SEROQUEL- quetiapine 50mg tablet, film coated
Advanced Rx Pharmacy of Tennessee, LLC

Quetiapine 50mg tablets #90

Medication Guide

MEDICATION GUIDE

Medication Guide

Quetiapine Tablets

(kwe-TYE-a-peen)

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

What is the most important information I should know about quetiapine tablets?

Quetiapine tablets may cause serious side effects, including:

1. risk of death in the elderly with dementia: Medicines like quetiapine tablets can increase the risk of death in elderly people who have memory loss (dementia). Quetiapine tablet 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:

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

Antidepressant medications 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?

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 a quetiapine tablet?

Quetiapine tablet is a prescription medicine used to treat.

schizophrenia in people 13 years of age or older

bipolar disorder in adults, including:

depressive episodes associated with bipolar disorder

manic episodes associated with bipolar I disorder alone or with lithium or divalproex

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

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

What should I tell my healthcare provider before taking quetiapine tablets?

Before you take quetiapine tablets, 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 quetiapine tablets 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 quetiapine will harm your unborn baby.

If you become pregnant while receiving quetiapine, talk to your healthcare provider about registering with the National Pregnancy Registry for Atypical Antipsychotics. You can register by calling 1-866-961-2388 or go to http://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/

breast-feeding or plans to breast-feed. quetiapine can pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you receive quetiapine.

if you have or have had a condition where you cannot completely empty your bladder (urinary retention), have an enlarged prostate, or constipation, or increased pressure inside your eyes.

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.

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

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

How should I take quetiapine tablets?

Take quetiapine tablets exactly as your healthcare provider tells you to take it. Do not change the dose yourself.

Take quetiapine tablets by mouth, with or without food.

- If you feel you need to stop quetiapine tablets, talk with your healthcare provider first. If you suddenly stop taking quetiapine tablets, you may have side effects such as trouble sleeping or trouble staying asleep (insomnia), nausea, and vomiting.

- If you miss a dose of quetiapine tablets, 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 quetiapine tablets?

- Do not drive, operate machinery, or do other dangerous activities until you know how quetiapine tablets affects you. Quetiapine tablets 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 quetiapine tablets. It may make some side effects of quetiapine tablets worse.

What are possible side effects of quetiapine tablets?

Quetiapine tablets can cause serious side effects, including:

• See “What is the most important information I should know about quetiapine tablets?”

• stroke that can lead to death can happen in elderly people with dementia who take medicines like quetiapine tablets

• neuroleptic malignant syndrome (NMS). NMS is a rare but very serious condition that can happen in people who take antipsychotic medicines, including quetiapine tablets. 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

• falls can happen in some people who take quetiapine tablets. These falls may cause serious injuries.

• 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 quetiapine tablets. 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 quetiapine tablets and during therapy.

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

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 quetiapine tablets. You may not have any symptoms, so your healthcare provider may decide to check your cholesterol and triglycerides during your treatment with quetiapine tablets.

• increase in weight (weight gain). Weight gain is common in people who take quetiapine tablets 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 quetiapine tablets. Tardive dyskinesia may also start after you stop taking quetiapine tablets.

• 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 quetiapine tablets and during therapy.

• low white blood cell count. Tell your healthcare provider as soon as possible if you have a fever, flu-like symptoms, or any other infection, as this could be a result of a very low white blood cell count. Your healthcare provider may check your white blood cell level to determine if further treatment or other action is needed.

• cataracts

• seizures

• abnormal thyroid tests: Your healthcare provider may do blood tests to check your thyroid hormone level.

• increases in 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 quetiapine tablets. These symptoms usually get better 1 week after you start having them.

The most common side effects of quetiapine tablets include:

In Adults:

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

In Children and Adolescents:

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

These are not all the possible side effects of quetiapine tablets. 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 quetiapine tablets?

• Store quetiapine tablets at room temperature, between 68°F to 77°F (20°C to 25°C).

• Bottles of 100’s count comes in a child-resistant package.

