PART III: CONSUMER INFORMATION

PrPRO-RISPERIDONE
Risperidone Tablets, USP

This leaflet is Part III of a three-part "Product Monograph" published when PRO-RISPERIDONE was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about PRO-RISPERIDONE. Contact your doctor or pharmacist if you have any questions about the drug.

If you are a caregiver helping someone to take PRO-RISPERIDONE, read this leaflet before you give the first dose.

ABOUT THIS MEDICATION

What the medication is used for:
PRO-RISPERIDONE belongs to a group of medicines called antipsychotic drugs.

Use in Schizophrenia
PRO-RISPERIDONE is used to treat the symptoms of schizophrenia and related psychotic disorders, which may include hallucinations (hearing or seeing things that are not there), delusions, unusual suspiciousness, emotional withdrawal. Patients suffering from schizophrenia may also feel depressed, anxious or tense.

Use in Severe Dementia related to Alzheimer's disease
PRO-RISPERIDONE may also be used for short-term treatment in dementia related to Alzheimer's disease, specifically to control aggression or psychotic symptoms (such as believing things that are not true or seeing, feeling or hearing things that are not there) when there is a risk of harm to self or others.

Use in Acute Mania Associated with Bipolar Disorder
PRO-RISPERIDONE may be used for the acute treatment of manic episodes associated with bipolar disorder. Signs and symptoms of bipolar mania include but are not limited to: feeling invincible or all powerful, inflated self-esteem, racing thoughts, easily lose your train of thought, overreaction to what you see or hear, misinterpretation of events, speeded-up activity, talking very quickly, talking too loudly, or talking more than usual, decreased need for sleep, and poor judgment.

The doctor has prescribed PRO-RISPERIDONE to help relieve the symptoms that are bothering you/the patient you are caring for. Although PRO-RISPERIDONE cannot cure the illness, it can keep the symptoms under control and reduce the risk of relapse as you/the patient you are caring for continues treatment.

What it does:
Antipsychotic medications affect the chemicals that allow communication between nerve cells (neurotransmitters). These chemicals are called dopamine and serotonin. Exactly how PRO-RISPERIDONE works is unknown. However, it seems to readjust the balance of dopamine and serotonin.

When it should not be used:
Do not take/give PRO-RISPERIDONE if an allergic reaction to the medicine or any of the non-medicinal ingredients of the product has occurred.

Symptoms of an allergic reaction may include: itching, skin rash, swelling of the face, lips or tongue, shortness of breath. **If you experience any of these symptoms/if these symptoms are experienced by the patient you are caring for, your doctor/the treating physician should be contacted immediately.**

The safety and efficacy of risperidone in children under the age of 18 have not been established.

What the medicinal ingredient is:
risperidone

What the non-medicinal ingredients are:
PRO-RISPERIDONE tablets: All tablets contain the following non-medicinal ingredients: Colloidal Silicon Dioxide, Corn Starch, Lactose Monohydrate, Magnesium Stearate, Microcrystalline Cellulose, Polyethylene Glycol and Sodium Lauryl Sulphate. The **0.25 mg** tablets also contain Iron Oxide Yellow, Polyvinyl Alcohol and Titanium Dioxide. The **0.5 mg** tablets also contain Iron Oxide Red, Polyvinyl Alcohol, Talc and Titanium Dioxide. The **1 mg** tablets also contain Hydroxypropyl Methylcellulose, Polydextrose, Titanium Dioxide and Triethyl Citrate. The **2 mg** tablets also contain FD & C Yellow No.6 Aluminum Lake, Polyvinyl Alcohol, Talc and Titanium Dioxide. The **3 mg** tablets also contain D & C Yellow No.10 Aluminum Lake, FD & C Yellow No.6 Aluminum Lake, Polyvinyl Alcohol, Talc and Titanium Dioxide. The **4 mg** tablets also contain D & C Yellow No.10 Aluminum Lake, FD & C Blue No.2 Aluminum Lake, Polyvinyl Alcohol and Talc.

