

**PATIENT MEDICATION INFORMATION**

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

**PRO-ZOLPIDEM ODT**

**Zolpidem Tartrate Sublingual Orally Disintegrating Tablets (ODT)**

Read this carefully before you start taking **PRO-ZOLPIDEM ODT** 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-ZOLPIDEM ODT**.

**Serious Warnings and Precautions**

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

- opioids
- alcohol or
- illicit drugs

Your healthcare professional should:

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

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

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

**PRO-ZOLPIDEM ODT with Opioids:** Taking **PRO-ZOLPIDEM ODT** with opioid medicines can cause:

- severe drowsiness
- decreased awareness
- breathing problems

- coma
- death

**Complex Sleep-Related Behaviours: Taking PRO-ZOLPIDEM ODT can cause complex sleep behaviours. This includes sleepwalking, sleep-driving and doing other activities while you are not fully awake. These behaviours can cause serious injuries, including death. Stop taking PRO-ZOLPIDEM ODT right away if you experience any complex sleep behaviours.**

### **What is PRO-ZOLPIDEM ODT used for?**

PRO-ZOLPIDEM ODT is used in adults for short term (usually not more than 7 to 10 days) treatment of insomnia. This is a sleep disorder that makes it hard to fall asleep, hard to stay asleep, or causes you to wake up too early. PRO-ZOLPIDEM ODT should only be used when the effects of insomnia affect your daytime activities.

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

### **How does PRO-ZOLPIDEM ODT work?**

PRO-ZOLPIDEM ODT works by increasing the activity of a chemical in your brain called gamma-aminobutyric acid (GABA). This calms the brain which helps you go to sleep.

### **What are the ingredient in PRO-ZOLPIDEM ODT?**

Medicinal ingredients: Zolpidem tartrate

Non-medicinal ingredients: Colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, microcrystalline cellulose and saccharin sodium.

### **PRO-ZOLPIDEM ODT comes in the following dosage forms:**

Rapidly disintegrating oral tablets (that you put under tongue): 5 mg, 10 mg.

### **Do not use PRO-ZOLPIDEM ODT if:**

- you are allergic to zolpidem tartrate or any of the ingredients in PRO-ZOLPIDEM ODT.
- you have a muscular disease known as myasthenia gravis (muscle weakness).
- you have liver problems.
- you have severe lung or breathing problems such as sleep apnea (sleep disorder which causes pauses in breathing or shallow breathing while sleeping).
- you have a past history of unexpected reactions to other sedative medications. This can include driving, eating, making a phone call or having sex while not being fully awake.
- you have a history or family history of sleepwalking.

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

- have a lung or breathing problems.

- have signs of depression or a history of depression.
- have or have a history of suicidal thoughts or attempts or mental health problems.
- are taking any other medicines, including central nervous system (CNS) depressants (slow down brain activity).
- drink or plan to drink alcohol. Do not drink alcohol while you take PRO-ZOLPIDEM ODT.
- have disorders that affect sleep such as Periodic Limb Movement (involuntary movement of limbs during sleeps) or Restless Leg Syndrome (urge to move legs, typically in the evening and night).
- have had an unexpected reaction to sedative medications in the past, including alcohol and benzodiazepines.
- have a history of violent behaviour.
- have a liver or kidney problems.
- 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.

**Other warnings you should know about:**

**Complex Sleep Behaviours:** PRO-ZOLPIDEM ODT can cause dangerous sleeping-related behaviours such as getting out of bed while not fully awake and doing activities that you do not know you are doing. You may not remember doing these activities when you wake up. These unusual behaviours are more likely to happen when PRO-ZOLPIDEM ODT is taken with alcohol or other medicines that can make you sleepy, such as medicines used to treat depression or anxiety. If you drink alcohol, do not take PRO-ZOLPIDEM ODT. The activities you may do in these situations can put you and people around you in danger. This can include driving a car (“sleep-driving”), leaving the house, making and eating food, and talking on the phone.

