



## COVID-19 Information

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# Quetiapine

pronounced as (kwe tye' a peen)

## IMPORTANT WARNING:

Important warning for older adults with dementia:

Studies have shown that older adults with dementia (a brain disorder that affects the ability to remember, think clearly, communicate, and perform daily activities and that may cause changes in mood and personality) who take antipsychotics (medications for mental illness) such as quetiapine have an increased risk of death during treatment.

Quetiapine is not approved by the Food and Drug Administration (FDA) for the treatment of behavioral problems in older adults with dementia. Talk to the doctor who prescribed this medication if you, a family member, or someone you care for has dementia and is taking quetiapine. For more information visit the FDA website: <http://www.fda.gov/Drugs> [<http://www.fda.gov/Drugs>]

Important warning for people who have depression:

A small number of children, teenagers, and young adults (up to 24 years of age) who took medications for depression during clinical studies became suicidal (thinking about harming or killing oneself or planning or trying to do so). Children, teenagers, and young adults who take antidepressants to treat depression or other mental illnesses may be more likely to become suicidal than children, teenagers, and young adults who do not take antidepressants to treat these conditions. However, experts are not sure about how great this risk is and how much it should be considered in deciding whether a child or teenager should take an antidepressant. Children younger than 10 years

of age should not normally take quetiapine, but in some cases, a doctor may decide that quetiapine is the best medication to treat a child's condition.

You should know that your mental health may change in unexpected ways when you take quetiapine or other antidepressants even if you are an adult over age 24. You may become suicidal, especially at the beginning of your treatment and any time that your dose is increased or decreased. You, your family, or your caregiver should call your doctor right away if you experience any of the following symptoms: new or worsening depression; thinking about harming or killing yourself, or planning or trying to do so; extreme worry; agitation; panic attacks; difficulty falling asleep or staying asleep; aggressive behavior; irritability; acting without thinking; severe restlessness; and frenzied abnormal excitement. Be sure that your family or caregiver knows which symptoms may be serious so they can call the doctor when you are unable to seek treatment on your own.

Your healthcare provider will want to see you often while you are taking quetiapine, especially at the beginning of your treatment. Be sure to keep all appointments for office visits with your doctor.

The doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with quetiapine. Read the information carefully and ask your doctor or pharmacist if you have any questions. You also can obtain the Medication Guide from the FDA website: <http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> [<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>] .

No matter what your age, before you take an antidepressant, you, your parent, or your caregiver should talk to your doctor about the risks and benefits of treating your condition with an antidepressant or with other treatments. You should also talk about the risks and benefits of not treating your condition. You should know that having depression or another mental illness greatly increases the risk that you will become suicidal. This risk is higher if you or anyone in your family has or has ever had bipolar disorder (mood that changes from depressed to abnormally excited) or mania (frenzied, abnormally excited mood) or has thought about or attempted suicide. Talk to your doctor about your condition, symptoms, and personal and family medical history. You and your doctor will decide what type of treatment is right for you.

## Why is this medication prescribed?

Quetiapine tablets and extended-release (long-acting) tablets are used to treat the symptoms of schizophrenia (a mental illness that causes disturbed or unusual thinking, loss of interest in life, and strong or inappropriate emotions). Quetiapine tablets and extended-release tablets are also used alone or with other medications to treat episodes of mania (frenzied, abnormally excited or irritated mood) or depression in patients with bipolar disorder (manic depressive disorder; a disease that causes episodes of depression, episodes of mania, and other abnormal moods). In addition, quetiapine tablets and extended-release tablets are used with other medications to prevent episodes of mania or depression in patients with bipolar

disorder. Quetiapine extended-release tablets are also used along with other medications to treat depression. Quetiapine tablets may be used as part of a treatment program to treat bipolar disorder and schizophrenia in children and teenagers. Quetiapine is in a class of medications called atypical antipsychotics. It works by changing the activity of certain natural substances in the brain.

## How should this medicine be used?

Quetiapine comes as a tablet and as an extended-release tablet to take by mouth. The tablets are usually taken one to three times a day with or without food. The extended-release tablets are usually taken once a day in the evening without food or with a light meal. Take quetiapine at around the same time(s) every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take quetiapine exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow quetiapine extended-release tablets whole; do not split, chew, or crush them.

