PART III: CONSUMER INFORMATION

[Pr] PRO-ZOPICLONE
Zopiclone tablets

This leaflet is part III of a three-part "Product Monograph" published when PRO-ZOPICLONE was approved for sale in Canada and is designed specifically for Consumers. Please read this information before you start to take your medicine. Keep this leaflet until you have finished all your tablets, as you may need to read it again. This leaflet should not replace a discussion between you and your doctor about the risks and benefits of PRO-ZOPICLONE. This leaflet is a summary and will not tell you everything about PRO-ZOPICLONE. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
PRO-ZOPICLONE is a prescription medication intended to help you sleep if you have transient and short-term insomnia. Symptoms of insomnia may vary: you may have difficulty in falling asleep, or awaken often during the night, or awaken early in the morning, or you may have all three symptoms.

Treatment with PRO-ZOPICLONE should usually not go on for more than 7-10 days and should be restricted for insomnia where disturbed sleep results in impaired daytime functioning. PRO-ZOPICLONE does not treat the underlying cause of your insomnia.

What it does:
PRO-ZOPICLONE is one of several prescription sleeping pills that have generally similar properties such as a calming effect.

If you are prescribed sleep medications, you should consider both their benefits and risks. Important risks and limitations include the following:

- you may become dependent on the medication,
- the medication may affect your mental alertness or memory, particularly when not taken as prescribed.

(see **Warnings and Precautions**)

When it should not be used:
Do not use PRO-ZOPICLONE if you have:

- a muscular disease known as myasthenia gravis
- a severe hepatic insufficiency (liver problems)
- severe lung or respiratory disease, including sleep apnea.
- a known allergy to zopiclone or any of the ingredients PRO-ZOPICLONE contains (see **What the nonmedicinal ingredients are**).

What the medicinal ingredient is:
The active ingredient in PRO-ZOPICLONE is zopiclone.

What the nonmedicinal ingredients are:
5.0 mg: croscarmellose sodium, dibasic calcium phosphate, hydroxypropyl cellulose, hydroxypropyl methylcellulose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, titanium dioxide.

7.5 mg: croscarmellose sodium, dibasic calcium phosphate, FD&C Blue No. 1 Aluminum Lake, FD&C Yellow No. 6 Aluminum Lake, hydroxypropyl methylcellulose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, pregelatinized starch, titanium dioxide

What dosage forms it comes in:
Tablets: 5 mg and 7.5 mg

WARNINGS AND PRECAUTIONS

Complex sleep-related behaviours
There have been reports of people getting out of bed while not fully awake after taking PRO-ZOPICLONE and doing activities that they did not know they were doing. The next morning, they did not remember doing those activities. This unusual behaviour is more likely to occur when PRO-ZOPICLONE is taken with alcohol or other drugs that can make you sleepy such as those for the treatment of depression or anxiety. The activities you may do in these situations can put you and people around you in danger. Reported activities included driving a car ("sleep-driving"), leaving the house, making and eating food, talking on the phone, etc.

Important:

1. Do not take more PRO-ZOPICLONE than prescribed.
2. Do not take PRO-ZOPICLONE if you drink alcohol.
3. Talk to your doctor if you have had episodes of sleepwalking in the past, or if there is a history of sleepwalking in your family.
4. Talk to your doctor if you have a condition that affects your sleep, such as Periodic Limb Movement Disorder (involuntary movement of limbs during sleep) or Restless Legs Syndrome (urge to move legs, usually accompanied by uncomfortable and unpleasant sensations, that begins or worsens during periods of inactivity, typically in the evening and night).
5. Talk to your doctor about all of your medicines, including over-the-counter medicines and herbal products. Your doctor will tell you if you can take PRO-ZOPICLONE with your other medicines.
6. You and people close to you should watch for the type of unusual behaviour described above. If you find out that you have done *any* such activities for which you have no memory you should call your doctor immediately.

Mental Alertness: PRO-ZOPICLONE may affect your ability to be alert. DO NOT DRIVE A CAR or operate potentially dangerous machinery until you experience how this drug will affect you.

Memory problems: PRO-ZOPICLONE may cause a special type of memory loss (amnesia); you may not recall events that occurred during some period of time, usually several hours, after taking the drug. This lapse is usually not a problem, because the person taking the sleeping pill intends to be asleep during this critical period of time. But it can be a problem if you take the medication to induce sleep while travelling, such as during an airplane flight, because you may wake up before the effect of the drug is gone.

This has been called "traveller's amnesia". DO NOT TAKE PRO-ZOPICLONE when a full night's sleep is not possible before you would again need to be active and functional; e.g., an overnight flight of less than 8 hours. Memory lapses may occur in such situations. Your body needs time to eliminate the medication from your system.

