

**PATIENT MEDICATION INFORMATION**

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

**T/C PRO-OXAZEPAM**

**Oxazepam Tablets, Mfr. Std.**

Read this carefully before you start taking **PRO-OXAZEPAM** 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-OXAZEPAM** .

**Serious Warnings and Precautions**

**Addiction, Abuse and Misuse:** Even if you take **PRO-OXAZEPAM** exactly as you were told to, 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 **PRO-OXAZEPAM** with:

- opioids,
- alcohol, or
- illicit drugs.

Your healthcare professional should:

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

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

**Withdrawal:** If you suddenly stop taking **PRO-OXAZEPAM** , 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-OXAZEPAM** or changing your medicine.

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

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

### **What is PRO-OXAZEPAM used for?**

PRO-OXAZEPAM is used in adults to relieve:

- short-term anxiety and tension from anxiety neurosis (a type of anxiety); and
- symptoms of sudden alcohol withdrawal (e.g., agitation and mental status changes).

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

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

PRO-OXAZEPAM belongs to the group of medicines called benzodiazepines, which are Central Nervous System (CNS) depressants. It affects certain substances in your brain called neurotransmitters to reduce symptoms caused by anxiety and stress.

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

Medicinal ingredient: Oxazepam.

Non-medicinal ingredients: D&C Yellow #10 Aluminum Lake (10 mg and 15 mg only), FD&C Yellow #6 Aluminum Lake (10 mg and 15 mg only), lactose, magnesium stearate, microcrystalline cellulose and starch.

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

Tablets: 10 mg, 15 mg and 30 mg of oxazepam.

### **Do not use PRO-OXAZEPAM if:**

- you are allergic to benzodiazepines, such as oxazepam, or to any other ingredient in PRO-OXAZEPAM ;
- you are under 12 months of age;
- you have a history of glaucoma (increased pressure in your eye causing damage to the optic nerve); and
- you have myasthenia gravis (a condition characterized by weakness of your muscles used for movement).

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take PRO-OXAZEPAM . 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).
- are 65 years of age or older.
- have or have had a mental health disorder (e.g., psychosis, personality disorder and obsessive-compulsive disorder).
- have depression or signs of depression.
- have a condition that causes weakness or frailty.

- have liver problems.
- have kidney problems.
- are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed.
- drink or plan to drink alcohol. Do NOT drink alcohol while you take PRO-OXAZEPAM .
- unable to digest some milk sugars (e.g., lactose intolerance). PRO-OXAZEPAM contains the milk sugar lactose.

**Other warnings you should know about:**

**Severe Allergic Reaction:** In rare cases, benzodiazepines like PRO-OXAZEPAM have caused severe allergic reactions including anaphylaxis, which can be life-threatening. The symptoms of a severe allergic reaction include angioedema of the tongue or throat (swelling of tissues under the skin), shortness of breath, throat closing, nausea or vomiting. Angioedema can lead to a blocked airway and can be life-threatening. If you develop angioedema or you notice signs of a severe allergic reaction after taking PRO-OXAZEPAM , you should stop taking PRO-OXAZEPAM and tell your healthcare professional right away.

**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-OXAZEPAM .

Your risk of going through withdrawal is higher if you are taking PRO-OXAZEPAM for a long time or at high doses. However, symptoms can still occur if you are taking PRO-OXAZEPAM 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-OXAZEPAM 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.

**PRO-OXAZEPAM with Opioids:** Taking PRO-OXAZEPAM 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-OXAZEPAM .

**Driving and Using Machines:** Do NOT drive or operate heavy machinery or do tasks that require special attention while taking PRO-OXAZEPAM . This is especially important if you are taking other depressants like an opioid medicine.

**Falls and Fractures:** Benzodiazepines like PRO-OXAZEPAM 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,
- consume alcohol,
- are elderly, or
- have a condition that causes weakness or frailty.

**Monitoring and Testing:** Your healthcare professional may conduct blood tests to assess your health, especially at the start of your treatment. Your healthcare professional will interpret your results and may adjust or stop your dose of PRO-OXAZEPAM .

**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-OXAZEPAM and opioids may cause:**

- **severe drowsiness,**
- **trouble breathing,**
- **coma,**
- **death.**

**The following may interact with PRO-OXAZEPAM :**

- alcohol. Do not take PRO-OXAZEPAM if you drink alcohol;
- medicines used to treat allergies such as, sedative antihistamines;
- medicines used to prevent or treat seizures (anticonvulsants);
- medicines used to produce a local or general loss of sensation, including pain (anesthetics);
- medicines used to treat depression (antidepressants);
- medicines used to treat mental health disorders or change your mental state or mood (antipsychotic and psychotropic medications);

- medicines that inhibit certain liver enzymes, particularly cytochrome P450 (e.g., cimetidine and erythromycin). If you are unsure, talk to your healthcare professional;
- other benzodiazepines typically used to treat anxiety, insomnia and seizures.

DO NOT USE PRO-OXAZEPAM along with other medications without first discussing this with your healthcare professional.

