

Brightside Specialty Pharmacy

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Patient Education for QUETIAPINE ER 400 MG TABLET



Call doctor if signs of tardive dyskinesia occur or get worse Avoid taking with other CNS depressant drugs or alcohol Do not chew or crush tablets.OK to divide before swallowing if scored May cause drowsiness or dizziness Use caution driving. Worsening depression/thoughts of suicide should be reported ASAP Not recommended for dementia-related behavioral problems. Dispense & explain patient package insert and medication guide. May cause problems in newborns. Use with caution in 3rd trimester

Call doctor if unusual muscle movements occur Avoid alcohol/other drugs that make you sleepy Do not chew or crush. OK to split tablet if scored May make you drowsy or dizzy. Drive with caution Immediately report to MD any thoughts of suicide. Tell doctor your complete medical history Important to read patient package insert& med guide Discuss risk vs benefits of use during pregnancy.

.....Education Section.....

IMPORTANT:

HOW TO USE THIS INFORMATION: This is a summary and

does NOT have all possible information about this product. This information does not assure that this product is safe, effective, or appropriate for you. This information is not individual medical advice and does not substitute for the advice of your health care professional. Always ask your health care professional for complete information about this product and your specific health needs.

QUETIAPINE SUSTAINED-RELEASE - ORAL

(kweh-TIE-ah-peen)

COMMON BRAND NAME(S):

Seroquel XR

WARNING:

There may be a slightly increased risk of serious,

possibly fatal side effects (such as stroke, heart failure, fast/irregular heartbeat, pneumonia) when this medication is used for older adults with dementia. This medication is not approved for the treatment of dementia-related behavior problems. Discuss the risks and benefits of this medication, as well as other effective and possibly safer treatments for dementia-related behavior problems, with the doctor.

If you are using quetiapine in combination with other medication to treat depression, also carefully read the drug information for the other medication.

Quetiapine sustained-release is used to treat certain mental/mood disorders (such as schizophrenia, bipolar disorder, sudden episodes of mania or depression associated with bipolar disorder). It is also used with other medications to treat depression. Drugs used to treat depression can help prevent suicidal thoughts/attempts and provide other important benefits. However, studies have shown that a small number of people (especially people younger than 25) who take drugs to treat depression may experience worsening depression, other mental/mood symptoms, or suicidal thoughts/attempts. It is very important to talk with the doctor about the risks and benefits of drugs used to treat depression (especially for people younger than 25), even

if treatment is not for a mental/mood condition.

Tell the doctor right away if you notice worsening depression/other psychiatric conditions, unusual behavior changes (including possible suicidal thoughts/attempts), or other mental/mood changes (including new/worsening anxiety, panic attacks, trouble sleeping, irritability, hostile/angry feelings, impulsive actions, severe restlessness, very rapid speech). Be especially watchful for these symptoms when a new drug to treat depression is started or when the dose is changed.

This medication is not approved for use in children under 10 years old.

USES:

This medication is used to treat certain mental/mood

conditions (such as schizophrenia, bipolar disorder, sudden episodes of mania or depression associated with bipolar disorder). It is also used with other medications to treat depression. Quetiapine is known as an anti-psychotic drug (atypical type). It works by helping to restore the balance of certain natural substances (neurotransmitters) in the brain.

This medication can decrease hallucinations and improve your concentration. It helps you to think more clearly and positively about yourself, feel less nervous, and take a more active part in everyday life. It may also improve your mood, sleep, appetite, and energy level. Quetiapine can help prevent severe mood swings or decrease how often mood swings occur.

HOW TO USE:

Read the Medication Guide and, if available, the

Patient Information Leaflet provided by your pharmacist before you start using quetiapine and each time you get a refill. If you have any questions, ask your doctor or pharmacist.

Take this medication by mouth as directed by your doctor, usually once daily in the evening without food or with a light meal. Do not crush or chew this medication. Doing so can release all of the drug at once, increasing the risk of side effects. Also, do not split the tablets unless they have a score line and your doctor or pharmacist tells you to do so. Swallow the whole or split tablet without crushing or chewing.

The dosage is based on your medical condition, response to

treatment, and other medications you may be taking. Be sure to tell your doctor and pharmacist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products).

To reduce your risk of side effects, your doctor may direct you to start this medication at a low dose and gradually increase your dose. Follow your doctor's instructions carefully. Take this medication regularly to get the most benefit from it. To help you remember, take it at the same time each day.

