



Seroquel

Generic Name: **quetiapine** (kwe TYE a peen)

Brand Names: *SEROquel*, *SEROquel XR*

What is Seroquel?

Seroquel (quetiapine) is an antipsychotic medicine. It works by changing the actions of chemicals in the brain.

Seroquel is used to treat **schizophrenia** in adults and children who are at least 13 years old.

Seroquel is used to treat **bipolar disorder** (manic depression) in adults and children who are at least 10 years old.

Seroquel is also used together with antidepressant medications to treat major depressive disorder in adults.

Extended-release Seroquel XR is for use only in adults and should not be given to anyone younger than 18 years old.

Important information

Never take Seroquel in larger amounts, or for longer than recommended by your doctor. High doses or long-term use can cause a serious movement disorder that may not be reversible. Symptoms of this disorder include tremors or other uncontrollable muscle movements.

Stop using Seroquel and call your doctor at once if you have the following symptoms: very stiff (rigid) muscles, high fever, sweating, confusion, fast or uneven heartbeats, tremors, uncontrolled muscle movements, feeling light-headed, blurred vision, eye pain, increased thirst and urination, excessive hunger, fruity breath odor, weakness, nausea and vomiting.

Some young people have thoughts about suicide when first taking Seroquel. Stay alert to changes in your mood or symptoms. Report any new or worsening symptoms to your doctor.

Seroquel is not approved for use in psychotic conditions related to dementia. Quetiapine may increase the risk of death in older adults with dementia-related conditions.

Before taking this medicine

You should not use Seroquel if you are allergic to quetiapine.

Seroquel is not approved for use in psychotic conditions related to dementia. Quetiapine may increase the risk of death in older adults with dementia-related conditions.

To make sure Seroquel is safe for you, tell your doctor if you have:

- liver or kidney disease;
- heart disease, heart rhythm problems, a history of heart attack or stroke;
- high or low blood pressure;
- a history of low white blood cell (WBC) counts;
- abnormal thyroid tests or prolactin levels;
- seizures or epilepsy;
- cataracts;
- high cholesterol or triglycerides;
- a personal or family history of diabetes; or

- trouble swallowing.

Some young people have thoughts about suicide when first taking Seroquel. Your doctor will need to check your progress at regular visits. Your family or other caregivers should also be alert to changes in your mood or symptoms.

Taking antipsychotic medication during the last 3 months of pregnancy may cause problems in the newborn, such as withdrawal symptoms, breathing problems, feeding problems, fussiness, tremors, and limp or stiff muscles. However, you may have withdrawal symptoms or other problems if you stop taking your medicine during pregnancy. **If you become pregnant while taking Seroquel, do not stop taking it without your doctor's advice.**

Quetiapine can pass into breast milk and may harm a nursing baby. You should not breast-feed while you are using Seroquel.

Do not give Seroquel to a child without a doctor's advice. **Extended-release Seroquel XR is for use only in adults** and should not be given to anyone younger than 18 years old.

How should I take Seroquel?

Never take Seroquel in larger amounts, or for longer than recommended by your doctor. Follow all directions on your prescription label. High doses or long-term use of quetiapine can cause a serious movement disorder that may not be reversible. Symptoms of this disorder include tremors or other uncontrollable muscle movements.

Take this medicine with a full glass of water. You may take Seroquel with or without food.

Do not crush, chew, or break an extended-release tablet. Swallow it whole.

Seroquel may cause you to have high blood sugar (hyperglycemia). If you are diabetic, check your blood sugar levels on a regular basis while you are taking Seroquel.

You should not stop using Seroquel suddenly. Stopping suddenly may make your condition worse.

Blood pressure may need to be checked often in a child or teenager taking Seroquel.

Quetiapine can cause you to have a false positive drug screening test. If you provide a urine sample for drug screening, tell the laboratory staff that you are taking Seroquel.

Store at room temperature away from moisture and heat.

Seroquel dosing information

Usual Adult Dose of Seroquel for Schizophrenia:

Immediate-release tablets:

Initial Dose: 25 mg orally twice a day.