Your doctor will probably start you on a low dose of quetiapine and gradually increase your dose during the first week of your treatment. Ask your doctor or pharmacist if you have any questions about the amount of medication you should take each day at the beginning of your treatment.

If you do not take quetiapine for one week or longer, you should call your doctor before you start taking the medication again. Your doctor will probably tell you to start taking a low dose of the medication and gradually increase your dose as you did when you first started taking quetiapine.

Quetiapine may help control your symptoms but will not cure your condition. Continue to take quetiapine even if you feel well. Do not stop taking quetiapine without talking to your doctor. If you suddenly stop taking quetiapine, you may experience withdrawal symptoms such as nausea, vomiting, and difficulty falling asleep or staying asleep. Your doctor will probably want to decrease your dose gradually.

## Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

## What special precautions should I follow?

### Before taking quetiapine,

- tell your doctor and pharmacist if you are allergic to quetiapine, any other medications, or any of the ingredients in quetiapine tablets or extended-release tablets. Ask your doctor or pharmacist or check the Medication Guide for a list of the ingredients.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements and herbal products you are taking or plan to take. Be sure to mention any of the following: antidepressants; certain antifungals such as fluconazole (Diflucan), itraconazole (Onmel, Sporanox), ketoconazole (Nizoral), and voriconazole (Vfend); antihistamines; barbiturates such as phenobarbital; carbamazepine (Tegretol); chlorpromazine; divalproex (Depakote); certain medications

for irregular heartbeat such as amiodarone (Nexterone), procainamide, quinidine, and sotalol (Betapace, Betapace AF, Sorine); dopamine agonists such as bromocriptine (Parlodel), cabergoline (Dostinex), levodopa (Dopar, Larodopa), pergolide (Permax), and ropinirole (Requip); erythromycin (E.E.S., E-Mycin, Erythrocin); gatifloxacin (Zymar, Zymaxid); levodopa (in Parcopa, in Sinemet, in Stalevo); levomethadyl acetate (Orlaam) (not available in the U.S.), medications for anxiety, high blood pressure, irritable bowel disease, mental illness, motion sickness, Parkinson's disease, ulcers, or urinary problems; medications for human immunodeficiency virus (HIV) such as indinavir (Crixivan), nelfinavir (Viracept), ritonavir (Norvir, in Kaletra), and saquinavir (Invirase); methadone (Dolophine, Methadose); moxifloxacin (Avelox, Moxeza, Vigamox); pentamidine (Nebupent, Pentam); phenytoin (Dilantin); rifampin (Rifadin, Rimactane); sedatives; oral steroids such as dexamethasone, methylprednisolone (Medrol), and prednisone (Rayos); sleeping pills; thioridazine (Mellaril); tranquilizers; and ziprasidone (Geodon). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.

- tell your doctor if you or anyone in your family has or has ever had diabetes or a prolonged QT interval (a rare heart problem that may cause irregular heartbeat, fainting, or sudden death). Also tell your doctor if you have ever used street drugs or overused prescription medications. Tell your doctor if you have or have ever had a low level of potassium or magnesium in your blood, a low number of white blood cells, are unable to completely empty your bladder, any condition that makes it difficult for you to swallow, trouble keeping your balance, seizures, cataracts, high cholesterol, high prolactin levels, an enlarged prostate, high or low blood pressure, a heart attack, a stroke, breast cancer or thyroid, heart or liver disease. Tell your doctor if you have constipation, severe vomiting, diarrhea or signs of dehydration now, or if you develop these symptoms at any time during your treatment. Also, if you have ever had to stop taking a medication for mental illness because of severe side effects, be sure to tell your doctor.
- tell your doctor if you are pregnant, especially if you are in the last few months of your pregnancy, or if you plan to become pregnant or are breastfeeding. If you become pregnant while taking quetiapine, call your doctor. Quetiapine may cause problems in newborns following delivery if it is taken during the last months of pregnancy. You should not breastfeed while taking quetiapine.
- you should know that this medication may decrease fertility in women. Talk to your doctor about the risks of taking quetiapine.
- if you are having surgery, including dental surgery, tell your doctor or dentist that you are taking quetiapine.
- you should know that quetiapine may make you drowsy. Do not drive a car or operate machinery and take precautions to avoid falls until you know how this medication affects you.
- you should know that alcohol can add to the drowsiness caused by this medication. Do not drink alcohol while taking quetiapine.
- you should know that you may experience hyperglycemia (increases in your blood sugar) while you are taking this medication, even if you do not already have diabetes. If you have schizophrenia, you are more likely to develop diabetes than people who do not have schizophrenia, and taking quetiapine or similar medications may increase this risk. Tell your doctor immediately if you have any of the following symptoms while you are taking quetiapine: extreme thirst, frequent urination, extreme hunger, blurred vision, or weakness. It is very important to call your doctor as soon as you have any of these symptoms, because high blood sugar can cause a serious condition called ketoacidosis. Ketoacidosis may become life-threatening if it is not treated at an early stage. Symptoms of ketoacidosis include: dry mouth, nausea and vomiting, shortness of breath, breath that smells fruity, and decreased consciousness.

