

## PATIENT MEDICATION INFORMATION

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

#### **PRO-CLONAZEPAM**

##### **clonazepam tablets**

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

#### **Serious Warnings and Precautions**

**Addiction, Abuse and Misuse: Even if you take PRO-CLONAZEPAM 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-CLONAZEPAM with:**

- Opioids
- Alcohol or
- Illicit drugs

**Your healthcare professional should:**

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

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

**Withdrawal: If you suddenly stop taking PRO-CLONAZEPAM, lower your dose too fast, or switch to another medication, you can experience severe or life-threatening withdrawal symptoms (see the Withdrawal section below)**

- Always contact your doctor before stopping or lowering your dose of PRO-CLONAZEPAM or changing your medicine.

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

- Severe drowsiness
- Decreased awareness
- Breathing problems
- Coma
- Death

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

PRO-CLONAZEPAM is used alone or with other anti-seizure medicines to treat certain types of seizures called:

- myoclonic seizures,

- akinetic seizures,
- petit mal seizures in patients who suffer from Lennox-Gastaut syndrome, a type of epilepsy and
- petit mal seizures in patients who do not respond to anti-seizure medicines called succinimides.

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

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

PRO-CLONAZEPAM contains the active ingredient clonazepam. Clonazepam belongs to a group of medicines called benzodiazepines. It can slow down electrical impulses in the brain that cause seizures.

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

Medical ingredient: clonazepam

Non-medicinal ingredients: Corn Starch, FD&C Yellow # 6 Lake (0.5 mg), FD&C Red # 40 Lake (1 mg) Lactose, Magnesium Stearate, and Microcrystalline Cellulose.

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

**PRO-CLONAZEPAM** Tablet: 0.5 mg, 1 mg and 2 mg.

### **Do not use PRO-CLONAZEPAM if you/your child:**

- are allergic to the group of medicines known as benzodiazepines (such as diazepam, chlordiazepoxide, bromazepam, or flurazepam).
- are allergic to clonazepam or to any other ingredient in PRO-CLONAZEPAM.
- have severe breathing problems.
- have severe liver problems.
- have narrow angle glaucoma (increased pressure in the eye).
- have myasthenia gravis (muscle weakness).
- suffer from sleep apnea (pauses in breathing during sleep).

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

- have lung or breathing problems.
- have liver or kidney problems.
- regularly or occasionally drink alcohol or use recreational drugs. Do not drink alcohol while taking PRO-CLONAZEPAM without first talking to your healthcare professional.
- suffer from ataxia (inability to coordinate muscle movements).
- have a history of depression and/or suicide attempts.
- are lactose intolerant or have one of the following rare hereditary diseases:
  - galactose intolerance,
  - total lactase deficiency,
  - glucose-galactose malabsorption.

- 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).
- have porphyria (a condition that affects the nervous system and skin).
- are 65 years of age or older.

**Other warnings you should know about:**

**Do not stop your treatment with PRO-CLONAZEPAM without first checking with your healthcare professional. This could lead to a sudden worsening of your seizures.**

**Worsening Seizures:** During treatment with PRO-CLONAZEPAM, your seizures may get worse or you may develop a new type of seizure. If you start to have more seizures or your seizures get worse, 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 to severe or life threatening. Some of your withdrawal symptoms can last for months after you stop PRO-CLONAZEPAM.

Your risk of going through withdrawal is higher if you are taking PRO-CLONAZEPAM for a long time or at high doses. However, symptoms can still occur if you are taking PRO-CLONAZEPAM 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 doctor **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 heartrate and excessive sweating (delirium tremens)
- Feeling depressed
- Feeling disconnected from reality (dissociation)
- Seeing or hearing things that are not there (hallucinations)
- Overactive behaviour 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 doctor before stopping or reducing your dose of PRO-CLONAZEPAM 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.

**Driving and Using Machines:** PRO-CLONAZEPAM may affect your ability to be alert. It may make you feel dizzy, drowsy and affect your coordination. These effects may be worse if you drink alcohol, increase your dose or change the timings of when you take your medication.

While you are taking PRO-CLONAZEPAM, **do not** drive, use machinery, or do activities that require you to be alert:

- for the first few days, or until you know how PRO-CLONAZEPAM affects you.
- if you are also taking an opioid medicine.

**Falls and Fractures:** Benzodiazepines like PRO-CLONAZEPAM can cause you to feel sleepy, dizzy and affect your balance. This increases the 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.

**Mental and Behavioural Changes:** A variety of abnormal thinking and behaviour changes may occur when you take PRO-CLONAZEPAM. Some of these changes include aggressiveness, irritability, agitation, anger, delusions, strange behaviour, anxiety, nightmares, restlessness, hallucinations, and inappropriate behaviour. If you develop any unusual thoughts or behaviour while using PRO-CLONAZEPAM, tell your healthcare professional right away

**Self-harm or Suicide:** If you have thoughts of harming or killing yourself at any time, contact your healthcare professional or go to a hospital **right away**. You may find it helpful to tell a relative or close friend that you are depressed or have other mental illnesses. Ask them to read this leaflet. You might ask them to tell you if they:

- think your depression or mental illness is getting worse, or
- are worried about changes in your behaviour

**Pregnancy and breastfeeding:**

- If you take PRO-CLONAZEPAM during pregnancy, your baby is at risk for serious birth defects, and cognitive disabilities.
- Tell your healthcare professional right away if you become pregnant or think you are pregnant during treatment with PRO-CLONAZEPAM. You and your healthcare professional should decide if you will continue to take PRO-CLONAZEPAM while you are pregnant.
- **Pregnancy Registry:** If you become pregnant while taking clonazepam, talk to your healthcare professional about registering with the North American Antiepileptic Drug Pregnancy Registry.