• Keep quetiapine tablets and all medicines out of the reach of children.

General information about the safe and effective use of quetiapine tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use quetiapine tablets for a condition for which it was not prescribed. Do not give quetiapine tablets 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 quetiapine tablets. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about quetiapine tablets that is written for health professionals.

For more information, call 1-800-206-7821.

What are the ingredients in quetiapine tablets?

Active ingredient: quetiapine

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

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

Medication guide available at www.northstarrxllc.com/products or call 1800-206-7821

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Dosage and Administration Section

2 DOSAGE AND ADMINISTRATION

2.1 Important Administration Instructions

Quetiapine tablets can be taken with or without food.

2.2 Recommended Dosing

The recommended initial dose, titration, dose range and maximum quetiapine tablets dose for each approved indication is displayed in Table 1. After initial dosing, adjustments can be made upwards or downwards, if necessary, depending upon the clinical response and tolerability of the patient [see CLINICAL STUDIES (14.1 and 14.2)].

Table 1: Recommended Dosing for Quetiapine Tablets
Indication Initial Dose and Titration Recommended Dose Maximum Dose

Schizophrenia-Adults

Day 1: 25 mg twice daily. Increase in increments of 25 mg to 50 mg divided two or three times on Days 2 and 3 to range of 300 to 400 mg by Day 4.

Further adjustments can be made in increments of 25 to 50 mg twice a day, in intervals of not less than 2 days.

150 to 750 mg/day

750 mg/day

Schizophrenia-Adolescents (13 to 17 years)

Day 1: 25 mg twice daily.

Day 2: Twice daily dosing totaling 100 mg.

Day 3: Twice daily dosing totaling 200 mg.

Day 4: Twice daily dosing totaling 300 mg.

Day 5: Twice daily dosing totaling 400 mg.

Further adjustments should be in increments no greater than 100 mg/day within the recommended dose range of 400 to 800 mg/day. Based on response and tolerability, may be administered three times daily.

400 to 800 mg/day

800 mg/day

Schizophrenia-Maintenance

Not applicable.

400 to 800 mg/day

800 mg/day

Bipolar Mania- Adults Monotherapy or as an adjunct to lithium or divalproex

Day 1: Twice daily dosing totaling 100 mg.

Day 2: Twice daily dosing totaling 200 mg.

Day 3: Twice daily dosing totaling 300 mg.

Day 4: Twice daily dosing totaling 400 mg.

Further dosage adjustments up to 800 mg/day by Day 6 should be in increments of no greater than 200 mg/day.

400 to 800 mg/day

800 mg/day

Bipolar Mania- Children and Adolescents (10 to 17 years), Monotherapy

Day 1: 25 mg twice daily.

Day 2: Twice daily dosing totaling 100 mg.

Day 3: Twice daily dosing totaling 200 mg.

Day 4: Twice daily dosing totaling 300 mg.

Day 5: Twice daily dosing totaling 400 mg.

Further adjustments should be in increments no greater than 100 mg/day within the recommended dose range of 400 to 600 mg/day. Based on response and tolerability, may be administered three times daily.

400 to 600 mg/day

600 mg/day

Bipolar Depression-Adults

Administer once daily at bedtime.

Day 1: 50 mg

Day 2: 100 mg

Day 3: 200 mg

Day 4: 300 mg

300 mg/day

300 mg/day

Bipolar I Disorder Maintenance Therapy- Adults

Administer twice daily totaling 400 to 800 mg/day as adjunct to lithium or divalproex. Generally, in the maintenance phase, patients continued on the same dose on which they were stabilized.

400 to 800 mg/day

800 mg/day

Maintenance Treatment for Schizophrenia and Bipolar I Disorder

Maintenance Treatment — Patients should be periodically reassessed to determine the need for maintenance treatment and the appropriate dose for such treatment [see CLINICAL STUDIES (14.2)].