Tolerance/Withdrawal Symptoms:
After nightly use, sleeping pills may lose some of their effectiveness and you may also develop a degree of dependence.

When taking PRO-ZOPICLONE, you may get awakened during the last third of the night or feel anxious or nervous during the day. If this occurs, tell your doctor.

You may also experience "withdrawal effects" when you stop the medication after taking it for only a week or two. But usually, these withdrawal effects are more common and severe after long periods of continuous use. For instance, on the first few nights after stopping the medication, you may find that insomnia is worse than before taking the sleeping pills. This type of withdrawal symptom is known as "rebound insomnia".

Other withdrawal effects following abrupt stopping of sleeping pills may range from unpleasant feelings to a major withdrawal syndrome that may include abdominal and muscle cramps, vomiting, sweating, tremor, and rarely, convulsions. The severe symptoms are uncommon. If you have been taking sleeping pills for a long time, discuss with your physician when and how it would be best for you to stop.

Dependence/Abuse:
All prescription sleeping pills can cause dependence (addiction) especially when used regularly for more than a few weeks, or at higher doses. Some people develop a need to continue taking these drugs, not only for continued therapeutic effect, but also to avoid withdrawal symptoms or to achieve non-therapeutic effects.
Individuals who depend, or have depended at any time in the past, on alcohol or other drugs may be at particular risk of becoming dependent on drugs of this class. But **all people are at some risk**. Consider this matter before you take these medications beyond a few weeks.

Mental and Behavioural Changes:
A variety of abnormal thinking and behavioural changes may occur when you use prescription sleeping pills. Some of these changes include aggressiveness and extroversion which seem out of character. Other changes, although rare, can be more unusual and extreme. These include confusion, strange behaviour, restlessness, agitation, irritability, nightmares, hallucinations, delusion (a false belief or wrong judgment, held with conviction despite evidence to the contrary), feeling like you are not yourself, and feeling more depressed, which may lead to suicidal thinking.

It is rarely clear whether such symptoms are caused by the medication, or by an illness that was present before the medication was used, or are simply spontaneous happenings. If you develop any unusual disturbing thoughts or behaviour while using PRO-ZOPICLONE, discuss the matter immediately with your doctor.

Worsening of Side Effects
DO NOT CONSUME ALCOHOL WHILE TAKING PRO-ZOPICLONE.
Some medicines may also worsen side effects that some patients experience with PRO-ZOPICLONE (see **Interactions with this medication**).

Elderly: An increased risk of falls and fractures has been reported in elderly people who take sleeping pills such as PRO-ZOPICLONE.

Effects on Pregnancy:
Certain sleeping pills have been linked to birth defects when taken during the early months of pregnancy. It is not yet known if PRO-ZOPICLONE could cause similar effects. In addition, sleeping pills taken during the last weeks of pregnancy have been known to sedate the baby and may also cause withdrawal symptoms after birth. Therefore, **DO NOT TAKE** PRO-ZOPICLONE at anytime during pregnancy, it may affect the developing baby.

Use in Nursing Mothers: PRO-ZOPICLONE 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 PRO-ZOPICLONE talk to your doctor or pharmacist if:

- You have a lung disease or breathing problems.
- You have liver or kidney condition.
- You have a history of depression and/or suicide thoughts or attempts.
- You have had unexpected reactions to alcohol or sedative medications in the past, such as irritability, aggression, hallucinations, etc.
- You have a history of drug or alcohol abuse or addiction.
- You are planning to become pregnant, if you are pregnant, or if you become pregnant while taking this medication.
- You are breastfeeding.
- You consume alcohol.
- You are taking any other medicines, including over-the counter medicines and herbal products.
- You have lactose intolerance.

INTERACTIONS WITH THIS MEDICATION

Do not use PRO-ZOPICLONE if you drink alcohol. **Do not use PRO-ZOPICLONE** along with other medications, over-the counter medicines or herbal products without first discussing this with your doctor or pharmacist.

PRO-ZOPICLONE may produce more pronounced side effects when co-administered with:

- Alcohol
- Other tranquilizers or sleeping pills
- Sedative antihistamines
- Anticonvulsants (medicines used to control or prevent convulsions)
- Narcotic analgesics
- Antipsychotics, antidepressants and other psychotropic medications (mood altering drugs) which themselves can make you sleepy.

Other drugs which may interact with PRO-ZOPICLONE by affecting the way the drug is metabolized by the enzyme CYP3A4 in the liver include:

- CYP3A4 inhibitors, such as erythromycin, clarithromycin, ketoconazole, itraconazole, and ritonavir;
- CYP3A4 inducers, such as rifampicin or rifampin, carbamazepine, phenobarbital, phenytoin, and St. John's wort.

