

## IMPORTANT: PLEASE READ

### PART III: CONSUMER INFORMATION

<sup>Pr</sup> APO-HALOPERIDOL  
Haloperidol Tablets  
Haloperidol Oral Solution

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

#### ABOUT THIS MEDICATION

##### What the medication is used for:

This medication is used for the management of manifestations of chronic schizophrenia.

##### What it does:

APO-HALOPERIDOL is an antipsychotic medication which affects chemicals in the brain that allow communication between nerve cells (neurotransmitters). These chemicals are called dopamine and serotonin. Exactly how APO-HALOPERIDOL works is unknown. However, it seems to readjust the balance of dopamine and serotonin.

##### When it should not be used:

You should not use APO-HALOPERIDOL if you have:

- An allergy to haloperidol, to any of its ingredients or to phenothiazines
- A medical condition known as pheochromocytoma (a tumor of the adrenal gland)
- A severe heart or blood vessel disorder
- Severe kidney problems
- Had brain damage
- Liver disease
- A blood cell disorder such as anemia, low white blood cell counts, or low platelets
- Drowsiness, slow breathing, weak pulse
- Decreased alertness caused by taking certain medications or drinking alcohol
- You are going to receive anesthesia in the spine or for a region (such as an arm, leg or the lower part of your body)

##### What the medicinal ingredient is:

Haloperidol

##### What the nonmedicinal ingredients are:

The APO-HALOPERIDOL tablets contain cornstarch, magnesium stearate and microcrystalline cellulose.

Additionally the 1 mg, 2 mg, 5 mg and 10 mg tablets contain as follows:

- 1 mg: D&C Yellow #10 aluminum lake and FD&C Yellow #6 aluminum lake
- 2 mg: D&C Red #7 calcium lake
- 5 mg: D&C Yellow #10 aluminum lake and FD&C Blue #1
- 10 mg: D&C Yellow #10 aluminum lake and FD&C Blue #1

The APO-HALOPERIDOL Oral Solution 2 mg/mL contains lactic acid, methyl paraben, and purified water.

##### What dosage forms it comes in:

APO-HALOPERIDOL is available in 0.5 mg, 1 mg, 2 mg, 5 mg and 10 mg tablets as well as 2 mg/mL solution.

#### WARNINGS AND PRECAUTIONS

##### **Serious Warnings and Precautions**

*Studies with various medicines of the group to which APO-HALOPERIDOL belongs, when used in the elderly patients with dementia, have been associated with an increased rate of death. APO-HALOPERIDOL is not indicated in elderly patients with dementia.*

BEFORE you use APO-HALOPERIDOL talk to your doctor or pharmacist if:

- You have heart disease, glaucoma or prostatic hypertrophy
- You are addicted to alcohol. You should not take APO-HALOPERIDOL if you are under the effects of alcohol.
- You are pregnant. Apo-Haloperidol should not be used during pregnancy unless your doctor considers the benefits to you markedly outweigh the potential risks to the fetus
- You are taking barbiturates, painkillers, narcotics or antihistamines or other drugs that make you drowsy.
- You have any allergies to this drug or its ingredients
- You have or ever had a blackout or seizure
- You are breast feeding.
- You 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").

APO-HALOPERIDOL may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery, especially during the first few days of therapy. You should be cautious when performing potentially hazardous tasks.

##### **Effects on Newborns:**

In some cases babies born to a mother taking APO-HALOPERIDOL 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

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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.

People who take APO-HALOPERIDOL are cautioned:

- Against exposure to extreme heat
- That drugs such as APO-HALOPERIDOL increase the toxicity of certain types of insecticides ("organophosphorous" insecticides) including insecticides for agriculture (farming), treating animals (flea and tick control) and for treating pests around the house and garden. Be cautious if you must use these products while taking APO-HALOPERIDOL.

### INTERACTIONS WITH THIS MEDICATION

APO-HALOPERIDOL can add to the effects of alcohol. You should avoid consuming alcoholic beverages while on APO-HALOPERIDOL therapy.

Tell your doctor about all your prescription and over-the-counter medications, vitamins, minerals, herbal products (such as St. John's Wort), and drugs prescribed by other doctors. Do not start a new medication without telling your doctor.

Before using APO-HALOPERIDOL, tell your doctor if you regularly use other medicines that make you sleepy (such as cold or allergy medicine, narcotic pain medicine, sleeping pills, muscle relaxants, and medicine for seizures, depression, or anxiety). You should not take APO-HALOPERIDOL if you have drowsiness caused by other medications.