The dosage may be increased in increments of 25 to 50 mg two times a day or three times a day on the second and third days (as tolerated). By the fourth day a dosage range of 300 mg to 400 mg daily (divided into 2 or 3 doses a day) may be achieved. Additional dosage adjustments (increases or decreases) of 25 to 50 mg twice a day may be made, as needed. However, at least 2 days should pass between the additional dosage adjustments.

Efficacy in schizophrenia has been reported with doses ranging from 150 to 750 mg/day. Maximum clinical effect has been reported at 300 mg/day. The safety of doses above 800 mg/day has not been evaluated in clinical trials.

Extended-release tablets:

Initial dose: 300 mg orally once daily without food or with a light meal.

Maintenance dose: 400 to 800 mg orally once daily depending on response and tolerance.

Maximum dose: Doses above 800 mg daily have not been studied.

The dosage of the extended-release tablets may be increased in increments of up to 300 mg daily at intervals as short as 1 day.

The efficacy of quetiapine in long-term use (over 6 weeks) has not been studied in clinical trials. Patients who respond favorably to quetiapine may be continued on the lowest dose which is effective in maintaining their remission. Patients should be periodically reassessed to determine their need for maintenance treatment.

Usual Adult Dose of Seroquel for Bipolar Disorder:

Immediate-release tablets:

Mania associated with bipolar I disorder as monotherapy or as adjunct therapy to lithium or divalproex:

Initial Dose: 50 mg orally twice a day

The dose may be increased to 200 mg orally twice daily on day 4 in increments of up to 50 mg twice daily. Further dosage adjustments up to 800 mg per day by day 6 should be in increments of no greater than 200 mg/day. Data has been reported to indicate that the majority of patients responded between 400 mg per day to 800 mg per day. The safety of doses above 800 mg per day has not been evaluated in clinical trials.

Immediate-release tablets:

Depressive episodes associated with bipolar disorder:

Initial dose: 50 mg orally once a day

The dose may be increased to reach 300 mg orally once a day by day 4. Some patients may require a further increase to 600 mg once a day by increasing the daily dose to 400 mg on day 5 and 600 mg on day 8 of treatment. Efficacy was demonstrated in this patient population at both 300 mg and 600 mg per day. However, no additional benefit was observed in patients receiving 600 mg per day as compared to those patients receiving 300 mg per day.

Extended-release tablets:

Bipolar Depression:

(Depressive Episodes Associated with Bipolar Disorder)

Usual dose of Seroquel for Acute Treatment: administer orally once daily in the evening starting with 50 mg per day and increasing doses to reach 300 mg per day by day 4.

Recommended Dosing Schedule: Day 1 - 50 mg, Day 2 - 100, mg, Day 3 - 200 mg, & Day 4 - 300 mg

Bipolar Mania:

Usual dose of Seroquel for Acute Monotherapy or Adjunct Therapy (with lithium or divalproex): administer orally once daily in the evening starting with 300 mg on day 1, 600 mg on day 2, and adjust between 400 mg and 800 mg per day thereafter depending on the clinical response and tolerance of the individual patient.

Bipolar Maintenance:

Continue treatment at the dosage required to maintain symptom remission.

While there is no body of evidence available to specifically address how long patients should remain on quetiapine extended-release tablets, maintenance of efficacy in Bipolar I Disorder has been demonstrated with quetiapine (administered orally twice daily totaling 400 to 800 mg per day) as adjunct therapy to lithium or divalproex. Generally, in the maintenance phase, patients continued on the same dose on which they were stabilized during the stabilization phase. Patients should be periodically reassessed to determine the need for maintenance treatment and the appropriate dose for such treatment.

Usual Adult Dose of Seroquel for Depression:

As adjunctive therapy to antidepressants for use in the treatment of major depressive disorder:

Extended-release tablets:

Initial dose: 50 mg orally once daily in the evening

On day 3, the dose can be increased to 150 mg once daily in the evening.

Range: 150 mg to 300 mg orally daily. Doses above 300 mg have not been studied.

Usual Geriatric Dose of Seroquel for Schizophrenia:

Immediate-release tablets:

Initial Dose: 25 mg orally once a day.

The dose may be increased daily in increments of 25 mg/day to 50 mg/day to an effective dose, depending on the clinical response and tolerability of the patient.

Efficacy in schizophrenia has been reported with doses ranging from 150 to 750 mg/day. Maximum clinical effect has been reported at 300 mg/day. The safety of doses above 800 mg/day has not been evaluated in clinical trials.