- you should know that quetiapine may make it harder for your body to cool down when it gets very hot. While you are taking quetiapine, you should avoid excessive exercise, stay inside as much as possible and dress lightly in hot weather, stay out of the sun, and drink plenty of fluids.
- you should know that quetiapine may cause dizziness, lightheadedness, and fainting when you get up too quickly from a lying position. This is more common when you first start taking quetiapine and when your dose is increased. To avoid this problem, get out of bed slowly, resting your feet on the floor for a few minutes before standing up.
- you should know that quetiapine may cause an increase in blood pressure in children and teenagers taking quetiapine. When quetiapine is used in children or teenagers, your doctor will check your blood pressure before starting treatment and regularly while you are taking this medication.
- you should know that when quetiapine is used to treat schizophrenia or bipolar disorder in children, it should be used as part of a total treatment program which may include counseling and special education. Make sure to follow all of your doctor's and/or therapist's instructions.

## What special dietary instructions should I follow?

Talk to your doctor about eating grapefruit and drinking grapefruit juice while taking this medicine.

You should know that you may gain weight while you are taking this medication. Talk to your doctor about ways to control weight gain, such as eating a healthy, balanced diet and exercising. You and your doctor should check your weight regularly while you are taking quetiapine.

Be sure to drink plenty of water every day while you are taking this medication.

## What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

## What side effects can this medication cause?

**Quetiapine may cause side effects. Tell your doctor if any of these symptoms or those listed in the SPECIAL PRECAUTIONS section are severe or do not go away:**

- dizziness, feeling unsteady, or having trouble keeping your balance
- pain in the joints, back, neck, or ears
- weakness
- dry mouth
- vomiting
- indigestion
- constipation

- gas
- stomach pain or swelling
- increased appetite
- excessive weight gain
- stuffy nose
- headache
- pain
- irritability
- difficulty thinking or concentrating
- difficulty speaking or using language
- loss of coordination
- unusual dreams
- numbness, burning, or tingling in the arms or legs
- missed menstrual periods
- breast enlargement in males
- discharge from the breasts
- decreased sexual desire or ability

**Some side effects can be serious. If you experience any of the following symptoms or those listed in the IMPORTANT WARNING or SPECIAL PRECAUTIONS section, call your doctor immediately or get emergency medical treatment:**

- fainting
- falling
- seizures
- changes in vision
- uncontrollable movements of your arms, legs, tongue, face, or lips
- painful erection of the penis that lasts for hours
- fever
- muscle stiffness, pain, or weakness
- excess sweating
- fast or irregular heartbeat
- confusion

- unusual bleeding or bruising
- sore throat, fever, chills, difficult or painful urination, or other signs of infection
- hives
- rash
- blisters
- tightening of the neck muscles or the throat
- tongue sticking out
- difficulty breathing or swallowing

Quetiapine may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

Quetiapine may cause cataracts. You will need to have eye exams to check for cataracts at the beginning of your treatment and every six months during your treatment. Talk to your doctor about the risks of taking quetiapine.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>] ) or by phone (1-800-332-1088).

## What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>] ) for more information if you do not have access to a take-back program.

## In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

### Symptoms of overdose may include the following:

- drowsiness
- dizziness
- fainting
- fast heartbeat

### What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor may order certain lab tests to check your body's response to quetiapine.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

### Brand names

- Seroquel<sup>®</sup>
- Seroquel<sup>®</sup> XR

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