

17.2 Medication Guide

[The Medication Guides should be as similar as possible for SEROQUEL and SEROQUEL XR].

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?

Serious side effects may happen when you take SEROQUEL XR, including:

- **Risk of death in the elderly with dementia: Medicines like SEROQUEL XR can raise the risk of death in elderly people who have lost touch with reality due to confusion and memory loss (dementia).** SEROQUELXR 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 XR?

- SEROQUEL XR is a prescription medicine used to treat schizophrenia in adults.
- SEROQUEL XR is a prescription medicine used to treat bipolar disorder in adults, including:
 - manic episodes associated with bipolar disorder alone or with lithium or divalproex.
 - depressive episodes associated with bipolar disorder.
 - long-term treatment of bipolar I disorder with lithium or divalproex.
- SEROQUEL XR is a prescription medicine used to treat major depressive disorder as add-on treatment with antidepressant medicines when your doctor determines that one antidepressant alone is not enough to treat your depression.

SEROQUEL XR is not approved for patients under 18 years of age.

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

Before taking 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. It is not known if SEROQUEL XR will 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, non-prescription 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.

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

- depression
- high blood pressure
- Parkinson's disease
- trouble sleeping

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 XR. Your doctor can tell you if it is safe to take SEROQUEL XR with your other medicines. Do not start or stop any medicines while taking SEROQUEL XR 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.

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 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 XR, call your healthcare provider or poison control center at 1-800-222-1212 right away or go to the nearest hospital emergency room.

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 over-heated 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 XR. It may make some side effects of SEROQUEL XR worse.

What are possible side effects of SEROQUEL XR?

Serious side effects have been reported with SEROQUEL XR including:

Also see “What is the most important information I should know about SEROQUEL XR?” 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 XR and call your healthcare provider right away.

- **High blood sugar (hyperglycemia):** 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 while taking SEROQUEL XR:

- 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 XR. 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 XR and during therapy.
 - **Increase in weight (weight gain):** Weight gain has been seen in patients who take SEROQUEL XR 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 XR. Tardive dyskinesia may also start after you stop taking SEROQUEL XR.

- **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 XR and during therapy. SEROQUEL XR is not approved for patients under 18 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 test to check your prolactin levels.
- **Increases in liver enzymes:** Your healthcare provider may do blood test to check your liver enzyme levels.
- **Long lasting and painful erection**
- **Difficulty swallowing**

Common possible side effects with SEROQUEL XR include:

- drowsiness
- dry mouth
- constipation
- dizziness
- increased appetite
- upset stomach
- weight gain
- fatigue
- disturbance in speech and language
- abdominal pain
- stuffy nose

These are not all the possible side effects of SEROQUEL XR. 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 XR?

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

General information about SEROQUEL XR

Do not take SEROQUEL unless your healthcare provider has prescribed it for you for your condition. Do not share SEROQUEL XR 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 XR. For more information about SEROQUEL XR, talk with your healthcare provider or pharmacist or call 1-800-236-9933. You can ask your healthcare provider for information about SEROQUEL XR that is written for health professionals.

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 tablets) are included in the film coating of specific strengths.

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) and
- 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 and
- Thoughts of death or suicide.

The symptoms of Major Depressive Disorder (MDD) include:

- Feeling of sadness, emptiness and increase tearfulness,
- Loss of interest in activities that you once enjoyed and loss of energy
- Problems focusing and making decisions,
- Feeling of worthlessness or guilt
- Changes in sleep or eating patterns
- Thoughts of death or suicide.
- MDD symptoms last most of the day, nearly every day for at least two weeks, and interfere with daily life at home and at work

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

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