider before taking SEROQUEL XR?

Before you take SEROQUEL XR, 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 XR 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 XR will harm your unborn baby
- breast-feeding or plans to breast-feed. SEROQUEL XR can pass into your breast milk. You and your healthcare provider should decide if you will take SEROQUEL XR 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, over-the-counter medicines, herbal supplements and vitamins.

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

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

How should I take SEROQUEL XR?

- Take SEROQUEL XR exactly as your healthcare provider tells you to take it. Do not change the dose yourself.
- Take SEROQUEL XR by mouth, with a light meal or without food.
- SEROQUEL XR should be swallowed whole and not split, chewed or crushed.
- **If you feel you need to stop SEROQUEL XR, talk with your healthcare provider first.** If you suddenly stop taking SEROQUEL XR, you may have side effects such as trouble sleeping or trouble staying asleep (insomnia), nausea, and vomiting.
- If you miss a dose of SEROQUEL XR, take it as soon as you remember. If you are close to your 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.

What should I avoid while taking SEROQUEL XR?

- Do not drive, operate machinery, or do other dangerous activities until you know how SEROQUEL XR affects you. SEROQUEL XR may make you drowsy.
- Avoid getting overheated or dehydrated.
 - o Do not over-exercise.
 - o In hot weather, stay inside in a cool place if possible.
 - o Stay out of the sun. Do not wear too much or heavy clothing.
 - o Drink plenty of water.
- Do not drink alcohol while taking SEROQUEL XR. It may make some side effects of SEROQUEL XR worse.

What are possible side effects of SEROQUEL XR?

SEROQUEL XR can cause serious side effects, including:

- See **“What is the most important information I should know about SEROQUEL XR?”**
- **stroke that can lead to death can happen in elderly people with dementia who take medicines like SEROQUEL**
- **neuroleptic malignant syndrome (NMS).** NMS is a rare but very serious condition that can happen in people who take antipsychotic medicines, including SEROQUEL XR. NMS can cause death and must be treated in a hospital. Call your healthcare provider right away if you become severely ill and have some or all of these symptoms:
 - o high fever
 - o excessive sweating

- o rigid muscles
- o confusion
- o changes in your breathing, heartbeat, and blood pressure

• **high blood sugar (hyperglycemia).** High blood sugar can happen if you have diabetes already or if you have never had diabetes. High blood sugar could lead to:

- o build up of acid in your blood due to ketones (ketoacidosis)
- o coma
- o death

Increases in blood sugar can happen in some people who take SEROQUEL XR. 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 XR and during therapy.

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

- o feel very thirsty
- o need to urinate more than usual
- o feel very hungry
- o feel weak or tired
- o feel sick to your stomach
- o feel confused, or your breath smells fruity

• **high fat levels in your blood (increased cholesterol and triglycerides).** High fat levels may happen in people treated with SEROQUEL XR. You may not have any symptoms, so your healthcare provider may decide to check your cholesterol and triglycerides during your treatment with SEROQUEL XR.

• **increase in weight (weight gain).** Weight gain is common in people who take SEROQUEL XR so you and your healthcare provider should check your weight regularly. Talk to your healthcare provider about ways to control weight gain, such as eating a healthy, balanced diet, and exercising.

• **movements you cannot control in your face, tongue, or other body parts (tardive dyskinesia).** These may be signs of a serious condition. Tardive dyskinesia may not go away, even if you stop taking SEROQUEL XR. Tardive dyskinesia may also start after you stop taking SEROQUEL XR.

• **decreased blood pressure (orthostatic hypotension),** including 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 in children and teenagers.** Your healthcare provider should check blood pressure in children and adolescents before starting SEROQUEL XR and during therapy. SEROQUEL XR is not approved for patients under 10 years of age.

• **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.

• **sleepiness, drowsiness, feeling tired, difficulty thinking and doing normal activities**

• **increased body temperature**

• **difficulty swallowing**

• **trouble sleeping or trouble staying asleep (insomnia), nausea, or vomiting if you suddenly stop taking SEROQUEL XR.** These symptoms usually get better 1 week after you start having them.

The most common side effects of SEROQUEL XR include:

- dry mouth
- constipation
- dizziness
- increased appetite
- upset stomach
- fatigue
- stuffy nose
- difficulty moving

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

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

How should I store SEROQUEL XR?

- Store SEROQUEL XR at room temperature, between 68°F to 77°F (20°C to 25°C).
- **Keep SEROQUEL XR and all medicines out of the reach of children.**

General information about the safe and effective use of SEROQUEL XR.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use SEROQUEL XR for a condition for which it was not prescribed. Do not give SEROQUEL XR to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about SEROQUEL XR. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about SEROQUEL XR that is written for health professionals.

For more information, go to www.SEROQUELXR.com, or call 1-800-236-9933.

What are the ingredients in SEROQUEL XR?

Active ingredient: quetiapine fumarate

Inactive ingredients: lactose monohydrate, microcrystalline cellulose, sodium citrate, hypromellose, and magnesium stearate. The film coating for all SEROQUEL XR tablets contain hypromellose, polyethylene glycol 400 and titanium dioxide. In addition, yellow iron oxide (50, 200 and 300 mg tablets) and red iron oxide (50 mg tablets) are included in the film coating of specific strengths.

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

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