

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

#### LORAZEPAM INJECTION USP

Lorazepam 4 mg / mL

Read this carefully before you start taking **LORAZEPAM INJECTION USP** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **LORAZEPAM INJECTION USP**.

#### Serious Warnings and Precautions

##### Addiction, Abuse and Misuse:

Even if you take LORAZEPAM INJECTION USP exactly as you are told, you are at risk for abuse, misuse, addiction, physical dependence and withdrawal. Abuse and misuse can result in overdose or death, especially if you take LORAZEPAM INJECTION USP with:

- Opioids
- Alcohol or
- Illicit drugs

Your healthcare professional should:

- talk to you about the risks of treatment with LORAZEPAM INJECTION USP as well as other treatment (including non-drug) options
- assess your risk for these behaviours before prescribing LORAZEPAM INJECTION USP
- monitor you while you are taking LORAZEPAM INJECTION USP for the signs and symptoms of misuse and abuse. If you feel like you are craving LORAZEPAM INJECTION USP, or not using it as directed, talk to your healthcare professional right away

Store LORAZEPAM INJECTION USP in a secure place to avoid theft or misuse.

##### Withdrawal:

If you suddenly stop taking LORAZEPAM INJECTION USP, lower your dose too fast, or switch to another medication, you can experience severe or life-threatening withdrawal symptoms (see Other warnings you should know about).

- Always contact your healthcare professional before stopping or lowering your dose of LORAZEPAM INJECTION USP or changing your medicine

##### LORAZEPAM INJECTION USP with Opioids:

Taking LORAZEPAM INJECTION USP with opioid medicines can cause:

- severe drowsiness
- decreased awareness
- breathing problems
- coma
- death

### **What is LORAZEPAM INJECTION USP used for?**

LORAZEPAM INJECTION USP is used in adults for:

- the short-term relief of severe anxiety symptoms in people with anxiety problems.
- the relief of anxiety before surgery.
- to help control severe seizures known as status epilepticus.

LORAZEPAM INJECTION USP is not recommended for mild to moderate anxiety and tension associated with the stresses of everyday life.

If you are 65 years or older, talk to your healthcare professional before starting LORAZEPAM INJECTION USP. LORAZEPAM INJECTION USP may not be an effective treatment for you, and you may be more sensitive to experiencing side effects.

### **How does LORAZEPAM INJECTION USP work?**

LORAZEPAM INJECTION USP is a benzodiazepine with sedative (calming) properties which help in the treatment of anxiety.

### **What are the ingredients in LORAZEPAM INJECTION USP?**

Medicinal ingredient: Lorazepam.

Non-medicinal ingredients: Benzyl alcohol (preservative), polyethylene glycol and propylene glycol.

### **LORAZEPAM INJECTION USP comes in the following dosage forms:**

As a solution containing 4 mg / mL lorazepam.

### **Do not use LORAZEPAM INJECTION USP if you:**

- are allergic to the group of medicines known as benzodiazepines (such as diazepam, clonazepam, chlordiazepoxide, bromazepam, or flurazepam).
- are allergic to lorazepam or any of the other ingredients in LORAZEPAM INJECTION USP (see 'What are the ingredients in LORAZEPAM INJECTION USP').
- have myasthenia gravis (a chronic disease with muscle weakness).
- have acute narrow angle glaucoma (a disease of the eye which causes progressive vision loss).

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take LORAZEPAM INJECTION USP. Talk about any health conditions or problems you may have, including if you:**

- have ever had a problem with:
  - o substance abuse, including prescribed or illegal drugs or
  - o alcohol

- have ever had seizures or convulsions (violent uncontrollable shaking of the body with or without loss of consciousness)
- have a lung disease or breathing problems (such as chronic obstructive pulmonary disease (COPD), sleep apnea syndrome)
- have a history of depression, suicide attempts or a mental health problem called psychosis
- have liver problems
- have kidney problems

**Other warnings you should know about:**

**Severe Allergic Reactions:** Taking LORAZEPAM INJECTION USP can cause severe allergic reactions that can lead to death. For symptoms of severe allergic reactions, see the **Serious side effects and what to do about them** table below.

**Driving and Using Machines:** LORAZEPAM INJECTION USP may affect your ability to be alert. This may be made worse if you drink alcohol or take other sedatives. It might also be worse when your dose is changed. Do not drive or operate machinery while you are taking LORAZEPAM INJECTION USP, or for the first few days, until you know how LORAZEPAM INJECTION USP affects you. Avoid driving or using machinery if taking LORAZEPAM INJECTION USP with other sedatives.

**Addiction, Abuse and Misuse:** Taking LORAZEPAM INJECTION USP can lead to physical dependence, abuse, and misuse, even if you take as directed. See the **Serious Warnings and Precautions** box above.