Drugs that may interact with APO-HALOPERIDOL include: anti-anxiety agents, antidepressants, muscle relaxants, anti-seizure medicine, high blood pressure medicine, cabergoline, metrizamide, guanethidine, guanadrel, grepafloxacin, sparfloxacin, lithium, cisapride, atropine-like drugs, narcotic pain relievers (e.g., codeine), drugs used to aid sleep, drowsiness-causing antihistamines (e.g., diphenhydramine), other drugs that may make you drowsy.

Many cough-and-cold products contain ingredients that may add a drowsiness effect. Before using cough-and-cold medications, ask your doctor or pharmacist about the safe use of those products. Do not start or stop any medicine without doctor or pharmacist approval.

This list is not complete and there may be other drugs that can interact with APO-HALOPERIDOL.

### PROPER USE OF THIS MEDICATION

Take this medication by mouth exactly as prescribed. During the first few days your doctor may gradually increase your dose to allow your body to adjust to the medication. Do not take this more often or increase your dose without consulting your doctor. Your condition will not improve any faster but the risk of serious side effects will be increased. Do not stop taking this drug suddenly without your doctor's approval.

Your doctor will decide which dose is best for you.

### Usual dose:

Dose is individualized based on the severity of your symptoms, your age, weight, health, other diseases you may have, and previous response to drugs similar to haloperidol.

The initial dose is 1-2 mg twice or three times a day.

Some patients may require doses of 4-6 mg three times a day. For some patients doses as high as 30-40 mg a day have been used.

Rarely doses of 100 mg per day have been used.

The maintenance dose is commonly in the range of 1-2 mg three to four times a day.

Lower doses are recommended for children and elderly or debilitated patients as they may be more sensitive to the drug.

### 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.

Overdose symptoms may include agitation, and confusion, drowsiness, dizziness, muscle stiffness or twitching, increased salivation, trouble swallowing, weakness, loss of balance or coordination, and fainting.

### Missed Dose:

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not double your dose to make up the missed dose.

### SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like other medications, APO-HALOPERIDOL may cause some side effects. These side effects may be minor and temporary. However, some may be serious and need medical attention.

Side effects may include: sweating, urinary incontinence, dizziness, drowsiness, dry mouth, nasal congestion, nausea and vomiting, headache, menstrual changes, change in libido, swelling of the breasts and milk production in both men and women, weight changes and blurred vision.

If any of these affects you severely, tell your doctor.

Your doctor should check your body weight before starting APO-HALOPERIDOL and continue to monitor it for as long as you are being treated.

Your doctor should take blood tests before starting APO-HALOPERIDOL. They will monitor blood sugar, and the number of infection fighting white blood cells. Your doctor should continue to monitor your blood for as long as you are being treated.

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

<b>SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM</b>				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
		Only if severe	In all cases	
Unknown	<b>Allergic Reaction:</b> rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓
	<b>Neuroleptic Malignant Syndrome:</b> any group of symptoms which may include high fever, sweating, stiff muscles, fast heartbeat, fast breathing and feeling confused, drowsy or agitated			✓
	<b>Extrapyramidal Symptoms:</b> muscle stiffness, body spasms, upward eye rolling, exaggeration of reflexes, drooling, difficulty moving how and when you want.			✓
	Fast or irregular heartbeat		✓	
	Seizures or fits			✓
	Long-lasting (greater than 4 hours in duration) and painful erection of penis			✓

<b>SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM</b>			
Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
	Only if severe	In all cases	
<b>Tardive Dyskinesia:</b> uncontrollable movements or twitches of the body, face, eyes or tongue, stretching the neck and body		✓	
<b>Low Blood Pressure:</b> feeling of Lightheadedness or fainting especially when getting up from a lying or sitting position		✓	
<b>High Blood Pressure:</b> headaches, vision disorders, nausea and vomiting		✓	
Decreased sweating		✓	
<b>Jaundice:</b> yellow colour to skin and eyes, dark urine		✓	
<b>Respiratory Infection:</b> fever, flu-like symptoms, coughing, difficult or fast breathing		✓	
New or worsening constipation		✓	
<b>Akathisia:</b> a feeling of restlessness, inability to remain motionless		✓	
<b>Vision Changes:</b> blurred vision, glaucoma or other eye disorder		✓	
<b>Increased Blood Sugar:</b> frequent urination, thirst and hunger	✓		

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

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
		Only if severe	In all cases	
Uncommon	<b>Blood clots:</b> 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		✓	

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

### HOW TO STORE IT

Store at controlled room temperature (15°-30°C).

Keep this and all medications out of the reach and sight of children.

### REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program  
Health Canada  
Postal Locator 0701E  
Ottawa, Ontario  
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect).

*NOTE: Should you require information related to the management of side effects, contact your health professional. 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.

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