

PART III: CONSUMER INFORMATION

CO ZOPICLONE
(Zopiclone Tablets)

This leaflet is part III of a three-part "Product Monograph" published when CO ZOPICLONE was approved for sale in Canada and is designed specifically for Consumers.

This leaflet is a summary and will not tell you everything about CO ZOPICLONE. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

CO ZOPICLONE is a prescription medication, intended to help you sleep.

What it does:

Zopiclone helps to relieve your difficulty in falling asleep.

Zopiclone is an effective medication and is relatively free of serious problems when used for the short-term management of 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.

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.

When it should not be used:

Do not use CO ZOPICLONE

- if you have a known sensitivity or are allergic to Zopiclone or any of the ingredients in this medication (for a complete listing of components, see *What the important non medicinal ingredients are*),
- if you have breathing problems (i.e. sleep apnea)

What the medicinal ingredient is:

Zopiclone

What the important nonmedicinal ingredients are:

CO ZOPICLONE 5.0 mg contains: Calcium Hydrogen Phosphate, HPMC 2910/Hypromellose 6cP, Lactose Monohydrate, Macrogol/PEG 3000, Magnesium stearate, Potato Starch Dried, Silicon Dioxide, Sodium Starch Glycolate, Titanium dioxide, and Triacetine/Glycerol triacetate.

CO ZOPICLONE 7.5 mg contains: Calcium Hydrogen Phosphate, FD&C Blue #1/Brilliant blue FCF Aluminum Lake, Macrogol/PEG 3350, Magnesium stearate, Polyvinyl alcohol (Partially hydrolyzed), Potato Starch Dried, Silicon Dioxide, Sodium Starch Glycolate, Talc and Titanium dioxide.

What dosage forms it comes in:

CO ZOPICLONE is available in 2 strengths, namely: tablets 5 mg and 7.5 mg.

WARNINGS AND PRECAUTIONS

- Sleep disturbance may be a sign of underlying physical or mental condition your doctor will evaluate your condition and decide what to do.
- Do not use CO ZOPICLONE if you have, in the past, showed inconsistent reactions to alcohol and/or sleep medications.
- Do not take CO ZOPICLONE if you cannot obtain a complete night's sleep before resuming to normal activity.
- CO ZOPICLONE can cause damage to the developing baby if taken during pregnancy.
- Do not drive or operate machinery if you are taking CO ZOPICLONE as it may make you drowsy.
- Do not take alcohol or other drugs when taking CO ZOPICLONE as it may depress brain function.

If you are prescribed sleeping medication, you should consider both the benefits and risks with your doctor. Important risks and limitations include the following:

- The medication may cause dependence.
- The medication may affect your mental alertness or memory, particularly when not taken as prescribed.

BEFORE you use CO ZOPICLONE make sure that you talk to your doctor or pharmacist:

- about any alcohol consumption (present or past) or any medicine you are taking now, including drugs you can buy without a prescription. **DO NOT CONSUME ALCOHOL WHILE TAKING zopiclone.**
- if you are planning to become pregnant, if you are pregnant, or if you become pregnant while taking this medication. **DO NOT TAKE zopiclone at any time during pregnancy.**
- if you develop any unusual disturbing thoughts or behaviour while using zopiclone, discuss the matter immediately with your doctor.
- if you have liver problem or severe breathing problems.

IMPORTANT NOTE

Regardless of the cause, if you take these medications, report any mental or behavioural changes promptly to your doctor.

Effects on Pregnancy:

Certain benzodiazepine sleeping pills have been linked to birth defects when taken during the early months of pregnancy. It is not yet known if Zopiclone could cause similar effects. In addition, sleeping pills taken during the last weeks of pregnancy have been known to sedate the baby. Therefore, **DO NOT TAKE THIS MEDICATION AT ANYTIME DURING PREGNANCY.**

INTERACTIONS WITH THIS MEDICATION

Zopiclone may produce additive CNS depressant effect (a condition of the brain causing dizziness, drunkenness, fatigue, clumsiness, unconsciousness or death) when co-administered with alcohol, sedative antihistamines (drugs reducing inflammation, swelling), anticonvulsants (medicines used to control or to prevent convulsions), or psychotropic (mood altering) medications which themselves can produce CNS depression.

If you notice any unexplainable change in your feelings or behaviour, discuss with your doctor.

Compounds which inhibit certain hepatic enzymes (particularly cytochrome P450) may enhance the activity of benzodiazepines (medications often prescribed for sleep problems) and benzodiazepine-like agents. Examples include cimetidine or erythromycin.

PROPER USE OF THIS MEDICATION

Usual dose:

Zopiclone should be taken just before retiring for the night. The usual adult dose is 5.0 mg to 7.5 mg. The 7.5 mg dose should not be exceeded.

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

DO NOT take *CO 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.
- if it is not prescribed for you.
- for more than 7-10 days without first consulting your doctor.

DO NOT INCREASE THE PRESCRIBED DOSE.

DO NOT DRIVE A CAR or operate potentially dangerous machinery until you experience how this drug will affect you the next day.

Overdose:

If you think that you or someone else may have taken an overdose of Zopiclone, get emergency help at once.

In voluntary or accidental cases of zopiclone overdosage involving doses up to 340 mg, the principal effects reported were prolonged sleep, drowsiness, lethargy and ataxia.

Zopiclone overdosage symptoms are somnolence, confusion and coma.

Missed Dose:

Zopiclone should be taken just before retiring for the night. If you missed a dose of zopiclone, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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.

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.

You may experience an increase in sleep difficulties (rebound insomnia) and/or "increased daytime anxiety" (rebound anxiety) for one or two days after discontinuing zopiclone.

Memory Problems:

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".

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 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, illusions, hallucinations, 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 underlying illness, or are simply spontaneous happenings. In fact, worsened insomnia may in some cases be associated with illnesses that were present before the medication was used.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common*	- drowsiness - dizziness - light-headedness - poor coordination	✓ ✓ ✓ ✓		
Uncommon	- unusual disturbing thought and behaviour - abdominal and muscle cramps, sweating, vomiting, tremor, rarely convulsions - severe breathing problems (sleep apnea) - severe allergic reactions (rash, spots on skin, swelling)		✓	✓ ✓

*Note: If these symptoms persist or are extremely severe, the patient may be experiencing symptoms of an overdose. In such cases, get immediate emergency help.

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

HOW TO STORE IT

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

Keep out of the reach of children.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs . If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

toll-free telephone: 866-234-2345

toll-free fax 866-678-6789

By email: cadmp@hc-sc.gc.ca

By regular mail:

National AR Centre

Marketed Health Products Safety and Effectiveness

Information Division

Marketed Health Products Directorate

Tunney's Pasture, AL 0701C

Ottawa ON K1A 0K9

NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found by contacting the sponsor, Cobalt Pharmaceuticals Inc., at: 1-866-254-6111

This leaflet was prepared by:

Cobalt Pharmaceuticals, Inc
6500 Kitimat Road
Mississauga, Ontario L5N 2B8
Canada

Last revised: November 03, 2005.