**Behavioural Problems:** Changes in thinking and behaviour may happen when you take LORAZEPAM INJECTION USP. This can include aggressiveness, extroversion, confusion, strange behaviour, restlessness, illusions, hallucinations, feeling like you are not yourself, worsening of insomnia or worsening of depression including suicidal thinking. If you develop any unusual or disturbing thoughts or behavior while taking LORAZEPAM INJECTION USP, talk to your healthcare professional immediately.

**Pregnancy:** Do not take LORAZEPAM INJECTION USP if you are pregnant. LORAZEPAM INJECTION USP may harm your unborn baby. It may also cause side effects and withdrawal symptoms in your baby after birth. Talk to your healthcare professional if you think you are pregnant or become pregnant while taking LORAZEPAM INJECTION USP.

**Breastfeeding:** LORAZEPAM INJECTION USP passes into breast milk. You should not breastfeed while taking LORAZEPAM INJECTION USP. Talk to your healthcare professional about the best way to feed your baby while you are taking LORAZEPAM INJECTION USP.

**Withdrawal:** If you suddenly stop your treatment, lower your dose too fast, or switch to another medication, you can experience withdrawal symptoms that can range from mild symptoms to severe or life threatening. Some of your withdrawal symptoms can last for months after you stop LORAZEPAM INJECTION USP.

Your risk of going through withdrawal is higher if you are taking LORAZEPAM INJECTION USP for a long time or at high doses. However, symptoms can still occur if you are taking LORAZEPAM INJECTION USP as directed for a short period of time or slowly reducing the dose.

The symptoms of withdrawal often resemble the condition that you are being treated for. After stopping your treatment, it may be hard to tell if you are experiencing withdrawal or a return of your

condition (relapse).

Tell your healthcare professional **right away** if you experience any symptoms of withdrawal after changing or stopping your treatment.

Severe symptoms of withdrawal include:

- feeling like you cannot move or respond (catatonia)
- severe confusion, shivering, irregular heart rate and excessive sweating (delirium tremens)
- feeling depressed
- feeling disconnected from reality (dissociation)
- seeing or hearing things that are not there (hallucinations)
- overactive behavior and thoughts (mania)
- believing in things that are not true (psychosis)
- convulsions (seizures), including some that do not stop
- thoughts or actions of suicide

For other symptoms of withdrawal, see the **Serious side effects and what to do about them** table (below).

To reduce your chances of going through withdrawal:

- always contact your healthcare professional before stopping or reducing your dose of LORAZEPAM INJECTION USP or changing medications
- always follow your healthcare professional's instructions on how to reduce your dose carefully and safely
- tell your healthcare professional **right away** if you experience any unusual symptoms after changing or stopping your treatment

**LORAZEPAM INJECTION USP with Opioids:** Taking LORAZEPAM INJECTION USP with opioid medicines can cause severe drowsiness and breathing problems.

Tell your healthcare professional if you:

- are taking opioid medicines
- are prescribed an opioid medicine after you start taking LORAZEPAM INJECTION USP

Do NOT drive or operate heavy machinery or do tasks that require special attention if you are taking an opioid medicine and LORAZEPAM INJECTION USP.

**Falls and Fractures:** Benzodiazepines like LORAZEPAM INJECTION USP can cause you to feel sleepy, dizzy and affect your balance. This increases your risks of falling, which can cause fractures or other fall related-injuries, especially if you:

- take other sedatives
- drink alcohol
- are elderly or
- have a condition that causes weakness or frailty

**Blood Tests:** LORAZEPAM INJECTION USP can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and will interpret the results.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

#### **Serious Drug Interactions**

Taking LORAZEPAM INJECTION USP with opioids may cause:

- Severe drowsiness
- Trouble breathing
- Coma
- Death

#### **The following may interact with LORAZEPAM INJECTION USP:**

- medicines used to treat anxiety and insomnia
- sedative / hypnotics (sleeping pills)
- monoamine oxidase inhibitors (MAOIs) and other antidepressants
- medicines used to treat mental health problems such as Haloperidol, Clozapine
- narcotic analgesics (pain relievers, opioids) see **Serious Warnings and Precautions box**
- allergy medication
- medicines used to prevent seizures such as valproate
- anesthetics, used during surgery
- probenecid, used to treat gout
- medicines used to treat breathing problems such as theophylline, aminophylline

**Do not take LORAZEPAM INJECTION USP if you drink alcohol.**

#### **How to take LORAZEPAM INJECTION USP:**

- LORAZEPAM INJECTION USP will be given to you by a healthcare professional
- Your healthcare professional will prescribe the dose that is right for you depending on your medical condition and how you respond to LORAZEPAM INJECTION USP
- Your healthcare professional will decide when to stop giving you LORAZEPAM INJECTION USP. Always follow your healthcare professional's instructions.

