

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **PRO-QUETIAPINE**

Quetiapine Tablets

Read this carefully before you start taking **PRO-QUETIAPINE** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **PRO-QUETIAPINE**.

Serious Warnings and Precautions

- PRO-QUETIAPINE belongs to a group of medicines called atypical antipsychotics. These medicines have been linked to a higher rate of death when used in elderly patients with dementia (loss of memory and other mental abilities).
- PRO-QUETIAPINE is not to be used if you are elderly and have dementia.

What is PRO-QUETIAPINE used for?

PRO-QUETIAPINE is used to treat symptoms of schizophrenia in adults. Not all people with this disorder have the same symptoms. Some of the most common symptoms of schizophrenia may include:

- hallucinations (seeing, feeling, hearing or smelling things that are not there)
- delusions (believing things that are not true)
- paranoia (not trusting others or feeling very suspicious)
- avoiding family members and friends and wanting to be alone
- feeling depressed, anxious or tense.

PRO-QUETIAPINE is also used to treat adults who suffer from manic or depressive episodes in bipolar disorder.

Bipolar disorder is a condition with symptoms such as:

- feeling invincible or an all powerful inflated self-esteem
- having racing thoughts, easily losing train of thought
- overreacting to what you see or hear
- misinterpreting events
- speeding-up your activities, talking very quickly, too loudly, or more than usual
- needing less sleep
- having poor judgment
- severe irritability
- feeling sad or hopeless
- loss of interest and enjoyment
- feeling tired

PRO-QUETIAPINE is not a cure for your condition, but it can help manage your symptoms and help you feel better.

How does PRO-QUETIAPINE work?

Antipsychotic medications affect the chemicals that allow communication between nerve cells (neurotransmitters). Illnesses that affect the brain may be due to certain chemicals (dopamine and serotonin) in the brain being out of balance. These imbalances may cause some of the symptoms you may be experiencing. Exactly how PRO-QUETIAPINE works is unknown. However, it seems to adjust the balance of these chemicals.

What are the ingredients in PRO-QUETIAPINE?

Medicinal ingredients: quetiapine fumarate

Non-medicinal ingredients: Calcium hydrogen phosphate dihydrate, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, and sodium starch glycolate.

The film coating contains:

25 mg: FD&C yellow #6, FD&C red #40, FD&C blue #2, polyethylene glycol 3350, polyvinyl alcohol, talc, titanium dioxide.

100 mg: iron oxide yellow, polyethylene glycol 3350, polyvinyl alcohol, talc, titanium dioxide

150 mg: FD&C red # 40, FD&C blue #2, iron oxide yellow,
polyethylene glycol 3350, polyvinyl alcohol, talc, titanium dioxide

200 mg & 300 mg: polyethylene glycol 3350, polyvinyl alcohol, talc, titanium dioxide

PRO-QUETIAPINE comes in the following dosage forms:

Immediate-release tablets: 25 mg, 100 mg, 150 mg, 200 mg and 300 mg.

Do not use PRO-QUETIAPINE if:

- You are allergic to quetiapine fumarate or to any of the ingredients in PRO-QUETIAPINE (see list of Non-medicinal ingredients).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take PRO-QUETIAPINE. Talk about any health conditions or problems you may have, including if you:

- Have had an allergic reaction to any medicine which you have taken previously to treat your condition.
- Are pregnant, think you may be pregnant or plan to become pregnant.
- Are breast-feeding or are planning on breast-feeding. You should not breast-feed while taking PRO-QUETIAPINE
- Drink alcohol or use street drugs.
- Have a history of alcohol or drug abuse.
- Have low or high blood pressure.
- Have had a stroke or are at risk for stroke.
- Have or have a family history of:
 - heart problems
 - any problems with the way your heart beats
 - heart disease
- Have a history of seizures (fits).
- Have diabetes or a family history of diabetes as PRO-QUETIAPINE may increase your high blood sugar levels.
- Have a history of liver or kidney problems.
- Know that you had a low white blood cell count in the past.
- Exercise vigorously or work in hot or sunny places.
- Have risk factors for developing blood clots such as:
 - a family history of blood clots
 - being over the age of 65
 - smoking
 - being overweight
 - having a recent major surgery (such as hip or knee replacement)
 - not being able to move due to air travel or other reasons
 - taking oral birth control (“The Pill”).
- Suffer or have ever suffered from severe constipation, a blocked bowel or any other condition that affects your large bowel.
- Have or have had sleep apnea (a sleep disorder where your breathing is interrupted during sleep) or are taking medicines that slow down normal activity of the brain (“depressants”) or breathing.

- Have or have had a condition where your bladder does not empty or does not empty completely (urinary retention).
- Have narrow angle glaucoma or pressure inside your eyes.
- Are at risk for aspiration pneumonia.

Other warnings you should know about:

Self-harm: If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away. You may find it helpful to tell a relative or close friend that you are depressed or have other mental illnesses. Ask them to read this leaflet. You might ask them to tell you if they:

- Think your depression or mental illness is getting worse.
- Are worried about changes in your behaviour.

