

Seroquel (quetiapine)

FDA ALERT [04/2005] Seroquel is a type of medicine called an atypical antipsychotic. FDA has found that older patients treated with atypical antipsychotics for dementia had a higher chance for death than patients who did not take the medicine. This is not an approved use.

Brand and Generic Names:

Available forms...

- Brand Name: Seroquel®
 - Tablets: 25 mg, 50 mg, 100 mg, 200 mg, 300 mg, 400 mg
- Generic name: quetiapine

What is Seroquel® and what does it treat?

Quetiapine is used to treat schizophrenia and acute manic episodes of bipolar disorder, and is manufactured by AstraZeneca Pharmaceuticals. It affects a wide range of neurotransmitters, including dopamine and serotonin. Quetiapine has been shown to be as effective as standard treatments for each illness.

Quetiapine is effective for the treatment of both positive (e.g., delusions, thought disorder, and hallucinations) and negative (e.g., social withdrawal, lack of energy, apathy, and reduced ability to express emotion) symptoms of schizophrenia. Quetiapine is also effective by itself or in combination with other drugs for the treatment of symptoms that occur in the manic phase of bipolar disorder (e.g., elevated mood, increased physical activity and pressured speech).

What is the most important information I should know about Seroquel®?

Exacerbations are very common in schizophrenia and bipolar disorder. The most frequent cause is due to patients stopping their medication. Therefore you should try to take your medication exactly as prescribed by your healthcare provider.

- Schizophrenia and bipolar disorder require long-term treatment. Only your healthcare provider can determine the length of quetiapine treatment that is right for you.
- Do not stop taking quetiapine or change your dose without talking to your healthcare provider first.
- Although less common compared with the other atypical antipsychotics, some people may develop side effects known as "extrapyramidal" effects (for example: restlessness, tremor, stiffness) or tardive dyskinesia (slow or jerky movements that one cannot control). These adverse effects are likely to be less severe and occur less often than with the older antipsychotic medications (for example: Haldol® [haloperidol], Prolixin® [fluphenazine], Thorazine® [chlorpromazine]). Seroquel treatment was also similar to placebo treatment in scores measuring akathisia (complaints of restlessness accompanied by fidgety movements) or involuntary movements. Tremor did not develop in any patient receiving active treatment. If you develop movement problems, call your healthcare provider as soon as possible.
- Quetiapine treatment may be associated with low levels of thyroid hormone. While this safety concern is probably rare, there is evidence that it could happen in some people. Talk with your health care provider if you are concerned or have questions.
- Quetiapine treatment must be monitored by a healthcare provider. Be sure to keep all of your scheduled appointments so that you stay healthy while on quetiapine.

What should I discuss with my healthcare provider before taking Seroquel®?

- Which symptoms of schizophrenia and/or bipolar disorder are most bothersome to you.
- The medications you have taken in the past for schizophrenia or bipolar disorder. It would be helpful for your provider to know which medications were effective and which were not.
- If you had any serious side effects to other antipsychotic medications like muscle stiffness, muscle cramping, shaking, tardive dyskinesia, neuroleptic malignant syndrome, weight gain, or diabetes.
- All other prescription and non-prescription medications you are currently taking.
- If you smoke cigarettes, use illegal drugs, or drink alcohol.
- About any medication allergies you have.
- If you are pregnant, plan to get pregnant, or are breast feeding.
- What medical problems you have, especially diabetes, high cholesterol or triglycerides, increased body weight, irregular heart beats, seizures or dementia.
- Tell your doctor if you have thoughts of suicide.

How should I take Seroquel®?

Quetiapine is usually taken two or three times each day. Generally, doses start low (for example, 25 mg twice daily), and then increase by 50-100 mg every day until 300–400 mg/day is reached around day four for schizophrenia. Higher starting doses (50mg twice a day) are used for bipolar mania. Additional increases may be needed; doses of quetiapine greater than 800 mg/day may sometimes be used by your health care provider. Elderly or very sick patients or those with hepatic impairment may have slower dose increases and lower final targets depending on their tolerability and clinical response

- Take quetiapine exactly as directed, do not change your own dose without talking with your health care provider.
- Quetiapine can be taken with, or without food.
- Tell your health care provider if you get any side effects from quetiapine.
- Use a calendar or pill box to help you remember to take your medication. Or, have a family member or friend remind you to be sure you are taking your medication on a daily basis.

What happens if I miss a dose?

If a dose of quetiapine is missed, take it as soon as you remember to, if it is not too close to when your next dose is due—always discuss this with your health care provider. Do not double your next dose, or take more than what is prescribed.