#### **Usual Adult Dose:**

LORAZEPAM INJECTION USP will be given to you by a healthcare professional. They will either inject it into a large muscle, such as your arm or buttock, or will be diluted and infused into a vein. Your healthcare professional will decide how much LORAZEPAM INJECTION USP you will receive. This will be based on your weight.

If you are 65 years of age or older, you may be more sensitive to the effects of LORAZEPAM INJECTION USP. Your healthcare professional might give you a lower dose. LORAZEPAM INJECTION USP is not for use in children under 18 years of age.

#### **Overdose:**

If you think you, or a person you are caring for, have taken too much LORAZEPAM INJECTION USP, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you miss a dose of LORAZEPAM INJECTION USP, contact your healthcare professional for instructions.

**What are possible side effects from using LORAZEPAM INJECTION USP?**

These are not all the possible side effects you may have when taking LORAZEPAM INJECTION USP. If you experience any side effects not listed here, tell your healthcare professional. Side effects may include:

- Drowsiness
- Dizziness
- Confusion
- Weakness
- Falls and fractures
- Change in weight
- Hypothermia
- Nausea
- Constipation
- Change in appetite
- Change in libido, impotence, decreased orgasm, sexual arousal

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>UNCOMMON</b>			
<b>Mental and behavioural changes:</b> Unexpected reactions such as agitation, hyperactivity, excitement, hallucination, worsened insomnia, feeling nervous, irritable, increased muscle spasticity, aggressiveness, rages, psychoses and violent behavior		✓	
<b>Severe Allergic Reactions:</b> red skin, hives, itching, swelling of the lips, face, tongue, throat, trouble breathing, wheezing, shortness of breath, skin rashes, blisters of the skin, sores or pain in the mouth or eyes, nausea, vomiting			✓
<b>Myasthenia Gravis:</b> muscle weakness, drooping eyelid, vision changes, difficulty chewing and swallowing, trouble breathing			✓
<b>Liver Problems:</b> abdominal pain, nausea, vomiting, yellowing of		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
skin and eyes, dark urine			
<b>RARE</b>			
<b>Depression:</b> difficulty sleeping, changes in weight, feelings of worthlessness, guilt, regret, helplessness or hopelessness, withdrawal from social situations, family gatherings and activities with friends, reduced libido (sex drive), and thoughts of death or suicide.		✓	
<b>Memory Loss</b>		✓	
<b>VERY RARE</b>			
<b>Somnambulism</b> (sleep-walking): getting out of bed while not fully awake, including preparing and eating food, making phone calls, leaving the house, etc.		✓	
<b>UNKNOWN</b>			
<b>Visual disturbance</b> (changes in vision): Blurred vision, double vision		✓	
<b>Movement problems:</b> ataxia, (including unsteadiness and clumsiness), difficulty controlling movements, trembling (extrapyramidal symptoms) Vertigo, balance disorder		✓	
<b>Overdose:</b> extreme sleepiness, confusion, slurred speech, slow reflexes, slow shallow breathing, coma, loss of balance and coordination, uncontrolled rolling of the eyes, low blood pressure			✓
<b>Respiratory Depression:</b> slow, shallow or weak breathing			✓
<b>Withdrawal:</b>			
<b>Severe symptoms include:</b>			
<b>Catatonia:</b> feeling like you cannot move or respond			
<b>Delirium Tremens:</b> severe confusion, shivering, irregular heart rate and excessive sweating Feeling depressed		✓	
<b>Dissociation:</b> feeling disconnected from reality			
<b>Hallucinations:</b> seeing or hearing things that are not there			
<b>Mania:</b> overactive behaviour and thoughts			
<b>Psychosis:</b> Believing in things that are not true			

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<p><b>Convulsions:</b> (seizures – including some that do not stop): loss of consciousness with uncontrollable shaking</p> <p><b>Thoughts or actions of suicide</b></p> <p><b>Other symptoms include:</b> Stomach and muscle cramps; trouble remembering or concentrating; diarrhea; feeling uneasy or restless; severe anxiety or panic-attacks; headache; sensitivity to light, noise or physical contact; shaking; vomiting; trouble sleeping, feeling irritable; muscle pain or stiffness; a burning or prickling feeling in the hands, arms, legs or feet; sweating.</p>			

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

**Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*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.*

**Storage:**

Refrigerate between 2°C and 8°C. Protect from light and freezing. Do not use if solution is discoloured or contains a precipitate.

Discard within 28 days of initial use.

Keep out of the reach and sight of children.



**If you want more information about LORAZEPAM INJECTION USP:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website [www.pfizer.ca](http://www.pfizer.ca), or by calling 1-800-463-6001.

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