Do not increase your dose or use this drug more often or for longer than prescribed. Your condition will not improve any faster, and your risk of side effects will increase.

Keep taking this medication even if you feel well. Do not stop taking this medication without consulting your doctor. Some conditions may become worse when this drug is suddenly stopped. Also, you may experience symptoms such as trouble sleeping, nausea, headache, diarrhea, irritability. Your dose may need to be gradually decreased to reduce side effects. Report any new or worsening symptoms right away.

Tell your doctor if your condition lasts or gets worse.

SIDE EFFECTS:

See also Warning section.

Constipation, drowsiness, upset stomach, tiredness, weight gain, blurred vision, or dry mouth may occur. If any of these effects last or get worse, tell your doctor promptly.

Dizziness or lightheadedness may occur, especially when you first start or increase your dose of this drug. Dizziness and lightheadedness can increase the risk of falling. Get up slowly when rising from a sitting or lying position.

Remember that this medication has been prescribed because your doctor has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Tell your doctor right away if you have any serious side effects, including: nausea/vomiting that doesn't stop, constipation with abdominal pain that doesn't go away, restlessness/constant need to move, shaking (tremor), mental/mood changes (such as increased anxiety, depression, thoughts of suicide), difficulty swallowing, loss of appetite, yellowing eyes/skin, interrupted breathing during sleep, trouble urinating.

Get medical help right away if you have any very serious side effects, including: fainting, seizure, severe dizziness.

This medication may rarely make your blood sugar rise, which can cause or worsen diabetes. Tell your doctor right away if you have symptoms of high blood sugar such as increased thirst/urination. If you already have diabetes, check your blood sugar regularly as directed and share the results with your doctor. Your doctor may need to adjust your diabetes medication, exercise program, or diet.

This drug may also cause significant weight gain and a rise in your blood cholesterol (or triglyceride) levels. These effects, along with diabetes, may increase your risk for developing heart disease. Discuss the risks and benefits of treatment with your doctor. (See also Notes section.)

Quetiapine may rarely cause a condition known as tardive dyskinesia. In some cases, this condition may be permanent. Tell

your doctor right away if you develop any unusual/uncontrolled movements (especially of the face, lips, mouth, tongue, arms or legs).

This medication may rarely cause a very serious condition called neuroleptic malignant syndrome (NMS). Get medical help right away if you have any of the following symptoms: fever, muscle stiffness/pain/tenderness/weakness, severe tiredness, severe confusion, sweating, fast/irregular heartbeat, dark urine, signs of kidney problems (such as change in the amount of urine).

Quetiapine may increase a certain natural substance (prolactin) made by your body. For females, this increase in prolactin may result in unwanted breast milk, missed/stopped periods, or difficulty becoming pregnant. For males, it may result in decreased sexual ability, inability to produce sperm, or enlarged breasts. If you develop any of these symptoms, tell your doctor right away.

Rarely, males may have a painful or prolonged erection lasting 4 or more hours. If this occurs, stop using this drug and get medical help right away, or permanent problems could occur.

A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: fever, swollen lymph nodes, rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

In the US -

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch.

In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

PRECAUTIONS:

Before taking quetiapine, tell your doctor or

pharmacist if you are allergic to it; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: eye cataracts, liver disease, low white blood cell count (including history of low white blood cell count caused by medications), seizure disorder, trouble swallowing, thyroid problems, stomach/intestinal blockage (such as severe constipation, bowel obstruction), stomach/intestines that are not moving (such as ileus), personal or family history of diabetes, personal or family history of a substance use disorder (such as overuse of or addiction to drugs/alcohol), heart disease, high blood pressure, high cholesterol/triglyceride levels, breathing trouble during sleep (sleep apnea), difficulty urinating (for example, due to enlarged prostate).

This drug may make you dizzy or drowsy or blur your vision. Alcohol or marijuana (cannabis) can make you more dizzy or drowsy. Do not drive, use machinery, or do anything that needs

alertness or clear vision until you can do it safely. Avoid alcoholic beverages. Talk to your doctor if you are using marijuana (cannabis).

Quetiapine may cause a condition that affects the heart rhythm (QT prolongation). QT prolongation can rarely cause serious (rarely fatal) fast/irregular heartbeat and other symptoms (such as severe dizziness, fainting) that need medical attention right away.

