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Details for: LORAZEPAM INJECTION USP

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Company: PFIZER CANADA ULC

DIN	DIN name	Active Ingredient(s)	Strength	Dosage Form	Route of Administration
02388669	LORAZEPAM INJECTION USP	LORAZEPAM	4 MG / ML	SOLUTION	INTRAMUSCULAR
02388669	LORAZEPAM INJECTION USP	LORAZEPAM	4 MG / ML	SOLUTION	INTRAVENOUS

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Summary Reports

[Summary Safety Review - Benzodiazepines and barbiturates - Assessing the potential risk of negative effects on the development of children's brains \(neurodevelopmental disorders\)](#)

Consumer Information

This information was provided by the drug's manufacturer when this drug product was approved for sale in Canada. It is designed for consumers and care givers. It is a summary of information about the drug and will not tell you everything about the drug. Contact your doctor or pharmacist

if you have any questions about the drug.

What the medication is used for

What it does

When it should not be used

What the medicinal ingredient is

What the non-medicinal ingredients are

What dosage form it comes in

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

Proper use of this medication

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, nurse, or pharmacist <i>only if severe</i>	Talk with your doctor, nurse, or pharmacist <i>in all cases</i>	Stop taking drug and talk with your doctor or pharmacist
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		✓	

Symptom / effect	Talk with your doctor, nurse, or pharmacist <i>only if severe</i>	Talk with your doctor, nurse, or pharmacist <i>in all cases</i>	Stop taking drug and talk with your doctor or pharmacist
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)		✓	
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.

How to store

Reporting side effects

More information

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