**How to take PRO-OXAZEPAM :**

- Take PRO-OXAZEPAM exactly as prescribed by your healthcare professional.
- You should take PRO-OXAZEPAM with a glass of water.
- Do not consume any alcohol while taking PRO-OXAZEPAM .
- Always follow your healthcare professional’s instructions on how to lower and stop your dose carefully. This helps to avoid unwanted effects. However, if you notice any signs or symptoms of withdrawal, tell your healthcare professional right away.

**Usual dose:**

Your healthcare professional will determine the right dose and the length of PRO-OXAZEPAM treatment for you. This will depend on your age, current health, and if you take certain other medications. They may also adjust your dose to ensure that the lowest effective dose is prescribed.

**Overdose:**

Symptoms of an overdose with PRO-OXAZEPAM include:

- drowsiness,
- muscle weakness,
- loss of coordination,
- speaking problems,
- abnormal movements (paradoxical excitement),
- slower reflexes,
- confusion,
- coma,
- low blood pressure,
- breathing difficulties.

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

**Missed Dose:**

If you forget or miss a dose of PRO-OXAZEPAM , do not take the missed dose. Instead, take the next scheduled dose at the usual time. Do not try to make up for the missed dose by taking a double dose.

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

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

Side effects of PRO-OXAZEPAM include:

- falls and fractures,
- drowsiness,
- dizziness,
- fatigue,
- difficulties with coordination,
- slow response,
- headache,
- vertigo,
- blurred or double vision,
- weakness,
- memory loss,
- reduced activity or lack of energy,
- speech problems,
- a feeling or state of intense excitement and happiness,
- anorexia (an eating disorder characterized by not eating or loss of appetite),
- nausea,
- constipation,
- urinating difficulties,
- changes in sex drive (libido),
- anxiety,
- uncontrollable shaking, muscle twitches or spasms.

<b>Serious side effects and what to do about them</b>			
<b>Symptom / effect</b>	<b>Talk to your healthcare professional</b>		<b>Stop taking drug and get medical help</b>
	<b>Only if severe</b>	<b>In all cases</b>	
<b>RARE</b>			
<b>Severe allergic reaction:</b> fever, skin rash, hives, itching, swelling of the eyelids, face, lips, tongue or throat, trouble breathing, wheezing, nausea, chest pain, chest tightness, or vomiting.			✓
<b>UNKNOWN FREQUENCY</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, and low blood pressure.			✓
<b>Respiratory depression:</b> slow, shallow or weak breathing.			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get medical help
	Only if severe	In all cases	
<p><b>Withdrawal:</b></p> <p><b>Severe symptoms include:</b></p> <p><b>Catatonia:</b> feeling like you cannot move or respond.</p> <p><b>Delirium tremens:</b> severe confusion, shivering, irregular heart rate and excessive sweating.</p> <p><b>Feeling depressed</b></p> <p><b>Dissociation:</b> feeling disconnected from reality.</p> <p><b>Hallucinations:</b> seeing or hearing things that are not there.</p> <p><b>Mania:</b> overactive behaviour and thoughts.</p> <p><b>Psychosis:</b> believing in things that are not true.</p> <p><b>Convulsions:</b> (seizures – including some that do not stop): loss of consciousness <b>with uncontrollable shaking.</b></p> <p><b>Thoughts or actions of suicide</b></p> <p><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 in the hands, arms, legs or feet; sweating.</p>		✓	
<p><b>Edema:</b> unusual swelling of the arms, hands, legs, feet and ankles, face, or airway passages.</p>			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get medical help
	Only if severe	In all cases	
<b>Skin disorders:</b> rash, blistering, itching all over the body, reddening of the skin, itchy red spots, swelling of eyelids, face or lips, peeling, or lost skin.			✓
<b>Jaundice (build up of bilirubin in the blood):</b> yellowing of the skin and eyes, dark urine, light coloured stool, or itching all over your body.			✓
<b>Hypotension (low blood pressure):</b> dizziness, fainting, light-headedness, blurred vision, nausea, vomiting, fatigue (may occur when you go from lying or sitting to standing up).		✓	
<b>Depression (sad mood that won't go away):</b> difficulty sleeping, sleeping too much, changes in appetite or weight, feelings of worthlessness, guilt, regret, helplessness or hopelessness, withdrawal from social situations, family, gatherings and activities with friends, reduced libido (sex drive), thoughts of death, or thoughts of suicide.		✓	
<b>Leukopenia</b> (decreased white blood cells): infections, fatigue, fever, aches, pains and flu-like symptoms.		✓	

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:**

Store PRO-OXAZEPAM between 15°C and 30°C.

Keep PRO-OXAZEPAM in a safe place out of reach and sight of children.

### **If you want more information about PRO-OXAZEPAM:**

- 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>); or by contacting the sponsor Pro Doc Ltée at 1-800-361-8559, [www.prodoc.qc.ca](http://www.prodoc.qc.ca) or [medinfo@prodoc.qc.ca](mailto:medinfo@prodoc.qc.ca)

This leaflet was prepared by Pro Doc Ltée.

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