The risk of QT prolongation may be increased if you have certain medical conditions or are taking other drugs that may cause QT prolongation. Before using quetiapine, tell your doctor or pharmacist of all the drugs you take and if you have any of the following conditions: certain heart problems (heart failure, slow heartbeat, QT prolongation in the EKG), family history of certain heart problems (QT prolongation in the EKG, sudden cardiac death).

Low levels of potassium or magnesium in the blood may also increase your risk of QT prolongation. This risk may increase if you use certain drugs (such as diuretics/"water pills") or if you have conditions such as severe sweating, diarrhea, or vomiting. Talk to your doctor about using quetiapine safely.

This medication may make you sweat less, making you more likely to get heat stroke. Avoid doing things that may cause you to overheat, such as hard work or exercise in hot weather, or using hot tubs. When the weather is hot, drink a lot of fluids and dress lightly. If you overheat, quickly look for a place to cool down and rest. Get medical help right away if you have a fever that does not go away, mental/mood changes, headache, or dizziness.

Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products).

Children may be at higher risk for certain side effects while taking this medication, such as increased blood pressure or increased prolactin (see also Side Effects section). Talk with the doctor about the risks and benefits.

Older adults may be more sensitive to the side effects of this drug, especially drowsiness, dizziness, lightheadedness, and QT prolongation (see above). Drowsiness, dizziness, and lightheadedness can increase the risk of falling.

During pregnancy, this medication should be used only when clearly needed. Babies born to mothers who have used this drug during the last 3 months of pregnancy may rarely develop symptoms including muscle stiffness or shakiness, drowsiness, feeding/breathing difficulties, or constant crying. If you notice any of these symptoms in your newborn especially during their first month, tell the doctor right away.

Since untreated mental/mood problems (such as schizophrenia, bipolar disorder, depression) can be a serious condition, do not stop taking this medication unless directed by your doctor. If you are planning pregnancy, become pregnant, or think you may be pregnant, immediately discuss with your doctor the benefits and risks of using this medication during pregnancy.

This medication passes into breast milk and may have undesirable effects on a nursing infant. Tell the doctor right away if your baby develops symptoms such as muscle stiffness or shakiness, unusual sleepiness, or difficulty feeding. Consult

your doctor before breast-feeding.

DRUG INTERACTIONS:

Drug interactions may change how your

medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval.

Many drugs besides quetiapine may affect the heart rhythm (QT prolongation), including amiodarone, moxifloxacin, procainamide, quinidine, sotalol, thioridazine, among others.

Other medications can affect the removal of quetiapine from your body, which may affect how quetiapine works. Examples include azole antifungals (such as itraconazole, ketoconazole), rifamycins (such as rifampin), drugs used to treat seizures (such as phenytoin), among others.

Tell your doctor or pharmacist if you are taking other products that cause drowsiness such as opioid pain or cough relievers (such as codeine, hydrocodone), alcohol, marijuana (cannabis), drugs for sleep or anxiety (such as alprazolam, lorazepam, zolpidem), muscle relaxants (such as carisoprodol, cyclobenzaprine), or antihistamines (such as cetirizine, diphenhydramine).

Check the labels on all your medicines (such as allergy or cough-and-cold products) because they may contain ingredients that cause drowsiness. Ask your pharmacist about using those products safely.

This medication may interfere with certain laboratory tests (including urine tests), possibly causing false test results. Make sure laboratory personnel and all your doctors know you use this drug.

OVERDOSE:

If someone has overdosed and has serious symptoms such

as passing out or trouble breathing, call 911. Otherwise, call a poison control center right away. US residents can call their local poison control center at 1-800-222-1222. Canada residents can call a provincial poison control center. Symptoms of overdose may include: severe drowsiness, loss of consciousness.

NOTES:

Do not share this medication with others.

Keep all regular medical and psychiatric appointments. Laboratory and/or medical tests (such as blood sugar, blood pressure, cholesterol levels, eye exams, weight, blood counts) should be performed before you start treatment, periodically to monitor your progress, or to check for side effects. Consult your doctor for more details.

MISSED DOSE:

If you miss a dose, take it as soon as you

remember. If it is near the time of the next dose, skip the missed dose. Take your next dose at the regular time. Do not double the dose to catch up.

STORAGE:

Store at room temperature away from light and moisture.

Do not store in the bathroom. Keep all medications away from children and pets.

Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company.

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