Extended-release tablets:

When an effective immediate-release dose has been reached (above 200 mg), the patient may be switched to the extended-release formulation at an equivalent dose.

The efficacy of quetiapine in long-term use (over 6 weeks) has not been studied in clinical trials. Patients who respond favorably to quetiapine may be continued on the lowest dose which is effective in maintaining their remission. Patients should be periodically reassessed to determine their need for maintenance treatment.

Usual Geriatric Dose of Seroquel for Bipolar Disorder:

Extended-release tablets:

Initial dose: 50 mg/day

The dose can be increased in increments of 50 mg/day depending on the response and tolerance of the individual patient.

See also: Dosage Information (in more detail)

What happens if I miss a dose?

Take the missed dose as soon as you remember. Skip the missed dose if it is almost time for your next scheduled dose. Do not take extra medicine to make up the missed dose.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222. **An overdose of quetiapine can be fatal.**

What should I avoid while taking Seroquel?

Avoid drinking alcohol. Dangerous side effects could occur.

Seroquel may impair your thinking or reactions. Avoid driving or operating machinery until you know how this medicine will affect you.

Avoid getting up too fast from a sitting or lying position, or you may feel dizzy. Dizziness or severe drowsiness can cause falls, fractures, or other injuries.

Avoid becoming overheated or dehydrated during exercise and in hot weather. You may be more prone to heat stroke.

Seroquel side effects

Get emergency medical help if you have **signs of an allergic reaction to Seroquel**: hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

Report any new or worsening symptoms to your doctor, such as: mood or behavior changes, anxiety, panic attacks, trouble sleeping, or if you feel impulsive, irritable, agitated, hostile, aggressive, restless, hyperactive (mentally or physically), more depressed, or have thoughts about suicide or hurting yourself.

Call your doctor at once if you have:

- twitching or uncontrollable movements of your eyes, lips, tongue, face, arms, or legs;
- mask-like appearance of the face, trouble swallowing, problems with speech;

- a light-headed feeling, like you might pass out;
- blurred vision, tunnel vision, eye pain, or seeing halos around lights;
- severe nervous system reaction - very stiff (rigid) muscles, high fever, sweating, confusion, fast or uneven heartbeats, tremors, fainting;
- high blood sugar - increased thirst, increased urination, hunger, dry mouth, fruity breath odor, drowsiness, dry skin, blurred vision, weight loss; or
- low blood cell counts - sudden weakness or ill feeling, fever, chills, cold or flu symptoms, cough, sore throat, red or swollen gums, painful mouth sores, skin sores, trouble breathing.

Common Seroquel side effects may include:

- trouble with movement;
- dizziness, weakness;
- increased appetite, weight gain;
- sore throat;
- dry mouth; or
- nausea, vomiting, stomach pain, constipation.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

See also: Side effects (in more detail)

What other drugs will affect Seroquel?

Seroquel can cause a serious heart problem if you use certain medicines at the same time, including antibiotics, antidepressants, heart rhythm medicine, antipsychotic medicines, and medicines to treat cancer, malaria, HIV or AIDS. **Tell your doctor about all medicines you use, and those you start or stop using during your treatment with Seroquel.**

Taking Seroquel with other drugs that make you sleepy or slow your breathing can cause dangerous or life-threatening side effects. Ask your doctor before taking a sleeping pill, narcotic pain medicine, prescription cough medicine, a muscle relaxer, or medicine for anxiety, depression, or seizures.

Many drugs can interact with quetiapine. Not all possible interactions are listed here. Tell your doctor about all your current medicines and any you start or stop using, especially:

- antibiotic or antifungal medicine;
- antiviral medicine to treat hepatitis or HIV/AIDS;
- heart or blood pressure medicine;
- medicine to treat mental illness;
- St. John's wort;
- seizure medicine; or
- tuberculosis medicine.

This list is not complete and many other drugs can interact with quetiapine. This includes prescription and over-the-counter medicines, vitamins, and herbal products. Give a list of all your medicines to any healthcare provider who treats you.

Where can I get more information?

- Your pharmacist can provide more information about Seroquel.
- Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use Seroquel only for the indication prescribed.

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