What dosage forms it comes in:
PRO-RISPERIDONE tablets: 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg and 4 mg.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions
Increased Risk of Death in Elderly People with Dementia.
Medicines like PRO-RISPERIDONE can raise the risk of death in elderly people who have dementia.

BEFORE you use PRO-RISPERIDONE, talk to your doctor or pharmacist if you/the patient you are caring for:

- have/has serious allergic reactions to other medications, including paliperidone;
- have/has a history of stroke, mini-strokes, high cholesterol or high blood pressure. Medicines like PRO-RISPERIDONE can raise the risk of death in elderly people who have dementia;

- have/has neuroleptic malignant syndrome (a disorder that causes you to have high fever and stiffness in your muscles);
- have/has tardive dyskinesia (a disorder that causes you to have uncontrolled and repeated movements of the tongue, face or other body parts);
- have/has or are at risk for diabetes or high blood sugar or a family history of diabetes;
- are/is pregnant, think you may be pregnant or planning to become pregnant;
- are/is breast-feeding or planning to breast-feed;
- have or have had prolonged and/or painful erections;
- have/has ever had blackouts or seizures;
- have/has a history of kidney or liver problems;
- have/has a history of:
  - problems with the heart and/or blood vessels;
  - any problems with the way your heart beats;
- are being treated for high blood pressure;
- are taking any medications that affect how your heart beats;
- are/is prone to hypotension (low blood pressure), have or have had a heart disease or heart disease treatment that makes you more likely to have low blood pressure or feeling dizzy or faint when you stand up from lying or sitting positions;
- are at risk for developing blood clots. Risk factors include:
  - 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");
- have had low white blood cell counts in your blood. Let your doctor know right away if you develop a fever or infection while being treated with PRO-RISPERIDONE;
- have high levels of cholesterol or fats (triglycerides) in your blood;
- have, have a history of or are at risk of:
  - sleep apnea (a sleep disorder where your breathing is interrupted during sleep)
  - sleep walking
  - sleep-related eating disorder
- have/has Parkinson's disease;
- are/is taking or planning to take any other medicines (prescription, over-the-counter medicines, or natural health products);
- drink/drinks alcoholic beverages or use/uses drugs;
- have/has or have had/has had breast cancer;
- have/has pituitary tumours;
- suffer/suffers from Alzheimer's Disease;
- suffer/suffers from Lewy body dementia;
- are/is feeling thirsty and unwell;
- exercise/exercises strenuously. This kind of medication may interfere with your body's ability to adjust to heat. You should avoid becoming overheated or dehydrated (for example with vigorous exercise or exposure to extreme heat) while taking PRO-RISPERIDONE;
- are/is planning to have an operation on the eye(s). During surgery to treat the cloudiness of the lens in your eye(s) (known as cataract surgery):
  - the pupil (the black circle in the middle of your eye) may not increase in size as needed;
  - the iris (the coloured part of the eye) may become floppy during surgery. This may lead to eye damage.

Tell your eye doctor you are taking this medicine.

Elderly Patients with Dementia

- Studies in elderly patients with dementia have shown that PRO-RISPERIDONE taken by itself or with furosemide (a "water pill") is associated with a higher rate of death (see **Serious Warnings and Precautions Box**).

  Tell your doctor if you are taking furosemide. This drug can be used to treat:
  - high blood pressure
  - some heart problems
  - swelling of parts of the body caused by the build-up of too much fluid.

- In elderly patients with dementia:
  - a sudden change in mental state
  - sudden weakness or numbness of the face, arms or legs, especially on one side of the body
  - slurred speech
  - vision problems have been seen.

  If any of these should occur, even for a short period of time, seek medical attention right away.

If you are taking blood pressure medication

Low blood pressure can result from using PRO-RISPERIDONE together with medications used to treat high blood pressure. If you need to use both PRO-RISPERIDONE and medications used to reduce blood pressure, consult your doctor.