Effects on Newborns: In some cases, babies born to a mother taking PRO-QUETIAPINE during pregnancy have symptoms of withdrawal that are severe and require the newborn to be hospitalized. Sometimes, the symptoms may resolve on their own. Be ready to seek emergency medical help for your newborn if they:

- Have trouble breathing.
- Are overly sleepy.
- Have muscle stiffness, or floppy muscles (like a rag doll).
- Are shaking.
- Are having difficulty feeding.

Monitoring and Tests: Your doctor may do tests before you start treatment with PRO-QUETIAPINE and they may monitor you during treatment. These tests may include:

- Blood tests to monitor:
 - blood sugar
 - red and white blood cell count
 - amount of platelets
 - liver enzymes
 - lipid levels (a type of fatty substance in your body)
 - creatine phosphokinase levels (a substance in muscles)
 - prolactin levels (a hormone in your body)
- Body weight checks to monitor any weight gain.
- Eye examinations to monitor any lens changes in your eyes.

Dehydration and Overheating: It is important not to become too hot or dehydrated while you are taking PRO-QUETIAPINE.

- Do not exercise too much.
- In hot weather, stay inside in a cool place if possible.
- Stay out of the sun.
- Do not wear too much clothing or heavy clothing.
- Drink plenty of water.

Driving and Using Machines: PRO-QUETIAPINE may make you feel sleepy. Give yourself time after taking PRO-QUETIAPINE to see how you feel before driving a vehicle or using machinery.

Heart Problems: Cardiomyopathy (weakening of the heart muscle) and myocarditis (inflammation of the heart) have been reported in some patients. However, it is not known if PRO-QUETIAPINE treatment is related to these problems.

PRO-QUETIAPINE can cause serious side effects including:

- Neuroleptic Malignant Syndrome (NMS) a condition that affects the nervous system.

- Severe skin reactions that can be life-threatening such as Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), Acute Generalized Exanthematous Pustulosis (AGEP), Erythema Multiforme (EM) and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).
- Tardive Dyskinesia (TD) and Extrapyrarnidal Symptoms (EPS), disorders that affect your movements.
- Pancreatitis (inflammation of the pancreas).

See the **Serious side effects and what to do about them** table below for more information on these and other serious side effects. Talk to a healthcare professional **right away** if you think you are experiencing any of these serious side effects.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with PRO-QUETIAPINE:

- PRO-QUETIAPINE can increase the effects of the alcohol.
- Medicines used to treat high blood pressure such as diltiazem, verapamil.
- Medicines used to treat seizures such as carbamazepine, phenytoin, divalproex.
- Medicines used to treat psychosis such as thioridazine.
- Medicines used to treat depression such as nefazodone.
- Medicines used to treat infections (antibiotics) such as erythromycin, clarithromycin.
- Medicines called “anticholinergics”, which cause constipation or may affect your ability to empty your bladder.
- Ketoconazole, a drug used to treat fungal infections.
- Levodopa, a drug used to treat Parkinson’s and other drugs called “dopamine agonists”.
- Rifampin, a drug used to treat tuberculosis.
- Medicines that affect the way your heart beats, these include drugs known to cause electrolyte imbalance called “diuretics” (“water pills”).
- Drugs called “protease inhibitors” used to treat Human Immunodeficiency Virus (HIV).

Effect on Urine Drug Screens: PRO-QUETIAPINE may cause positive results for methadone or certain drugs for depression called “tricyclic antidepressants” (TCAs), even if you are not taking these drugs. Tell your healthcare professional that you are taking PRO-QUETIAPINE so more specific tests can be conducted.

How to take PRO-QUETIAPINE:

- Even if you feel better, do **NOT** change your dose or stop taking PRO-QUETIAPINE without talking to your healthcare professional.
- PRO-QUETIAPINE can be taken with or without food.
- Try to take PRO-QUETIAPINE at the same time each day.

Usual dose:

Schizophrenia

The usual starting dose is 25 mg, twice daily. The recommended dose range is 25 to 400 mg, taken twice daily.

Bipolar Mania

The usual starting dose is 50 mg, twice daily. The recommended dose range is 50 to 400 mg, taken twice daily.

Bipolar Depression

The usual dosing schedule is 50 mg on day 1, 100 mg on day 2, 200 mg on day 3, and 300 mg on day 4 and onwards taken once daily. Your doctor may increase the dose to 400 mg on day 5 and up to 600 mg per day from day 8 onwards depending on your response and tolerability. The maximum dose is 600 mg per day.

It takes time to feel better and you should expect some symptoms to improve slowly over the first few weeks of treatment. Do not stop taking PRO-QUETIAPINE, or change the times of day you take PRO-QUETIAPINE, without talking to your doctor first.