You and people close to you should watch out for unusual types of behaviour when you are asleep. If you find out that you have done any such activities for which you have no memory, you should call your healthcare professional right away.

**Driving and Using Machines:** PRO-ZOLPIDEM ODT may make you feel dizzy, drowsy and affect your coordination. DO NOT drive, use machinery, or do activities that requires you to be alert:

- if it has not been 12 hours or more since you took PRO-ZOLPIDEM ODT, especially if you are elderly or you take the 10 mg dose.
- if you do not feel fully awake.
- until you know how PRO-ZOLPIDEM ODT affects you.
- if you are also taking an opioid medicine.

**Memory problems:** PRO-ZOLPIDEM ODT cause a type of memory loss known as amnesia. This is characterized by having trouble remembering events that recently occurred, usually several hours after taking the medication. This is usually not a problem if you take PRO-

ZOLPIDEM ODT before sleeping. However, if you take PRO-ZOLPIDEM ODT to help sleep while travelling, such as during an airplane flight, you may wake up to a memory lapse caused by the drug. This has been called “traveller’s amnesia” and can be a problem. **DO NOT TAKE PRO-ZOLPIDEM ODT** when a full night’s sleep is not possible before you need to be active and functional (e.g., an overnight flight of less than 8 hours). Your body needs time to eliminate PRO-ZOLPIDEM ODT from your system.

**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-ZOLPIDEM ODT.

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

- a sudden and severe change in mental state that can cause a combination of confusion, disorientation and/or attention deficit (delirium).
- experiences of unreality or detachment from one’s surroundings (derealisation).
- experiences of unreality or detachment from one’s mind, self, or body (depersonalization).
- seeing or hearing things that are not there (hallucinations).
- sensitivity to sounds and noise (hyperacusis).
- convulsions (seizures), including some that do not stop.

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-ZOLPIDEM ODT 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

**Falls and Fractures:** Benzodiazepines or other sedative-hypnotic drugs, such as PRO-ZOLPIDEM ODT, 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

**Mental and Behavioural Changes:** A variety of abnormal thinking and behaviour changes may occur when you take PRO-ZOLPIDEM ODT. Some of these changes include aggressiveness and extroversion that seem out of character, confusion, strange behaviour, anxiety, restlessness, hallucinations, feeling like you are not yourself, worsening insomnia or depression. If you develop any unusual thoughts or behaviour while using PRO-ZOLPIDEM ODT, tell your healthcare professional right away.

**Self-harm:** 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:** Do not take PRO-ZOLPIDEM ODT if you are pregnant. PRO-ZOLPIDEM ODT may harm your unborn baby (e.g., birth defects) if you are pregnant. This risk is higher during the first trimester or last weeks of pregnancy. It may also cause side effects and withdrawal symptoms in your baby after birth. If you are able to get pregnant, want to be or think you are pregnant, there are specific risks you should discuss with your healthcare professional.

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

**Blood Tests:** PRO-ZOLPIDEM ODT 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.**

**The following may interact with PRO-ZOLPIDEM ODT:**

#### **Serious Drug Interactions**

**Taking PRO-ZOLPIDEM ODT and opioids may cause:**

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

**Tell your healthcare professional if you:**

- **are taking opioid medicines**

- **are prescribed an opioid medicine after you start taking PRO-ZOLPIDEM ODT**

- alcohol. Do not take PRO-ZOLPIDEM ODT if you drink alcohol.
- other hypnotics or sedatives that are used to help with sleeping.
- sedative antihistamines that are used to treat allergies.
- anticonvulsants used to prevent or treat seizures.
- anesthetics, used during surgery.
- medicines used to treat mental health disorders (antipsychotics and psychotropic medications).
- medicines used to treat fungal and bacterial infections such as ketoconazole, itraconazole, rifampicin, rifampin, erythromycin and clarithromycin.
- ritonavir, used to treat HIV.
- medicines used to treat or prevent seizures such as carbamazepine, phenytoin and phenobarbital.
- St. John's wort, an herbal medicine.

