

**CONSUMER INFORMATION****Pr** **LOXAPAC IM**  
(loxapine hydrochloride injection)

Read this carefully before you start taking LOXAPAC IM and each time you get a refill. This leaflet is a summary and will not tell you everything about LOXAPAC IM. Talk to your doctor, nurse or pharmacist about your medical condition and treatment and ask if there is any new information about LOXAPAC IM.

**ABOUT THIS MEDICATION****What the medication is used for:**

LOXAPAC IM is indicated in the management of the manifestations of schizophrenia.

**What it does:**

LOXAPAC IM 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 LOXAPAC IM works is unknown. However, it seems to readjust the balance of dopamine and serotonin.

**When it should not be used:**

You should not use LOXAPAC IM if you:

- Have an allergy to loxapine injection or tablets, to any of its nonmedicinal ingredients or to phenothiazines
- Have a medical condition known as pheochromocytoma (a tumor of the adrenal gland)
- Have a severe heart or blood vessel disorder
- Have severe kidney problems
- Had brain damage
- Have liver disease
- Have a blood cell disorder such as anemia, low white blood cell counts, or low platelets
- Have drowsiness, slow breathing, weak pulse
- Have coma or decreased alertness caused by taking certain medications or drinking alcohol
- Are going to receive anesthesia in the spine or for a region (such as an arm, leg or the lower part of your body)
- Have a circulatory collapse
- Are also taking metoclopramide, a drug used to improve stomach emptying after surgery or other procedures, or to prevent vomiting after surgery

**What the medicinal ingredient is:**

Loxapine hydrochloride

**What the nonmedicinal ingredients are:**

Polysorbate 80, propylene glycol, hydrochloric acid and/or sodium hydroxide to adjust pH and water for injection.

**What dosage forms it comes in:**

1 mL sterile ampoules, boxes of 10.

**Serious Warnings and Precautions**

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

**BEFORE you use LOXAPAC IM talk to your doctor or pharmacist if:**

- You have heart disease, glaucoma, difficulty passing urine or prostatic hypertrophy.
- 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").
- You are addicted to alcohol. You should not take LOXAPAC IM if you are under the effects of alcohol.
- You are pregnant. LOXAPAC IM should not be used during pregnancy unless your doctor considers the benefits to you markedly outweigh the potential risks to the fetus.
- You are breast feeding.
- You are taking barbiturates, painkillers, narcotics or, antihistamines or other drugs that make you drowsy.
- You have or ever had a blackout or seizure.
- You are below the age of 18.
- You have mental retardation.
- You have previously been diagnosed with breast cancer
- You have any allergies to this drug or its ingredients.

LOXAPAC IM 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 LOXAPAC IM 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.

**People who take LOXAPAC IM are cautioned:**

- Against exposure to extreme heat
- That drugs such as LOXAPAC IM 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 LOXAPAC IM.

**WARNINGS AND PRECAUTIONS**

**INTERACTIONS WITH THIS MEDICATION**

LOXAPAC IM can add to the effects of alcohol. You should avoid consuming alcoholic beverages while on LOXAPAC IM therapy.

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

Before using LOXAPAC IM, 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 LOXAPAC IM if you have drowsiness caused by other medications.

Drugs that may interact with LOXAPAC IM 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, dehydroepiandrosterone, metoclopramide, and zotepine.

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 LOXAPAC IM.

**PROPER USE OF THIS MEDICATION**

Dosage should be individualised. LOXAPAC IM is a medicine that a healthcare professional will give to you by injection into a muscle. During the first few days your doctor may gradually increase your dose to allow your body to adjust to the medication. Your doctor will decide which dose is best for you.

**Usual dose:**

**LOXAPAC PM is not recommended to:**

- Patients under 18 years of age
- Patients 65 years of age or older
- Elderly patients with dementia.

LOXAPAC IM is given as an intramuscular injection of 12.5 mg (1/4 mL) to 50 mg (1 mL) every four to six hours or longer, depending on how you respond.

Your doctor may decide that you need ongoing treatment for your symptoms. Your doctor may discontinue treatment with LOXAPAC IM and may continue therapy with loxapine by mouth,

or prescribe another drug for you depending on your individual situation and needs.

**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, weak pulse, slow heart rate, weak or shallow breathing, fainting, or seizure (convulsions).

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Like other medications, LOXAPAC IM 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 retention or incontinence, severe constipation, dizziness, fainting, difficulty walking, drowsiness, weakness, numbness, confusion, dry mouth, nasal congestion, nausea and vomiting, headache, difficulty sleeping, slurred speech, seizures, menstrual changes, change in libido, fluid retention, swelling of the breasts and milk production in both men and women, weight changes and blurred vision, flaky skin, insomnia, and unusual bruising or bleeding.

Skin rash, itching, swelling or puffiness of the face can occur.

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

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

Your doctor should take blood tests before starting LOXAPAC IM. 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.

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	

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Frequency 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>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.		√	

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<b>Tardive Dyskinesia:</b> uncontrollable movements or twitches of the body, face, eyes or tongue, stretching the neck and body			√	
Fast or irregular heartbeat			√	
<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</b>		√		

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<b>Sugar:</b> frequent urination, thirst and hunger			
<b>Rare</b> <b>Decreased White Blood Cells:</b> Infections, fatigue, fever, aches, pains, and flu-like symptoms			√

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

**HOW TO STORE IT**

Store between 15°C and 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**

This document plus the full product monograph, prepared for health professionals can be obtained 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](mailto:medinfo@sandoz.com)

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