PART III: CONSUMER INFORMATION

[Pr]PRO-RISPERIDONE
Risperidone Tablets, House Standard

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
Studies with various medicines of the group to which PRO-RISPERIDONE belongs, when used in elderly patients with dementia, have been associated with an increased rate of death. Some of these studies included treatment with risperidone.

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

- have/has a history of stroke, mini-strokes, high cholesterol or high blood pressure;
- have/has diabetes or a family history of diabetes;
- are/is pregnant or planning to become pregnant;
- are/is breast-feeding;
- 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;
- are/is prone to hypotension;
- have risk factors for developing blood clots such as: a family history of blood clots, age over 65, smoking, obesity, recent major surgery (such as hip or knee replacement), immobility due to air travel or other reason, or take oral contraceptives ("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/has Parkinson's disease;
- are/is taking or planning to take any other medicines (prescription or over-the-counter medicines);
- 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 dehydrated;
- exercise/exercises strenuously;
- are/is planning to have an operation on the eye.

Elderly Patients with Dementia
Studies in elderly patients with dementia have shown that risperidone taken by itself or with furosemide is associated with a higher rate of death (see **Serious Warnings and Precautions Box**).

Tell your doctor if you are taking furosemide. Furosemide is 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.

In elderly patients with dementia, a sudden change in mental state or sudden weakness or numbness of the face, arms or legs, especially on one side, or instances of slurred speech 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
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. Sometimes, the symptoms may resolve on their own. Be prepared to seek immediate emergency medical attention for your newborn if they have difficulty breathing, are overly sleepy, have muscle stiffness, or floppy muscles (like a rag doll), are shaking, or are having difficulty feeding.

Other cautions
Very rarely, a state of confusion, reduced consciousness, high fever or stiff muscles might occur. If this should happen, contact a doctor right away and tell him or her that you are receiving PRO-RISPERIDONE.

During long-term treatment, PRO-RISPERIDONE might cause involuntary twitching in the face. Should this happen, consult your doctor.

Since medications of this type may interfere with the ability of the body to adjust to heat, it is best to avoid becoming overheated or dehydrated (for example with vigorous exercise or exposure to extreme heat) while taking PRO-RISPERIDONE.

PRO-RISPERIDONE should be used with caution, and only after consultation with your doctor, if you have heart problems, particularly irregular heart rhythm, abnormalities in electrical activity of the heart, or if using medications that can change the heart's electrical activity.

Because some people experience drowsiness, you should not drive or operate machinery until you are reasonably certain that PRO-RISPERIDONE does not affect your ability to carry out these activities.

During an operation on the eye for cloudiness of the lens (cataract), the pupil (the black circle in the middle of your eye) may not increase in size as needed. Also, the iris (the colored part of the eye) may become floppy during surgery and that may lead to eye damage. If you are planning to have an operation on your eye, make sure you tell your eye doctor that you are taking this medicine.

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. 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 (antiparkinsonian agent), as these may decrease the effect of PRO-RISPERIDONE.

- 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 (anticonvulsants), as these may change the effect of PRO-RISPERIDONE.

- Fluoxetine and 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.

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 signs may occur: reduced consciousness, sleepiness, excessive trembling, excessive muscle stiffness, fast beating heart, dizziness or light-headedness when standing up.

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

Like other medications, PRO-RISPERIDONE can cause some side effects. Some side effects are minor and temporary; however, some may be serious and need medical attention. Many of the side effects are dose related, so it is important not to exceed your prescribed dose. Should you experience these symptoms, please consult your doctor.

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" (measured with a blood test). In women, medicines of this type may cause changes in the regularity of their monthly period, breast discomfort, or leakage of milk from the breast even if they are not pregnant. In some men, there may be difficulty in

getting or maintaining erections, or other sexual dysfunction and breast enlargement may be experienced.

Weight gain has been observed with risperidone. Your doctor may check your body weight before starting PRO-RISPERIDONE and during treatment.

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.

During cataract surgery, a condition called intraoperative floppy iris syndrome (IFIS) can happen if you take or have taken PRO-RISPERIDONE. If you need to have cataract surgery, be sure to tell your eye doctor if you take or have taken PRO-RISPERIDONE.

Your doctor may take blood tests before starting PRO-RISPERIDONE and during treatment, and may monitor blood sugar and the number of infection-fighting white blood cells.

If you have high levels of prolactin (measured with a blood test) 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.

Do not be alarmed by this list of possible side effects. You may not experience any of them. If any of these side effects are experienced, they are usually mild and temporary. However, do not hesitate to report any undesired side effects to your doctor.

If you have taken PRO-RISPERIDONE in the last three months of your pregnancy and you notice that your newborn baby develops shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding, seek immediate emergency medical attention.

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		✓	
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 or tongue		✓	
Allergic Reaction: itching, rash, hives, swelling of the face, lips, throat or tongue, difficulty swallowing or breathing, shortness of breath			✓
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			✓
Rare			
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			✓

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	
of several factors together including extreme heat or cold)			
Long-lasting (greater than 4 hours in duration) and painful erection of the penis			✓

This is not a complete list of side effects. For any unexpected effects while taking PRO-RISPERIDONE, contact your doctor or pharmacist.

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 help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.
3 ways to report:

- Online at MedEffect (http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program
    Health Canada, Postal Locator 0701E
    Ottawa, ON
    K1A 0K9

  Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect (http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php).

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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