#### **How to take PRO-ZOLPIDEM ODT:**

- Always take PRO-ZOLPIDEM ODT exactly as your healthcare professional tells you to. Do not change your dose without talking to your healthcare professional.
- Take PRO-ZOLPIDEM ODT just before going to bed. Do not take PRO-ZOLPIDEM ODT if a full night's sleep is not possible before you need to become active and functional again.
- Place the whole tablet under the tongue, where it will disintegrate. Do not chew or swallow or take with water.
- For earlier sleep onset, PRO-ZOLPIDEM ODT should NOT be taken with or right after a meal.
- Do not consume any alcohol while taking PRO-ZOLPIDEM ODT.

**Remember:** This medication is for YOU. Never give it to others. It may harm them even if their symptoms are the same as yours.

#### **Usual dose:**

- The usual starting dose for adult women is 5 mg
- The usual starting dose for adult men is 10 mg.
- Based on your response and tolerability of PRO-ZOLPIDEM ODT, your age, other medical conditions you have and other medicines you are taking, your healthcare professional may change your dose. Your healthcare professional will ensure the lowest effective dose is prescribed.

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:

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

## Missed Dose:

If you missed a dose of this medication, you do not need to make up the missed dose. Skip the missed dose and continue with your next scheduled dose. Do not take two doses at the same time.

## What are possible side effects from using PRO-ZOLPIDEM ODT?

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

Side effects may include:

- dry mouth
- drowsiness, “drugged feeling”
- dizziness or light-headedness
- headache
- abnormal dreams
- difficulty with coordination
- nausea or vomiting
- decreased appetite
- constipation or diarrhea
- abdominal pain
- lack of energy
- muscle weakness
- blurred vision
- rash, itching
- palpitations, chest pain
- back pain, muscle pain
- falls and fractures

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>COMMON</b>			
<b>Mental and behavioural changes:</b> excitement, agitation, hyperactivity, hallucination, worsened	✓		

<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 immediate medical help</b>
	<b>Only if severe</b>	<b>In all cases</b>	
insomnia, aggressiveness, irritability, rages, psychoses, and violent behaviour			
<b>Severe allergic reactions:</b> swelling of the tongue or throat, trouble breathing, sudden wheeziness, chest pain or tightness, shortness of breath, throat closing, nausea and vomiting. Other allergic reactions may include rashes, spots on your skin, or itchy skin.			✓
<b>RARE</b>			
<b>Complex sleep behaviours:</b> getting out of bed while not fully awake and doing activities you do not remember the day after, including sleep walking, driving, making phone calls, or having sex			✓
<b>VERY RARE</b>			
<b>Self-harm or Suicide:</b> thoughts or actions about hurting or killing yourself			✓
<b>UNKNOWN</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.			✓
<b>Respiratory Depression:</b> slow, shallow or weak breathing.			✓
<b>Withdrawal:</b> <b>Severe symptoms include:</b> <b>Delirium:</b> sudden and severe change in mental state that		✓	



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	
<p>can cause a combination of confusion, disorientation and/or attention deficit</p> <p><b>Derealization:</b> experiences of unreality or detachment from one's surroundings</p> <p><b>Depersonalization:</b> experiences of unreality or detachment from one's mind, self, or body</p> <p><b>Hallucinations:</b> seeing or hearing things that are not there</p> <p><b>Hyperacusis:</b> sensitivity to sounds and noise</p> <p><b>Convulsions:</b> (seizures – including some that do not stop): loss of consciousness with uncontrollable shaking</p> <p><b>Other symptoms include:</b> Stomach cramps; trouble remembering or concentrating; diarrhea; feeling uneasy or restless; severe anxiety; 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>			

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-ZOLPIDEM ODT between 15°C-30°C.
- Protect from light and moisture.
- Keep PRO-ZOLPIDEM ODT and all medicines out of reach and sight of children and pets.

## If you want more information about PRO-ZOLPIDEM ODT:

- 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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