

PART III: CONSUMER INFORMATION**PrHALOPERIDOL INJECTION USP
5 mg /mL**

This leaflet is part III of a three-part "Product Monograph" published when Haloperidol Injection USP was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Haloperidol Injection USP. 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:

Haloperidol Injection USP 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 Haloperidol Injection USP works is unknown. However, it seems to readjust the balance of dopamine and serotonin.

When it should not be used:

You should not use Haloperidol Injection USP 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)
- Severe depression
- Any type of spastic disease
- Parkinson's syndrome

What the medicinal ingredient is:

Haloperidol

What the nonmedicinal ingredients are:

Haloperidol Injection USP contains the following non-medicinal ingredients: lactic acid to adjust the pH and water for injection USP.

What dosage forms it comes in:

Haloperidol Injection USP 5 mg/mL (intramuscular) is

available in 1 mL ampoules, boxes of 10.

WARNINGS AND PRECAUTIONS**Serious Warnings and Precautions**

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

BEFORE you use Haloperidol Injection USP talk to your doctor or pharmacist if you:

- have heart disease, glaucoma or prostatic hypertrophy
- have problems with your thyroid
- are addicted to alcohol. You should not take Haloperidol Injection USP if you are under the effects of alcohol.
- are pregnant. Haloperidol Injection USP should not be used during pregnancy unless your doctor considers the benefits to you markedly outweigh the potential risks to the fetus
- are taking barbiturates, painkillers, narcotics or, antihistamines or other drugs that make you drowsy.
- are taking blood thinners (anticoagulants)
- have an electrolyte imbalance
- have a condition called Familial Long QT Syndrome
- have any allergies to this drug or its ingredients
- have or ever had a blackout or seizure
- 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").

Haloperidol Injection USP 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 who used Haloperidol Injection USP 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.

IMPORTANT: PLEASE READ

People who use Haloperidol Injection USP are cautioned:

- Against exposure to extreme heat
- That drugs such as Haloperidol Injection USP 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 using Haloperidol Injection USP.

INTERACTIONS WITH THIS MEDICATION

Haloperidol Injection USP can add to the effects of alcohol. You should avoid consuming alcoholic beverages while on Haloperidol Injection USP 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 Haloperidol Injection USP, 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 use Haloperidol Injection USP if you have drowsiness caused by other medications.

Drugs that may interact with Haloperidol Injection USP include:

anti-anxiety agents, antidepressants, antiparkinsonian agents, anticoagulants, muscle relaxants, anti-seizure medicine, high blood pressure medicine, cabergoline, metrizamide, guanethidine, guanadrel, grepafloxacin, sparfloxacin, lithium, cisapride, rifampin, 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 Haloperidol Injection USP.

PROPER USE OF THIS MEDICATION

This medication should be administered by deep intramuscular injection, preferably in the gluteus maximus, 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 increase the dosage or injection frequency without consulting your doctor. Your condition will not improve any faster but the risk of serious side effects will be increased. Do not stop using this drug suddenly without your doctor's approval.

Your doctor will decide which dose is best for you.

Usual dose:

The dose depends on your symptoms, and will be adjusted by your doctor to best treat those symptoms. The medication is delivered by injection in a large muscle, usually the buttocks.

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:

Get the injection of the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to get the injection of 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, Haloperidol Injection USP 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, confusion, insomnia, restlessness, anxiety, agitation, depression, worsening of psychotic symptoms, skin changes, diarrhea, increased salivation, heartburn and decreased appetite.

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

Your doctor should check your body weight before starting Haloperidol Injection USP and continue to monitor it for as long as you are being treated.

Your doctor should take blood tests before starting Haloperidol Injection USP. 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.

IMPORTANT: PLEASE READ

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.

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	
Unknown	Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓
	Neuroleptic Malignant Syndrome: any group of symptoms which may include high fever, sweating, stiff muscles, fast heartbeat, fast breathing and feeling confused, drowsy or agitated			✓
	Extrapyramidal Symptoms: 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			✓

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	
Tardive Dyskinesia: uncontrollable movements or twitches of the body, face, eyes or tongue, stretching the neck and body		✓	
Low Blood Pressure: feeling of Lightheadedness or fainting especially when getting up from a lying or sitting position		✓	
High Blood Pressure: headaches, vision disorders, nausea and vomiting		✓	
Decreased sweating		✓	
Jaundice: yellow colour to skin and eyes, dark urine		✓	
Respiratory Infection: fever, flu-like symptoms, coughing, difficult or fast breathing		✓	
New or worsening constipation		✓	
Akathisia: a feeling of restlessness, inability to remain motionless		✓	
Vision Changes: blurred vision, glaucoma or other eye disorder		✓	
Increased Blood Sugar: frequent urination, thirst and hunger	✓		

IMPORTANT: PLEASE READ

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	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.		✓	

This is not a complete list of side effects. For any unexpected effects while using Haloperidol Injection USP, contact your doctor or pharmacist.

HOW TO STORE IT

Haloperidol Injection USP should be protected from light and stored below 40°C, preferably between 15 and 30°C. Protect from freezing.

As with other depot neuroleptics, precipitation may occur if the drug is stored for long periods in the cold. The precipitate should clear on storage at room temperature.

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
- 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.

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 document plus the full product monograph, prepared for health professionals can be found by contacting the sponsor, Sandoz Canada Inc., at:

1-800-361-3062

or by written request at:
145 Jules-Léger
Boucherville QC
J4B 7K8

Or by e-mail at :
medinfo@sandoz.com

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