

PART III: CONSUMER INFORMATION

Lorazepam Injection USP

This leaflet is part of the “Product Monograph” published when Lorazepam 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 Lorazepam Injection USP. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

Lorazepam Injection USP is useful for the short-term relief of manifestations of severe anxiety in people with anxiety neurosis.

It is also useful for the relief of excessive anxiety that might be present prior to surgical interventions.

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

Lorazepam Injection USP is useful to help control severe seizures (status epilepticus).

What it does:

Lorazepam Injection USP is a benzodiazepine with sedative properties which help in the treatment of anxiety.

When it should not be used:

- If you are allergic to the group of medicines known as benzodiazepines (examples: diazepam, clonazepam, chlordiazepoxide, bromazepam, or flurazepam).
- If you are allergic to any of the ingredients it contains (see ‘**What the nonmedicinal ingredients are**’).
- If you have myasthenia gravis, a chronic disease characterized by weakness of the skeletal muscles.
- If you have acute narrow angle glaucoma (a disease of the eye which causes progressive vision loss).

What the medicinal ingredient is:

Lorazepam

What the nonmedicinal ingredients are:

Benzyl alcohol (preservative), polyethylene glycol and propylene glycol.

What dosage forms it comes in:

Injection: 4 mg/mL

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Taking Lorazepam Injection USP with opioid medicines can cause severe drowsiness, breathing problems, coma, and death.

- Severe anaphylactic/anaphylactoid allergic reactions have been reported with the use of benzodiazepines. Cases of angioedema (swelling inside the mouth and throat) involving the tongue, glottis or larynx have been reported in patients after taking the first or subsequent doses of benzodiazepines. Some patients taking benzodiazepines have had additional symptoms such as dyspnea (difficult respiration), throat closing, or nausea and vomiting. Some patients have required medical therapy in the emergency department. If angioedema involves the tongue, glottis or larynx, airway obstruction may occur and be fatal. Patients who develop angioedema after treatment with a benzodiazepine should not restart the drug.
- Lorazepam Injection USP may affect your ability to be alert. Driving, operating machinery and other hazardous activities should therefore be avoided altogether or at least during the first few days of treatment. This effect of Lorazepam Injection USP may be made worse if you take alcoholic drinks. If your doctor has increased your dose or if you have changed the timings of when you take your medication this may also modify your reactions.
- You must not consume alcohol or other drugs that affect the central nervous system while taking **Lorazepam Injection USP** (see INTERACTIONS WITH THIS MEDICATION below).
- Benzodiazepines such as **Lorazepam Injection USP** have produced dependence (addiction) and withdrawal symptoms can occur when treatment is stopped suddenly. The risk of dependence (addiction) increases with higher doses and longer duration of treatment.
- Always contact your doctor before stopping or reducing your dosage of **Lorazepam Injection USP**, as suddenly stopping treatment or a large decrease in dose can cause withdrawal symptoms (See Withdrawal-related side effects in the section **SIDE EFFECTS AND WHAT TO DO ABOUT THEM** below).
- An increased risk of falls and fractures has been reported in elderly people who take benzodiazepines such as **Lorazepam Injection USP**.
- Memory loss may occur when **Lorazepam Injection USP** is used at therapeutic doses.
- A variety of abnormal thinking and behaviour changes may occur when you use a benzodiazepine, including aggressiveness, extroversion, confusion, strange behaviour, restlessness, illusions, hallucinations, feeling like you are not yourself, worsening of insomnia or worsening of depression including suicidal thinking. It is rarely clear

whether such symptoms are caused by the medication, by an illness that was present before the medication was used or are simply spontaneous happenings. If you develop any unusual or disturbing thoughts or behavior while using **Lorazepam Injection USP**, discuss the matter immediately with your doctor.

- **Lorazepam Injection USP** is not recommended for use in depressive neurosis or in psychotic reactions.
- Certain benzodiazepines have been linked to birth defects when taken during the early months of pregnancy. In addition, benzodiazepines taken during the last weeks of pregnancy have been known to sedate the baby and may also cause withdrawal symptoms after birth. Do not take this medicine if you are pregnant, or might become pregnant, unless advised by your doctor. Contact your doctor if you think you may be pregnant, or are intending to become pregnant.
- **Lorazepam Injection USP** passes into breast milk. Therefore, if you are breast feeding, this medicine should be avoided. Your doctor will discuss this with you.