If you stop taking PRO-QUETIAPINE abruptly you may experience withdrawal symptoms such as insomnia (not being able to sleep), nausea, and vomiting. Keep your doctor well informed of how you are feeling, both good and bad. By doing this, you and your doctor will be able to make sure that you are getting the best dose of PRO-QUETIAPINE for you.

Overdose:

If you think you, or a person you are caring for, have taken too much PRO-QUETIAPINE, contact a healthcare professional, hospital emergency department or, regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose by only a few hours, take it as soon as possible. If most of the day has passed since your missed dose, skip that dose and wait until your next scheduled dose. Never take two doses at once.

What are possible side effects from using PRO-QUETIAPINE?

These are not all the possible side effects you may have when taking PRO-QUETIAPINE. If you experience any side effects not listed here, tell your healthcare professional.

- Light-headedness or feeling faint
- Dizziness or drowsiness
- Falls
- Headache
- Fever and flu-like symptoms
- Sore throat
- Nausea or vomiting
- Indigestion
- Upset stomach or stomach pain
- Constipation
- Diarrhea
- Irritability
- Shortness of breath
- Slow or fast heart rate
- Feeling weak
- Swelling of arms and legs
- Blurred vision
- Dry mouth
- Difficulty swallowing
- Feeling more hungry
- Weight gain
- Trouble sleeping or falling asleep
- Abnormal dreams and nightmares
- Problems with speech or language

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Abnormal muscle movements, including difficulty starting muscle movements, shaking, restlessness or muscle stiffness without pain.		√	
COMMON			
Hyperglycemia (high blood sugar): increased thirst, frequent urination, excessive hunger, headache, blurred vision and fatigue.		√	
Hypotension (low blood pressure): dizziness, fainting, light-headedness, blurred vision, nausea, vomiting, fatigue (may occur when you go from lying or sitting to standing up).		√	
New or worsening constipation.		√	
UNCOMMON			
Confusion: impaired orientation, reduced attention, impaired memory, abnormal thought process.		√	
Restless Legs Syndrome: unpleasant sensations in the legs.		√	
Seizure (fits): loss of consciousness with uncontrollable shaking.			√
Tardive Dyskinesia: muscle twitching or unusual/abnormal movement of your face or tongue or other parts of your body.		√	
Urinary Retention: not being able to pass urine.			√
RARE			
Agranulocytosis (decreased white blood cell counts): infections, fatigue, fever, aches, pains and flu-like symptoms.		√	
Blood clots: swelling, pain and redness in an arm or leg that can be warm to touch. You may develop sudden chest pain, difficulty breathing and heart palpitations.		√	
Hypothermia (low body temperature): shivering, slurred speech or mumbling, slow, shallow breathing, weak pulse, very low energy, confusion or memory loss.		√	
Intestinal blockage or obstruction (blockage that stops or impairs passage of contents of intestines): cramping pain in abdomen that may begin suddenly, bloating, loss of appetite, pain that comes and goes but will then last, nausea and vomiting, constipation or diarrhea.		√	
Liver Disorder: yellowing of the skin or eyes, dark urine and pale stools, abdominal pain, nausea, vomiting, loss of appetite.		√	
Neuroleptic Malignant Syndrome (NMS): severe muscle stiffness or inflexibility with high fever, rapid or irregular heartbeat, sweating, state of confusion or reduced			√

consciousness.			
Pancreatitis (inflammation of the pancreas): upper abdominal pain, fever, rapid heart beat, nausea, vomiting, tenderness when touching the abdomen.		√	
Priapism: Long-lasting (greater than 4 hours in duration) and painful erection of the penis.			√
Somnambulism (sleep-walking): getting out of bed while not fully awake and doing activities like walking, talking or eating that you do not remember doing the day after.		√	
VERY RARE			
Allergic Reaction: difficulty swallowing or breathing, wheezing, feeling sick to your stomach and throwing up, hives or rash, swelling of the face, lips, tongue or throat.			√
Rhabdomyolysis (breakdown of damaged muscle): unexplained muscle pain, muscle tenderness, muscle weakness, red-brown (tea-coloured) urine.		√	
Sleep Apnea: stop breathing for short periods during your normal nightly sleep.			√
NOT KNOWN			
Inflammation of blood vessels (cutaneous vasculitis): skin rash with small red or purple bumps.		√	
Severe skin reactions: fever, severe rash, swollen lymph glands, flu-like feeling, blisters and peeling skin that may start in and around the mouth, nose, eyes and genitals and spread to other areas of the body, yellow skin or eyes, shortness of breath, dry cough, chest pain or discomfort, feeling thirsty, urinating less often, less urine.			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store PRO-QUETIAPINE at room temperature (between 15 - 30°C). Protect from light.

The expiry date of this medicine is printed on the package label. Do not use the medicine after this date.

If your doctor tells you to stop taking PRO-QUETIAPINE or you find that they have passed their expiry date, please return any left over medicine to your pharmacist.

Keep out of reach and sight of children.

If you want more information about PRO-QUETIAPINE:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

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