

**PATIENT MEDICATION INFORMATION**

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



**PRO-LORAZEPAM**

**Lorazepam Tablets USP**

**Read this carefully before you start taking PRO-LORAZEPAM 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 PRO-LORAZEPAM. Serious Warnings and Precautions**

**Addiction, Abuse and Misuse:**

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

- Opioids
- Alcohol or
- Illicit drugs

Your healthcare professional should:

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

Store PRO-LORAZEPAM in a secure place to avoid theft or misuse.

**Withdrawal:**

If you suddenly stop taking PRO-LORAZEPAM, 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 PRO-LORAZEPAM or changing your medicine

**PRO-LORAZEPAM with Opioids:** Taking PRO-LORAZEPAM with opioid medicines can cause:

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

**What is PRO-LORAZEPAM used for?**

PRO-LORAZEPAM is used in adults for:

- the short-term relief of severe anxiety symptoms in people with anxiety problem.

- the relief of anxiety before surgery.

**PRO-LORAZEPAM** 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 PRO-LORAZEPAM. PRO-LORAZEPAM may not be an effective treatment for you and you may be more sensitive to experiencing side effects.

#### **How does PRO-LORAZEPAM work?**

**PRO-LORAZEPAM** is a benzodiazepine with sedative properties which help in the treatment of anxiety.

#### **What are the ingredients in PRO-LORAZEPAM?**

Medicinal ingredients: Lorazepam.

Non-medicinal ingredients: Croscarmellose Sodium, lactose monohydrate, magnesium stearate, and microcrystalline cellulose.

#### **PRO-LORAZEPAM comes in the following dosage forms:**

0.5 mg, 1 mg and 2 mg oral tablets.

#### **Do not use PRO-LORAZEPAM 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 PRO-LORAZEPAM (see What are the ingredients in PRO-LORAZEPAM)
- 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 PRO-LORAZEPAM. Talk about any health conditions or problems you may have, including if you:**

- have ever had a problem with:
  - substance use, including prescribed or illegal drugs, or
  - alcohol
- have ever had seizures or convulsions (violent uncontrollable shaking of the body with or without loss of consciousness)
- You have lung disease or breathing problems (such as chronic obstructive pulmonary disease (COPD), sleep apnea syndrome)
- You have a history of depression, suicide attempts or a mental health problem called psychosis
- have liver problems
- have kidney problems
- are lactose intolerant or have one of the following rare hereditary diseases:
  - Galactose intolerance
  - Lapp lactase deficiency
  - Glucose-galactose malabsorption

Because lactose is a non-medicinal ingredient in PRO-LORAZEPAM.

## Other warnings you should know about:

**Severe Allergic Reactions:** Taking PRO-LORAZEPAM 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:** PRO-LORAZEPAM may affect your ability to be alert. This may be made worse if you drink alcohol. It might also be worse when your dose is changed. Do not drive or operate machinery while you are taking PRO-LORAZEPAM, or for the first few days, until you know how PRO-LORAZEPAM affects you.

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

**Behavioural Problems:** Changes in thinking and behaviour may happen when you take PRO-LORAZEPAM. 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 PRO-LORAZEPAM, talk to your healthcare professional immediately.

**Pregnancy:** Do not take PRO-LORAZEPAM if you are pregnant. PRO-LORAZEPAM 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 PRO-LORAZEPAM.

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

**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 PRO-LORAZEPAM.

Your risk of going through withdrawal is higher if you are taking PRO-LORAZEPAM for a long time or at high doses. However, symptoms can still occur if you are taking PRO-LORAZEPAM 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 PRO-LORAZEPAM or changing medications
- always follow your doctor's instructions on how to reduce your dose carefully and safely
- tell your doctor **right away** if you experience any unusual symptoms after changing or stopping your treatment

**PRO-LORAZEPAM with Opioids:** Taking PRO-LORAZEPAM 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 PRO-LORAZEPAM

Do NOT drive or operate heavy machinery or do tasks that require special attention until you know how taking an opioid medicine and PRO-LORAZEPAM affects you.

**Falls and Fractures:** Benzodiazepines like PRO-LORAZEPAM 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:** PRO-LORAZEPAM 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 PRO-LORAZEPAM and opioids may cause:

- severe drowsiness
- trouble breathing
- coma
- death

**The following may interact with PRO-LORAZEPAM**

- 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**) (above)
- 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 PRO-LORAZEPAM if you drink alcohol.**

**How to take PRO-LORAZEPAM:**

- Always take PRO-LORAZEPAM exactly as your healthcare professional tells you to. Your healthcare professional will prescribe the dose that is right for you depending on your medical condition and how you respond to PRO-LORAZEPAM.
- Do not change your dose without talking to your healthcare professional.

**Usual adult dose:**

**Anxiety problems:** 2 to 3 mg per day, in divided doses. Maximum: 6 mg per day.

**Before surgery:** Your healthcare professional will decide on the dose that is best for you based on your weight.

If you are 65 years of age or older you may be more sensitive to the effects of PRO-LORAZEPAM. Your healthcare professional might prescribe you a lower dose.

Your doctor will slowly decrease your dose and will tell you when to stop taking the medicine. Always follow your doctor's instructions on how to lower your dose carefully and safely to avoid experiencing withdrawal symptoms.

**Overdose:**

If you think you, or a person you are caring for, have taken too much **PRO-LORAZEPAM**, 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 PRO-LORAZEPAM, contact your healthcare professional for instructions.

**What are possible side effects from using PRO-LORAZEPAM?**

These are not all the possible side effects you may have when taking PRO-LORAZEPAM. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- drowsiness
- dizziness
- confusion
- weakness and unsteadiness
- falls and fractures
- memory loss

Serious side effects and what to do about them			
Symptom / effect	Talk to your health care professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>UNCOMMON</b>			
<b>Behavioural Problems:</b> aggression, rage, sudden anxiety or excitation; restlessness, agitation, irritability; hallucinations (see or hear things that are not there) or		√	

**Serious side effects and what to do about them**

Symptom / effect	Talk to your health care professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
delusions; severe sleep disturbances, nightmares, inappropriate 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 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>UNKNOWN</b>			
<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</b> include: <b>Catatonia:</b> feeling like you cannot move or respond <b>Delirium Tremens:</b> severe confusion, shivering, irregular heart rate and excessive sweating <b>Feeling depressed</b> <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 <b>Convulsions:</b> (seizures – including some that do not stop): loss of consciousness with uncontrollable shaking <b>Thoughts or actions of suicide</b> <b>Other symptoms include:</b> Stomach 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		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your health care professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
in the hands, arms, legs or feet; sweating			

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.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:

**PRO-LORAZEPAM oral tablets:** Store at room temperature 15°C to 30°C. Protect from moisture.

Keep out of reach and out of sight of children.

### If you want more information about PRO-LORAZEPAM:

- 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/services/drugs-health-products/drug-products/drug-product-database.html>). Find the Consumer Information by contacting Pro Doc Ltée at 1-800-361-8559, [www.prodoc.qc.ca](http://www.prodoc.qc.ca) or [info@prodoc.qc.ca](mailto:info@prodoc.qc.ca).

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