What should I avoid while taking Seroquel®?

- Smoking cigarettes, using illegal drugs, or drinking alcohol.
- Some people get drowsy on quetiapine, avoid driving a car until you are sure how the medication will affect you.

What happens if I overdose?

- If an overdose occurs, whether intentional or accidental, immediate medical attention is necessary. Call your doctor or emergency medical service (911).
- The following may occur in an overdose: increased heart rate, low blood pressure, sedation, heart rhythm changes. In severe cases, people can develop coma, and death is possible.

What are the possible side effects of Seroquel®?

Quetiapine's more common side effects are usually relatively minor. Some people may experience sleepiness, low blood pressure or dizziness, especially when standing up suddenly; heart palpitations; daytime sleepiness; dry mouth, weakness, constipation; stomach upset; and headache. Some of these problems may be reduced by increasing the dose slowly and they generally will improve without specific treatment. Patients who already have low blood pressure, have poor liver function, are elderly, or are in a

weakened condition may require close monitoring and even more gradual dose changes. Although infrequent, extrapyramidal symptoms (muscle stiffness, tremors, and body shakes) may also occur. At higher doses, the chances for extrapyramidal side effects often increase. Cogentin[®] (benztropine) or Benadryl[®] (diphenhydramine) can be prescribed to treat stiffness and tremors.

More serious side effects include weight gain, diabetes, high cholesterol and triglycerides, low thyroid levels, neuroleptic malignant syndrome and tardive dyskinesia. Quetiapine has been shown to cause cataracts (the lens of the eye becomes dull, not clear) in animals. There have been case reports of this side effect when Seroquel is used in high doses in humans. An eye exam may be indicated for people who take high doses of Seroquel.

At the beginning of 2004, the Food and Drug Administration had all manufacturers of atypical antipsychotics include new warnings about each medication being associated with a possible risk of increased blood sugar and diabetes. All adverse effects should be monitored routinely by the professional prescribing treatment and preventive lifestyle changes are often needed.

Are there any risks for taking this medication for long periods of time?

Tardive dyskinesia (TD) is a side effect that develops with prolonged use of antipsychotics. Medications such as quetiapine have been shown to have a much lower risk of tardive dyskinesia compared to older antipsychotics, such as Haldol[®] (haloperidol). Should you develop symptoms of tardive dyskinesia, such as grimacing, sucking and smacking of lips, and other movements that you cannot control, contact your healthcare provider immediately.

Because of the risk of tardive dyskinesia, chronic antipsychotic treatment should be reserved for patients with a chronic illness where potentially less harmful treatments are not available or appropriate.

What other drugs interact with this medication?

Some medications, such as Luvox[®] (fluvoxamine) may increase the blood levels of quetiapine. It is possible that patients taking quetiapine with this agent may experience a change in side effects. Tell your doctor if you begin or stop taking Luvox[®] (fluvoxamine), Biaxin[®] (clarithromycin), erythromycin, or Nizoral[®] (ketoconazole), since they may also increase blood levels of quetiapine.

Studies have shown that carbamazepine (Tegretol[®]; an anticonvulsant commonly used as a mood stabilizer to treat bipolar disorder) can decrease the amount of quetiapine in the blood. Medications with similar effects to carbamazepine include: Mysoline[®] (primidone), and Dilantin[®] (phenytoin).

Quetiapine may increase the effects of warfarin and people on this combination may be at greater risk for bruising or bleeding.

How long does it take for Seroquel® to work?

It may take at least 2 to 3 weeks in order to see some improvement in your symptoms. The full benefit of quetiapine may not be seen for at least 4-6 weeks.

*Updated by Joanne Hawley, Pharm.D, BCPS, BCPP
(December 2006)*



NAMI wishes to thank the [College of Psychiatric and Neurological Pharmacists](#) for producing this fact sheet.

For further information please contact the pharmaceutical company listed below.

AstraZeneca Pharmaceuticals	1800 Concord Pike P.O. Box 15437 Wilmington, DE 19850-5437	302-886-8000	www.astrazeneca-us.com
--------------------------------	---	--------------	--

Free or low-cost medications provided by pharmaceutical companies

Some pharmaceutical companies offer medication assistance programs to low-income individuals and families. These programs typically require a doctor's consent and proof of financial status. They may also require that you have either no health insurance, or no prescription drug benefit through your health insurance. Please contact the pharmaceutical company directly for specific eligibility requirements and application information.

Seroquel Rx Assistance Program: 800-424-3727 or www.azandme.com