BEFORE you use talk to your doctor or pharmacist if:

- You have lung disease or breathing problems (e.g. chronic obstructive pulmonary disease (COPD), sleep apnea syndrome)
- You have a history of depression, suicide attempts or psychosis
- You regularly drink alcohol or use recreational drugs or have a history of dependence /addiction to alcohol or drugs.
- You have liver disease
- You have kidney disease
- You are pregnant or plan on becoming pregnant
- You are breastfeeding.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor if you are taking any other medicines, including medicines you can buy without a prescription and herbal products.

Drugs that may interact with Lorazepam Injection USP include:

- barbiturates
- antipsychotics
- sedative/hypnotics (sleeping pills)
- anxiolytics
- antidepressants
- antipsychotics (including Haloperidol, Clozapine)
- narcotic analgesics (pain relievers) (opioids) (see Serious Warnings and Precautions box)
- sedative antihistamines (allergy medications)
- anticonvulsants (including valproate)
- anesthetics
- probenecid (to reduce uric acid levels)
- theophylline or aminophylline (respiratory treatments)
- alcohol

Do not take Lorazepam Injection USP if you drink alcohol Do not use **Lorazepam Injection USP** along with other medications without first discussing this with your doctor.

PROPER USE OF THIS MEDICATION

Usual adult dose:

Your doctor will prescribe a suitable dose for you. The dose your doctor prescribes will depend on your illness and how you respond to the medicine.

Lorazepam Injection USP will be given to you either intramuscularly (IM) by injection into a large muscle, such as your arm or buttock, or intravenously (IV) directly into a vein.

Because elderly patients can be more sensitive to the effects of Lorazepam Injection USP, lower doses may be prescribed.

Lorazepam Injection USP is not for use in children under 18 years of age.

Overdose:

If you think you have taken too much Lorazepam Injection USP, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The adverse reaction most frequently reported for Lorazepam Injection USP was drowsiness. Dizziness, weakness and unsteadiness were also common.

Release of hostility and other paradoxical effects such as irritability and excitability, are known to occur with the use of benzodiazepines. Please tell your doctor right away if you feel these effects when taking Lorazepam Injection USP. Paradoxical reactions may be more likely to occur in children or the elderly. In addition, hypotension (low blood pressure), mental confusion, slurred speech, over sedation and abnormal laboratory test results indicating changes in the liver, kidney and blood cells have been reported with these drugs.

If you develop symptoms of myasthenia gravis or the symptoms of your existing myasthenia gravis worsen, tell your doctor right away. These symptoms could include muscle weakness that gets worse with activity and gets better with rest, drooping eyelid, blurred or double vision, difficulty chewing and swallowing, or trouble breathing.

Withdrawal-related side effects:

- With sudden discontinuation of treatment with Lorazepam Injection USP symptoms of withdrawal may occur, including headache, muscle pain, convulsions, extreme anxiety, tension, restlessness, confusion and irritability. In severe cases of withdrawal,

symptoms may include numbness and tingling of the extremities, hallucinations, increased sensitivity to light, noise and physical contact and seizures.

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

Symptom / effect	Talk with your doctor or pharmacist right away		Stop taking drug and seek immediate emergency help	
	Only if severe	In all cases		
Uncommon	Unusual behavioural problems (aggression, rage), sudden anxiety or excitation; restlessness, agitation, irritability; hallucinations (see or hear things that are not there) or delusions; severe sleep disturbances, nightmares, inappropriate behavior		✓	
	Anaphylactic /anaphylactoid reactions, severe allergic reactions (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)			✓
	Myasthenia gravis: muscle weakness, drooping eyelid, vision changes, difficulty chewing and swallowing, trouble breathing			✓
	Liver disorder: (symptoms include abdominal pain, nausea, vomiting, yellowing of skin and eyes, dark urine)		✓	

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

Symptom / effect	Talk with your doctor or pharmacist right away		Stop taking drug and seek immediate emergency help
	Only if severe	In all cases	
Rare Depression: Symptoms may include: 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.		✓	

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

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 \(https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html\)](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.

HOW TO STORE IT

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.

FOR MORE INFORMATION

Reminder: This medicine has been prescribed only for you. Do not give it to anybody else, even if you think they have the same symptoms that you have, as it may harm them. If you have any further questions, please ask your doctor or pharmacist.

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 Consumer Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada.html>); the manufacturer's website at: www.pfizer.ca, under Prescription Products, or by contacting the sponsor, Pfizer Canada ULC at: 1-800-463-6001.

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