PROPER USE OF THIS MEDICATION

PRO-ZOPICLONE is an effective medication and is relatively free of serious problems when used for the short-term management of insomnia. Sleeplessness may last only for a short time and may respond to brief treatment. The risks and benefits of prolonged use should be discussed with your doctor.

Usual dose:
PRO-ZOPICLONE should be taken at bedtime just before retiring for the night.

Adults: The usual adult dose is 5.0 mg to 7.5 mg.

Special population: Elderly (65 years of age or more), debilitated patients and/or patients with liver, kidney, or chronic respiratory problems should start with 3.75 mg (one-half of a 7.5 mg tablet) at bedtime just before retiring.

Follow your doctor's advice about how to take PRO-ZOPICLONE, when to take it, and how long to take it.

The lowest effective dose should be used.

Do not increase the prescribed dose of PRO-ZOPICLONE.

Do not take PRO-ZOPICLONE if it is not prescribed for you.

Treatment with PRO-ZOPICLONE should usually not exceed 7-10 consecutive days. **Do not take PRO-ZOPICLONE** for more than 7-10 days without first consulting your doctor. If you still have problems sleeping after you finish your capsules, contact your doctor again.

Do not take PRO-ZOPICLONE if you drink alcohol.

PRO-ZOPICLONE is not indicated for patients under 18 years of age. **Do not take PRO-ZOPICLONE if you are under 18 years of age.**

Do not take PRO-ZOPICLONE when a full night's sleep is not possible before you would again need to be active and functional.

Do not drive a car or operate potentially dangerous machinery until you experience how this drug will affect you the next day.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms. Show the doctor your bottle of tablets.

Missed Dose:
PRO-ZOPICLONE should be taken at bedtime just before retiring for the night. If you miss a dose, wait and take your next dose at your regular time. Do not take 2 doses at the same time. Do not make up for a missed dose

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Common Side Effects:
The most common adverse reaction seen with PRO-ZOPICLONE is taste alteration (bitter taste).

PRO-ZOPICLONE may cause drowsiness, dizziness, lightheadedness, and difficulty with coordination. Users must be cautious about engaging in hazardous activities requiring complete mental alertness, e.g., operating machinery or driving a motor vehicle. This risk is increased by concomitant intake of alcohol.

How sleepy you are the day after you use one of these sleeping pills depends on your individual response and on how quickly your body gets rid of the medication. The larger the dose, the more likely that you will experience drowsiness, etc., the next day. It is important that you comply with the dose your physician has prescribed. Prescription sleeping pills which are eliminated rapidly, tend to cause less drowsiness the next day, but may cause withdrawal problems the day after use (see below).

Withdrawal-related side effects: You may experience an increase in sleep difficulties (rebound insomnia) and/or "increased daytime anxiety" (rebound anxiety) for one or two days after discontinuing PRO-ZOPICLONE (see **Warnings and Precautions, Tolerance/Withdrawal Symptoms**).

Elderly patients are especially susceptible to side effects. Excessive drowsiness in the elderly may result in falls and fractures.

Do not drink alcohol while using PRO-ZOPICLONE. Do not use sleeping pills along with other medications without first discussing this with your doctor.

Allergic reactions:
Rare cases of severe allergic reactions have been reported. Symptoms may include:

- swelling of the tongue or throat, trouble breathing, nausea and vomiting. Get emergency medical help if you get these symptoms after taking PRO-ZOPICLONE.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Seek urgent medical attention
		Only if severe	In all cases	
Uncommon	Unexpected reactions such as excitement, agitation, hyperactivity, hallucination, worsened insomnia, aggression, irritability, rages, psychoses, and violent behaviour	✓		
	Depressed Mood		✓	
	Severe allergic reactions (swelling of the tongue or throat, trouble breathing, nausea and vomiting)			✓
	Trouble breathing		✓	
	Withdrawal effects (abdominal and muscle cramps, vomiting, sweating, tremor, and, very rare cases of convulsions)			✓
Rare	Somnambulism (sleepwalking) – getting out of bed while not fully awake and do activities you do not remember the day after		✓	
Very rare	Thoughts of death or suicide		✓	

This is not a complete list of side effects. For any unexpected effects while taking PRO-ZOPICLONE, contact your doctor or pharmacist.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 0701E
    Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect ™ Canada Web site at:
www.healthcanada.gc.ca/medeffect .

NOTE: Should you require information related to the management of side effects, please contact your health professional. The Canada Vigilance Program does not provide medical advice.

HOW TO STORE IT

Store in a dry place, at room temperature (15° - 30°C). Protect from light.

Keep in a safe place out of reach of children.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be obtained by contacting the sponsor, Pro Doc Ltée at 1-800-361-8559, http://www.prodoc.qc.ca or info@prodoc.qc.ca .

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