2.3 Dose Modifications in Elderly Patients

Consideration should be given to a slower rate of dose titration and a lower target dose in the elderly and in patients who are debilitated or who have a predisposition to hypotensive reactions [see CLINICAL PHARMACOLOGY (12.3)] . When indicated, dose escalation should be performed with caution in these patients.

Elderly patients should be started on quetiapine tablets 50 mg/day and the dose can be increased in increments of 50 mg/day depending on the clinical response and tolerability of the individual patient.

2.4 Dose Modifications in Hepatically Impaired Patients

Patients with hepatic impairment should be started on 25 mg/day. The dose should 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.

2.5 Dose Modifications when used with CYP3A4 Inhibitors

Quetiapine tablets dose should be reduced to one sixth of original dose when co-medicated with a potent CYP3A4 inhibitor (e.g., ketoconazole, itraconazole, indinavir, ritonavir, nefazodone, etc.). When the CYP3A4 inhibitor is discontinued, the dose of quetiapine tablets should be increased by 6-fold [see CLINICAL PHARMACOLOGY (12.3) and DRUG INTERACTIONS (7.1)] .

2.6 Dose Modifications when used with CYP3A4 Inducers

Quetiapine tablets dose should be increased up to 5-fold of the original dose when used in combination with a chronic treatment (e.g., greater than 7 to 14 days) of a potent CYP3A4 inducer (e.g., phenytoin, carbamazepine, rifampin, avasimibe, St. John's wort etc.). The dose should be titrated based on the clinical response and tolerability of the individual patient. When the CYP3A4 inducer is discontinued, the dose of quetiapine tablets should be reduced to the original level within 7 to 14 days [see CLINICAL PHARMACOLOGY (12.3) and DRUG INTERACTIONS (7.1)] .

2.7 Re-initiation of Treatment in Patients Previously Discontinued

Although there are no data to specifically address re-initiation of treatment, it is recommended that when restarting therapy of patients who have been off quetiapine tablets for more than one-week, the initial dosing schedule should be followed. When restarting patients who have been off quetiapine tablets for less than one-week, gradual dose escalation may not be required and the maintenance dose may be re-initiated.

2.8 Switching from Antipsychotics

There are no systematically collected data to specifically address switching patients with schizophrenia from antipsychotics to quetiapine tablets, or concerning concomitant administration with antipsychotics. While immediate discontinuation of the previous antipsychotic treatment may be acceptable for some patients with schizophrenia, more gradual discontinuation may be most appropriate for others. In all cases, the period of overlapping antipsychotic administration should be minimized. When switching patients with schizophrenia from depot antipsychotics, if medically appropriate, initiate quetiapine tablets therapy in place of the next scheduled injection. The need for continuing existing EPS medication should be re-evaluated periodically.

Indications and Usage Section

1 INDICATIONS AND USAGE

1.1 Schizophrenia

Quetiapine tablet is indicated for the treatment of schizophrenia. The efficacy of quetiapine tablets in schizophrenia was established in three 6-week trials in adults and one 6-week trial in adolescents (13 to 17 years). The effectiveness of quetiapine tablets for the maintenance treatment of schizophrenia has not been systematically evaluated in controlled clinical trials [see CLINICAL STUDIES (14.1)].

1.2 Bipolar Disorder

Quetiapine tablet is indicated for the acute treatment of manic episodes associated with bipolar I disorder, both as monotherapy and as an adjunct to lithium or divalproex. Efficacy was established in two 12-week monotherapy trials in adults, in one 3-week adjunctive trial in adults, and in one 3-week monotherapy trial in pediatric patients (10 to 17 years) [see CLINICAL STUDIES (14.2)] .

Quetiapine tablet is indicated as monotherapy for the acute treatment of depressive episodes associated with bipolar disorder. Efficacy was established in two 8-week monotherapy trials in adult patients with bipolar I and bipolar II disorder [see CLINICAL STUDIES (14.2)] .