Effects on newborns

You should not take PRO-RISPERIDONE while you are pregnant or if you are planning on becoming pregnant unless you have talked to your doctor about it.

If you took PRO-RISPERIDONE at any time while you were pregnant or if you took it before you became pregnant, the following symptoms may happen in your newborn baby:

- shaking
- stiffness in their muscles and/or weakness
- sleepiness
- agitation
- breathing problems
- difficulty feeding

Get medical help right away if your newborn baby has any of these symptoms.

In some cases, babies born to a mother taking risperidone during pregnancy have experienced symptoms that are severe and require the newborn to be hospitalized.

Other cautions
Driving and using machines: Do not drive or operate machinery until you know how you respond to PRO-RISPERIDONE. Some people experience drowsiness or blurred vision while taking PRO-RISPERIDONE.

Falls: Feeling sleepy, a fall in blood pressure when you stand up from sitting or lying down, vision and speech problems have been reported with the use of antipsychotic drugs. This can lead to falls that may cause fractures or other fall related injuries. Certain medications, diseases or conditions can make this worse.

Weight gain: Weight gain has been seen in patients who are taking antipsychotic drugs. Your doctor may monitor your body weight when you are taking PRO-RISPERIDONE.

Blood tests: Your doctor should do blood tests before you start taking PRO-RISPERIDONE. They will check your blood sugar levels, and for those with certain risk factors, the level of white blood cells in your blood. Your doctor should continue to check your blood for as long as you are being treated with PRO-RISPERIDONE.

It is important for the doctor to have all the above information before prescribing treatment and dosage. This list should be carefully reviewed by you/the caregiver and discussed with the doctor.

INTERACTIONS WITH THIS MEDICATION

Inform all doctors, dentists and pharmacists who are treating you that you are taking PRO-RISPERIDONE.

Inform them if you are taking or are planning on taking any other medicine, including other prescription or over-the-counter medications and natural health products. They will tell you which medicines you can take with PRO-RISPERIDONE.

PRO-RISPERIDONE can increase the effect of alcohol and medicines that reduce the ability to react (e.g., "tranquillizers", narcotic painkillers, certain antihistamines, certain antidepressants). It is recommended that you DO NOT drink alcohol when you are taking PRO-RISPERIDONE. You should only take these other medicines when they have been prescribed by your doctor.

Some medicines, when they are taken together with PRO-RISPERIDONE, may increase or decrease the level of PRO-RISPERIDONE in your blood. Therefore, tell your doctor if you start and/or stop taking any of the below medicines, since your doctor may need to change the dose:

- Dopamine agonists, e.g., levodopa (a drug used to treat Parkinson's disease), as these may decrease the effect of PRO-RISPERIDONE. Also, PRO-RISPERIDONE can affect how drugs used to treat Parkinson's disease work.
- Phenothiazines and some heart medications (e.g., medication for high blood pressure, antiarrhythmics, or beta-blockers), as these may interact with PRO-RISPERIDONE to cause your blood pressure to drop too low.
- PRO-RISPERDONE should be used with caution when taking medications that may change the electrical activity of the heart (QT prolongation), such as but not restricted to: medicines for malaria, heart rhythm disorders, allergies, other antipsychotics, antidepressants, water tablets or other medicines affecting body salts (sodium, potassium, magnesium).
- Carbamazepine and topiramate (drugs used to treat seizures), as these may change the effect of PRO-RISPERIDONE.
- Fluoxetine, paroxetine (antidepressants) and clozapine as these may increase the level of PRO-RISPERIDONE in your blood.
- Furosemide: Studies in elderly patients with dementia have shown that taking risperidone with furosemide, a medicine which is sometimes used to treat high blood pressure, some heart problems, or to treat swelling of parts of the body caused by the build-up of too much fluid, is associated with an increased rate of death (see **WARNINGS AND PRECAUTIONS).**
- Itraconazole and ketoconazole, medicines for treating fungal infections.
- Certain medicines used in the treatment of HIV/AIDS, such as ritonavir.
- Verapamil, a medicine used to treat high blood pressure and/or abnormal heart rhythm.
- Sertraline and fluvoxamine, medicines used to treat depression and other psychiatric disorders.
- Rifampicin, a medicine for treating some infections.
- PRO-RISPERIDONE should be used with caution with medicines that increase the activity of the central nervous system (psychostimulants such as methylphenidate).