You can enroll in this registry by calling 1-888-233-2334. The purpose of this registry is to collect information about the safety of antiepileptic medicines during pregnancy. Information about the registry can also be found at the website: <http://www.aedpregnancyregistry.org/>.

- PRO-CLONAZEPAM passes into breast milk and may harm your baby. Do not breastfeed during treatment with PRO-CLONAZEPAM. Talk to your healthcare professional about the best way to feed your baby during this time.

**Check-ups and testing:** PRO-CLONAZEPAM may cause changes in your blood and liver. During long-term treatment with PRO-CLONAZEPAM, your healthcare professional may perform tests to monitor your blood count and liver.

**Amnesia:** PRO-CLONAZEPAM can cause a type of memory loss known as amnesia. This is more likely to happen with higher doses of PRO-CLONAZEPAM.

**Hypersecretion:** PRO-CLONAZEPAM can cause increased secretion from the lungs (hypersecretion). Children should be watched carefully as this might cause difficulties in breathing and/or severe choking and coughing.

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

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

<p><b>Serious Drug Interactions</b></p> <p><b>Taking PRO-CLONAZEPAM and opioids may cause:</b></p> <ul style="list-style-type: none"><li>• <b>severe drowsiness</b></li><li>• <b>trouble breathing</b></li><li>• <b>coma</b></li><li>• <b>death</b></li></ul> <p><b>Tell your healthcare professional if you:</b></p> <ul style="list-style-type: none"><li>• <b>are taking opioid medicines</b></li><li>• <b>are prescribed an opioid medicine after you start taking PRO-CLONAZEPAM</b></li></ul>
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- other medicines to control seizures such as phenytoin, phenobarbital, carbamazepine, lamotrigine and valproate
- muscle relaxants
- medicines used to treat depression such as Monoamine Oxidase Inhibitors (MAOIs) and tricyclic antidepressants
- hypnotics and sedatives such as barbiturates, used to treat anxiety or sleep problems
- antihistamines, used to treat allergies
- antipsychotics, used to treat mental health problems
- fluconazole, used to treat fungal infections
- alcohol. **Do not** consume alcohol when taking PRO-CLONAZEPAM.
- grapefruit juice. Avoid drinking grapefruit juice or eating grapefruit when taking PRO-CLONAZEPAM.

**How to take PRO-CLONAZEPAM:**

- Take PRO-CLONAZEPAM exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.
- Swallow the tablets with water. DO NOT chew the tablets.

**Usual dose:****Adults and Children:**

Your healthcare professional will determine the dose that is right for you/your child. Your/your child's dose and how often you/your child take it will depend on your/your child's age, weight, other medical conditions, and severity of your/your child's seizures.

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

**Overdose:**

Signs of an overdose with PRO-CLONAZEPAM include:

- drowsiness,
- involuntary eye movements (side-to-side, up and down, circular motion),
- lack of muscle control or coordination,
- below normal or absence reflexes,
- low blood pressure,
- breathing or lung problems,
- coma.

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

**Missed Dose:**

If you/your child missed a dose of this medication, take it as soon as you/your child remember. However, if it is almost time for your/your child's next dose, skip the missed dose and continue with your/your child's next scheduled dose. Go back to the regular dosing schedule. Do not take two doses at the same time.

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

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

The most common side effects are:

- Feeling drowsy or tired, especially at the start of treatment.
- Some muscle weakness and dizziness.
- Increased salivation.
- Movement control and balance issues.

Less common possible side effects are:

- Increased secretion from the lungs (hypersecretion).
- Falls and fractures.

Other side effects may include:

- Fever, nausea, vomiting, constipation, diarrhea and headache
- Dry mouth
- Increased or decreased appetite
- Pain in the abdomen or lower back
- Sore gums
- Increased or decreased libido
- Weight gain or loss
- Dehydration
- Seeing double
- Trouble falling asleep
- Tremors
- Slurred speech

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>Self-harm or Suicide:</b> thoughts or actions about hurting or killing yourself		✓	
<b>RARE</b>			
<b>Allergic Reaction:</b> difficulty swallowing or breathing, wheezing, drop in blood pressure, feeling sick to your stomach and throwing up, hives or rash, swelling of the face, lips, tongue or throat			✓
<b>Depression</b> (sad mood that won't go away): difficulty sleeping or 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) and thoughts of death or suicide. If you have a history of depression, your depression may become worse		✓	
<b>Mental and Behavioural Changes:</b> unusual 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 behaviour		✓	
<b>UNKNOWN FREQUENCY</b>			
<b>Amnesia</b> (a type of memory loss): difficulty recalling events that recently happened		✓	
<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.			✓



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>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 heartrate 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): uncontrollable shaking, with or without loss of consciousness. <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 in the hands, arms, legs or feet; sweating.		✓	
<b>Worsening seizures</b>		✓	

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-CLONAZEPAM at room temperature (15-30°C) in the original light-resistant package provided by the healthcare professional.

Keep out of reach and sight of children.

**If you want more information about PRO-CLONAZEPAM:**

- 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 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).

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