

MEDICATION GUIDE
Quetiapine Fumarate Extended-Release Tablet
(kweh-TYE-uh-peen)

Read this Medication Guide before you start taking quetiapine fumarate extended-release tablet 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 quetiapine fumarate extended-release tablet?

Quetiapine fumarate extended-release tablet may cause serious side effects, including:

- 1. Risk of death in the elderly with dementia:** Medicines like quetiapine fumarate extended-release tablet can increase the risk of death in elderly people who have memory loss (dementia). Quetiapine fumarate extended-release 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 medicines 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 quetiapine fumarate extended-release tablet?

Quetiapine fumarate extended-release 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
- major depressive disorder as add-on treatment with antidepressant medicines when your healthcare provider determines that 1 antidepressant alone is not enough to treat your depression.

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

Who should not take quetiapine fumarate extended-release tablet?

Do not take quetiapine fumarate extended-release tablet if you are allergic to quetiapine fumarate or any of the ingredients in quetiapine fumarate extended-release tablet. See the end of this Medication Guide for a complete list of ingredients in quetiapine fumarate extended-release tablet.

What should I tell my healthcare provider before taking quetiapine fumarate extended-release tablet?

Before you take quetiapine fumarate extended-release tablet, 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 fumarate extended-release tablet 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 fumarate extended-release tablet will harm your unborn baby
- If you become pregnant while receiving quetiapine fumarate extended-release tablet, 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 fumarate can pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you receive quetiapine fumarate extended-release tablet
- 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 fumarate extended-release tablet and other medicines may affect each other causing serious side effects. Quetiapine fumarate extended-release tablet may affect the way other medicines work, and other medicines may affect how quetiapine fumarate extended-release tablet works.

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

How should I take quetiapine fumarate extended-release tablet?

- Take quetiapine fumarate extended-release tablet exactly as your healthcare provider tells you to take it. Do not change the dose yourself.
- Take quetiapine fumarate extended-release tablet by mouth, with a light meal or without food.
- Quetiapine fumarate extended-release tablet should be swallowed whole and not split, chewed or crushed.
- **If you feel you need to stop quetiapine fumarate extended-release tablet, talk with your healthcare provider first.** If you suddenly stop taking quetiapine fumarate extended-release tablet, you may have side effects such as trouble sleeping or trouble staying asleep (insomnia), nausea, and vomiting.
- If you miss a dose of quetiapine fumarate extended-release tablet, 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 fumarate extended-release tablet?

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

What are possible side effects of quetiapine fumarate extended-release tablet?

Quetiapine fumarate extended-release tablet can cause serious side effects, including:

See "What is the most important information I should know about quetiapine fumarate extended-release tablet?"

- **stroke that can lead to death can happen in elderly people with dementia who take medicines like quetiapine fumarate extended-release tablet**
- **neuroleptic malignant syndrome (NMS).** NMS is a rare but very serious condition that can happen in people who take antipsychotic medicines, including quetiapine fumarate extended-release tablet. 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:
 - high fever
 - excessive sweating
 - rigid muscles
 - confusion
 - changes in your breathing, heartbeat, and blood pressure
- **falls** can happen in some people who take quetiapine fumarate extended-release tablet. 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:
 - build up of acid in your blood due to ketones (ketoacidosis)
 - coma
 - death

Increases in blood sugar can happen in some people who take quetiapine fumarate extended-release tablet. 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 fumarate extended-release tablet and during therapy.

Call your healthcare provider if you have any of these symptoms of high blood sugar (hyperglycemia) while taking quetiapine fumarate extended-release tablet:

- 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 fat levels in your blood (increased cholesterol and triglycerides).** High fat levels may happen in people treated with quetiapine fumarate extended-release tablet. You may not have any symptoms, so your healthcare provider may decide to check your cholesterol and triglycerides during your treatment with quetiapine fumarate extended-release tablet.
- **increase in weight (weight gain).** Weight gain is common in people who take quetiapine fumarate extended-release tablet 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 fumarate extended-release tablet. Tardive dyskinesia may also start after you stop taking quetiapine fumarate extended-release tablet.
- **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 fumarate extended-release tablet and during therapy. Quetiapine fumarate extended-release tablet is not approved for patients under 10 years of age.
- **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:** Your healthcare provider may do blood tests to check your 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 fumarate extended-release tablet.** These symptoms usually get better 1 week after you start having them.

The most common side effects of quetiapine fumarate extended-release tablet include:

- dry mouth
- constipation
- dizziness
- increased appetite
- upset stomach
- fatigue
- stuffy nose
- difficulty moving
- disturbance in speech or language

Children and Adolescents:

- drowsiness
- dizziness
- fatigue
- stuffy nose
- increased appetite
- upset stomach
- vomiting
- dry mouth
- tachycardia
- weight increased

These are not all the possible side effects of quetiapine fumarate extended-release tablet. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088 or you may also report side effects to Lupin Pharmaceuticals, Inc. at 1-800-399-2561.

How should I store quetiapine fumarate extended-release tablet?

- Store quetiapine fumarate extended-release tablet at room temperature, between 15 to 30°C (59 to 86°F).

- **Keep quetiapine fumarate extended-release tablet and all medicines out of the reach of children.**

General information about the safe and effective use of quetiapine fumarate extended-release tablet.

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

For more information, call Lupin Pharmaceuticals, Inc. at 1-800-399-2561 or you can visit the Lupin website at www.lupinpharmaceuticals.com.

What are the ingredients in quetiapine fumarate extended-release tablet?

Active ingredient: quetiapine fumarate

Inactive ingredients: hypromellose, hypromellose 2208, hypromellose 2910, lactose monohydrate, macrogol, magnesium stearate, microcrystalline cellulose, red iron oxide (for 50 mg), sodium citrate dihydrate, titanium dioxide and yellow iron oxide (for 50 mg, 200 mg and 300 mg).

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

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