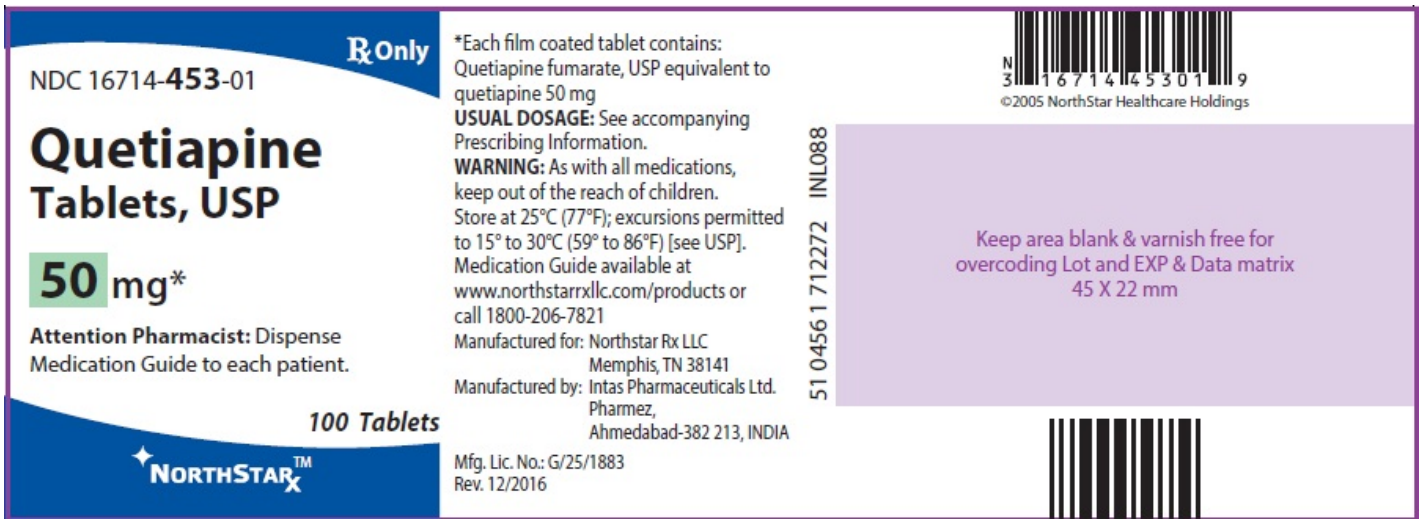
Quetiapine tablet is indicated for the maintenance treatment of bipolar I disorder, as an adjunct to lithium or divalproex. Efficacy was established in two maintenance trials in adults. The effectiveness of quetiapine tablets as monotherapy for the maintenance treatment of bipolar disorder has not been systematically evaluated in controlled clinical trials [see CLINICAL STUDIES (14.2)] .

1.3 Special Considerations in Treating Pediatric Schizophrenia and Bipolar I Disorder

Pediatric schizophrenia and bipolar I disorder are serious mental disorders, however, diagnosis can be challenging. For pediatric schizophrenia, symptom profiles can be variable, and for bipolar I disorder, patients may have variable patterns of periodicity of manic or mixed symptoms. It is recommended that

medication therapy for pediatric schizophrenia and bipolar I disorder be initiated only after a thorough diagnostic evaluation has been performed and careful consideration given to the risks associated with medication treatment. Medication treatment for both pediatric schizophrenia and bipolar I disorder is indicated as part of a total treatment program that often includes psychological, educational and social interventions.

Principal Display Panel



SEROQUEL

quetiapine 50mg tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:80425-0107(NDC:16714-453)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
QUETIAPINE FUMARATE (UNII: 2S3PL1B6UJ) (QUETIAPINE - UNII:BGL0JSY5SI)	QUETIAPINE	50 mg

Product Characteristics			
Color	white	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	50
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:80425-0107-3	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202152	12/01/2015	

Labeler - Advanced Rx Pharmacy of Tennessee, LLC (117023142)

Establishment

Name	Address	ID/FEI	Business Operations
Advanced Rx Pharmacy of Tennessee, LLC		117023142	repack(80425-0107)

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