PART III: CONSUMER INFORMATION

APO-RISPERIDONE
Risperidone Tablets

This leaflet is Part III of a three-part "Product Monograph" published when APO-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 APO-RISPERIDONE. Contact your doctor or pharmacist if you have any questions about the drug.

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

ABOUT THIS MEDICATION

What the medication is used for:
APO-RISPERIDONE (Risperidone Tablets) belongs to a group of medicines called antipsychotic drugs.

Use in Schizophrenia
APO-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 Inappropriate Behaviour Associated with Severe Dementia
APO-RISPERIDONE may also be used for the short-term symptomatic management of behavioural disturbances such as verbal aggression (e.g.. screaming, cursing) or physical aggression (e.g.. kicking, hitting, biting, scratching, throwing things), as well as unusual suspiciousness and agitation in patients with severe dementia.

Use in Acute Mania Associated with Bipolar Disorder
APO-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 APO-RISPERIDONE, also known as risperidone, to help relieve the symptoms that are bothering you / the patient you are caring for. Although APO-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 APO-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 APO-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 important nonmedicinal ingredients are:
APO-RISPERIDONE tablets: All tablets contain the following nonmedicinal ingredients: lactose monohydrate, microcrystalline cellulose, corn starch, magnesium stearate, hydroxypropyl methyl cellulose, hydroxypropyl cellulose, polyethylene glycol and titanium dioxide. The 0.25 mg tablets also contain yellow ferric oxide. The 0.5 mg tablets also contain red ferric oxide. The 2 mg tablets also contain sunset yellow aluminum lake 40%. The 3 mg tablets also contain D & C yellow #10 aluminum lake 14-18%. The 4 mg tablets also contain D & C yellow #10 aluminum lake 14-18% and indigotine AL lake 12-14% (blue #2).

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

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions
Studies with various medicines of the group to which APO-RISPERIDONE (Risperidone Tablets) 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 APO-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 your heart and/or blood vessels;
- have/has Parkinson's disease;
- are taking or planning to take any other medicines (prescription or over-the-counter medicines);
- drink/drinks alcoholic beverages or use/uses drugs;
- are/is prone to low blood pressure (hypotension);
- 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.

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 drug which is sometimes used to treat high blood pressure, some heart problems, or to treat swelling of parts of the body caused by 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 risperidone together with medications used to treat high blood pressure. If you need to use both APO-RISPERIDONE and medications used to reduce blood pressure, consult your doctor.

If you may be pregnant
Shaking, muscle stiffness and difficulty in feeding, all of which are reversible, may occur in newborns, if a mother used risperidone in the last trimester of her pregnancy.

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 APO-RISPERIDONE.

During long-term treatment, APO-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 APO-RISPERIDONE.

APO-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 APO-RISPERIDONE does not affect your ability to carry out these activities.

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 APO-RISPERIDONE (Risperidone Tablets).

Inform them if you are taking or are planning on taking any other medicine. They will tell you which medicines you can take with APO-RISPERIDONE.

APO-RISPERIDONE can increase the effect of alcohol and drugs that reduce the ability to react (e.g., "tranquillizers", narcotic painkillers, certain antihistamines, certain antidepressants). It is recommended that you DO NOT drink alcohol and only take drugs prescribed by your doctor.

Inform your doctor if you start or stop taking any of the following medications:
- Dopamine agonists, e.g. levodopa (antiparkinsonian agent), may decrease the effect of APO-RISPERIDONE.
- Phenothiazines and some heart medications (e.g., medication for high blood pressure, antiarrhythmics, or β-blockers), as these may interact with APO-RISPERIDONE to cause your blood pressure to drop too low.
- APO-RISPERIDONE should be used with caution when taking medications that may change the electrical activity of the heart, 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 APO-RISPERIDONE.
- PROZAC® (fluoxetine), PAXIL® (paroxetine) (anti-depressants) and CLOZARIL® (clozapine), as these may increase the level of APO-RISPERIDONE in your blood.
- LASIX® (furosemide): Studies in elderly patients with dementia have shown that taking APO-RISPERIDONE with furosemide, a drug, which is sometimes used to treat high blood pressure, some heart problems, or to treat swelling of parts of the body caused by build-up of too

much fluid, is associated with an increased rate of death (see WARNINGS AND PRECAUTIONS).