PROPER USE OF THIS MEDICATION

Usual dose

- It is very important that you take/give PRO-RISPERIDONE the way the doctor has prescribed it.
- The doctor has decided on the best dosage for you/the patient you are caring for based on individual needs. Dosage may be increased or decreased depending on the response.
- You may take/give PRO-RISPERIDONE together with meals or between meals. Once a regular dose has been established, the total amount can be taken once a day, or divided into two intakes, one in the morning and one in the evening.

- Try to take/give PRO-RISPERIDONE at the same time each day.
- **PRO-RISPERIDONE tablets** should be swallowed with some water or other liquid.
- It is important that you keep taking/giving PRO-RISPERIDONE even after your/the symptoms have improved or disappeared. Do not change or stop taking/giving PRO-RISPERIDONE without consulting the doctor.

DO NOT give PRO-RISPERIDONE to anyone else. The doctor has prescribed it for you/the patient you are caring for.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

In overdose, one or more of the following may occur:
- feeling sedated.
- feeling drowsy or sleepy.
- unusual movements of the face, body, arms or legs (such as excessive trembling or muscle stiffness).
- a fast heart rate.
- irregular heartbeat or other symptoms of an irregular heartbeat such as lightheadedness or fainting.
- abnormal electrical conduction in the heart (QT prolongation). Symptoms may include lightheadedness or fainting.
- low blood pressure that may include feeling dizzy or lightheaded when standing up.
- low blood sodium levels. Symptoms may include headache or confusion.
- low blood potassium levels. Symptoms may include muscle cramps or feeling weak.
- seizures.

Missed Dose:
If you miss a dose, try not to miss any more. DO NOT TAKE/GIVE TWO DOSES AT ONCE.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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

Side effects that may occur very commonly are difficulty falling or staying asleep, trembling, decreased motor function or activity such as slight muscle stiffness, increased saliva and/or drooling, feeling sleepy or less alert, and headache.

Side effects that may occur commonly include: pneumonia, infections of eye, infections of ear, urinary tract infection, feeling like you have the flu, sleep disorder, depression, anxiety, irritability, dizziness, uncontrollable movements of the face or body, rigid muscles, slowness of movement and muscle stiffness or spasm, tremor, a sensation of tingling, prickling, or numbness of skin, blurry vision, faster heart rate, high blood pressure, abdominal pain, nausea/vomiting, constipation, diarrhea, indigestion, dry mouth, muscle spasms, loss of urine, swelling of the body, arms or legs, weakness, and fatigue.

PRO-RISPERIDONE can raise your levels of a hormone called "prolactin". This is measured with a blood test. Symptoms may include:
- In men:
  - swelling in the breast
  - difficulty in getting or maintaining an erection or other sexual dysfunction
- In women:
  - discomfort in the breasts
  - leaking of milk from the breasts (even if not pregnant)
  - missing your menstrual period or other problems with your cycle

If you have high levels of prolactin and a condition called hypogonadism you may be at an increased risk of breaking a bone due to osteoporosis. This occurs in both men and women.

Uncommon side effects may include: anemia, increased cholesterol in your blood, weight loss, loss of appetite resulting in malnutrition and low body weight, mania, a restless urge to move parts of your body, concentration difficulties, nightmares, itching, flushing, a sensation of tingling, pricking, or numbness of skin, muscle weakness, thirst, infection of the breathing passages, bladder infection, infection of the skin, fungal infection of the nails, crackly lung sounds, wheezing, breathing passage disorder, chills, vaginal discharge, joint swelling or stiffness, ringing in your ears, sensation of spinning (vertigo), being unresponsive to what is going on around you, difficulty with your voice, changes in taste, difficult or painful urination, bowel incontinence, gas, stomach or intestinal infection, low blood pressure, heartbeat irregularities, changes in body temperature, and increased liver transaminases in your blood.

High blood sugar, diabetes mellitus or worsening of diabetes have been reported. See your doctor if you experience symptoms such as excessive thirst or urination.

PRO-RISPERIDONE may cause sudden dizziness or lightheadedness (symptoms of postural hypotension). You/the patient you are caring for should not rise rapidly after having been sitting or lying for prolonged periods, especially when you start taking PRO-RISPERIDONE

In rare cases, the following may happen: sugar in the urine, high blood triglycerides (a fat), chapped lips, eye rolling, glaucoma (increased pressure within the eyeball), eyelid margin crusting, swollen tongue, coldness in arms and legs, and low blood sugar.

Lack of bowel muscle movement that causes blockage may occur very rarely.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY OCCUR AND WHAT TO DO ABOUT THEM			
Symptom/effect	Call your doctor or pharmacist		Stop taking drug and seek immediate medical emergency help
	Only if severe	In all cases	
Common			
Skin rash on its own		✓	
Dystonia: twisting movements that you cannot control, and can affect posture or the face, including eyes, mouth, tongue or jaw		✓	
Uncommon			
Seizure (i.e., loss of consciousness with uncontrollable shaking)			✓
Decreased White Blood Cells: infections, fatigue, fever, aches, pains and flu-like symptoms		✓	
Tardive Dyskinesia: Muscle twitching or abnormal movements of the face, tongue or other parts of your body		✓	
Severe Allergic Reaction: fever, itching, skin rash, hives, swelling of the mouth, face, lips, throat or tongue, difficulty swallowing or breathing, shortness of breath and sometimes a drop in blood pressure (amounting to an "anaphylactic reaction")			✓
Strokes and Transient Ischemic Attacks: Sudden change in mental state or sudden weakness or numbness of the face, arms or legs, especially on one side, slurred speech or vision problems, even for a short period of time			✓
Dysphagia: difficulty swallowing that can cause food or liquid to get into your lungs		✓	
Rare			

SERIOUS SIDE EFFECTS, HOW OFTEN THEY OCCUR AND WHAT TO DO ABOUT THEM			
Symptom/effect	Call your doctor or pharmacist		Stop taking drug and seek immediate medical emergency help
	Only if severe	In all cases	
Rhabdomyolysis: Very dark ("tea coloured") urine, muscle tenderness and/or aching			✓
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.		✓	
A state of confusion, reduced consciousness, high fever, or pronounced muscle stiffness			✓
Inflammation of the pancreas: severe abdominal pain, fever, nausea, vomiting			✓
Jaundice: yellowing of the skin and eyes, dark urine		✓	
Very Rare			
Life-threatening complications of uncontrolled diabetes, such as shortness of breath, confusion and loss of consciousness			✓
Marked changes in body temperature (generally as a result of several factors together including extreme heat or cold)			✓
Priapism: long-lasting (greater than 4 hours in duration) and painful erection of the penis			✓
Serious allergic reactions even if you have previously tolerated oral risperidone or oral paliperidone; symptoms include rash, swelling of your throat, itching or problems breathing. These may be signs of a serious allergic reaction			✓
Catatonia: unable to move or respond while awake		✓	

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

HOW TO STORE IT

Store PRO-RISPERIDONE in its original package.

PRO-RISPERIDONE tablets should be stored between 15°C and 30°C. Protect from light and moisture.

Keep PRO-RISPERIDONE out of reach and sight of children.

The expiry date for PRO-RISPERIDONE is printed on the package. Do not use the medicine in the package after this date.

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.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be obtained by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

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