PROPER USE OF THIS MEDICATION

Usual dose:

- It is very important that you take / give APO-RISPERIDONE (Risperidone Tablets) 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 APO-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 APO-RISPERIDONE at the same time each day.
- APO-RISPERIDONE should be swallowed with some water or other liquid.
- It is important that you keep taking / giving APO-RISPERIDONE even after your / the symptoms have improved or disappeared. Do not change or stop taking / giving APO-RISPERIDONE without consulting the doctor.

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

Overdose:

In overdose, one or more of the following signs may occur in an overdose: reduced consciousness, drowsiness, sleepiness, rapid heartbeat, excessive trembling or excessive muscle stiffness, dizziness or lightheadedness when standing up.

If you take / give too much APO-RISPERIDONE, immediately contact the doctor, regional poison control centre or go / take the patient to the nearest hospital emergency department. Do this even if there are no signs of discomfort. Make sure to bring this medication bottle with you.

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, APO-RISPERIDONE (Risperidone Tablets) 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.

In patients with schizophrenia, the most common side effects of APO-RISPERIDONE include the following:

- sleeplessness / sleepiness
- anxiety
- trembling, decreased motor function or activity such as slight muscle stiffness
- a feeling of restlessness (akathisia)
- dizziness
- headache
- runny nose
- constipation
- weight gain
- increased heart rate

In severely demented patients, the most common side effects of APO-RISPERIDONE include the following:

- sleepiness
- trembling, decreased motor function or activity such as slight muscle stiffness
- a feeling of restlessness (akathisia)
- swelling of the ankles
- runny nose
- dizziness, lightheadedness
- difficulty breathing
- increased heart rate

In patients with bipolar disorder, the most common side effects of APO-RISPERIDONE were:

- sleeplessness / sleepiness
- trembling, decreased motor function or activity such as slight muscle stiffness
- dizziness
- headache
- constipation
- anxiety
- weight gain
- nausea
- heartburn
- increased salivation

APO-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 APO-RISPERIDONE.

In addition, the following undesired effects may occur in some cases: agitation, headache, dizziness.

In women, medicines of this type may cause changes in the regularity of their monthly periods or leakage of milk from the breast even if they are not pregnant. In some men, after prolonged treatment, there may be some diminished sexual function and breast enlargement may be experienced.

In rare cases, the following may happen: tiredness, concentration difficulties, blurred vision, indigestion, nausea, vomiting, abdominal pain, some loss of urine.

In very rare cases, high blood sugar has been reported. See your doctor if you experience symptoms such as excessive thirst or urination.

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 APO-RISPERIDONE in the last three months of your pregnancy and you notice that your newborn baby develops shaking, muscle stiffness and difficulty in feeding. These symptoms can be reversible. Contact your doctor immediately.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Call your doctor right away		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Rare			
Symptoms of allergic reaction, such as itching, skin rash, swelling of the face, lips, or tongue, or shortness of breath.		■	
Very Rare			
A state of confusion, reduced consciousness, high fever, or pronounced muscle stiffness.		■	
Marked changes in body temperature (generally as a result of several factors together including extreme heat or cold).		■	
Continuous erection of the penis		■	
Muscle twitching or abnormal movements of the face or tongue		■	
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.		■	

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

HOW TO STORE IT

Store APO-RISPERIDONE (Risperidone Tablets) in its original package.

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

Keep APO-RISPERIDONE out of the reach of children.

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

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected side effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

By toll-free telephone: 866-234-2345
By toll-free fax: 866-678-6789
Online: www.healthcanada.gc.ca/medeffect
By email: CanadaVigilance@hc-sc.gc.ca

By regular mail:
Canada Vigilance National Office
Marketed Health Products Safety and Effectiveness Information Bureau
Marketed Health Products Directorate
Health Products and Food Branch
Health Canada
Tunney's Pasture, AL 0701C
Ottawa ON K1A 0K9

NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying Canada Vigilance. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For more information, please contact your doctor, pharmacist or other healthcare professional. This leaflet plus the full product monograph, prepared for health professionals, can be obtained by contacting DISpedia, Apotex's Drug Information Service, at 1-800-667-4708. This leaflet can also be found at http://www.apotex.ca/products.

This leaflet was prepared by Apotex Inc., Toronto, Ontario, M9L 1T9.

Date of Revision: November 5, 2008

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