

PART III: CONSUMER INFORMATION

**Pr Sandoz Zopiclone
Zopiclone tablets**

This leaflet is part III of a three-part "Product Monograph" published when Sandoz 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 Sandoz Zopiclone. This leaflet is a summary and will not tell you everything about Sandoz Zopiclone. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

Sandoz Zopiclone (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 Sandoz 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. Sandoz Zopiclone does not treat the underlying cause of your insomnia.

What it does:

Sandoz 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 Sandoz 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 Sandoz Zopiclone contains (see **What the nonmedicinal ingredients are**).

What the medicinal ingredient is:

The active ingredient in Sandoz Zopiclone is zopiclone.

What the non-medicinal ingredients are:

Sandoz Zopiclone (zopiclone) 5.0 mg tablets contains: calcium phosphate dihydrate, cornstarch, hydroxypropyl methylcellulose, lactose, magnesium stearate, maltodextrin, polydextrose, polyethylene glycol, sodium croscarmellose, titanium dioxide and triacetin.

Sandoz Zopiclone (zopiclone) 7.5 mg tablets contains: calcium phosphate dihydrate, cornstarch, D&C yellow no.10 aluminum lake, FD&C blue no.1 aluminum lake, FD&C blue no.2 aluminum lake, hydroxypropyl methylcellulose, lactose, magnesium stearate, maltodextrin, polydextrose, polyethylene glycol, sodium croscarmellose, titanium dioxide and triacetin.

What dosage forms it comes in:

Tablets, 5.0 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 Sandoz 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 Sandoz 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 Sandoz Zopiclone than prescribed.
2. Do not take Sandoz 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 Sandoz 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: Sandoz Zopiclone may affect your ability to be alert the next day. **DO NOT DRIVE A CAR** or operate potentially dangerous machinery:

- If you do not feel fully awake

- If it has not been at least 12 hours since taking the medicine, even if you feel fully awake, especially in elderly patients and in patients who take the 7.5 mg dose
- In all cases, until you experience how the drug affects you the next day.

Memory problems: Sandoz 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 Sandoz 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 Sandoz 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, illusions, 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 Sandoz Zopiclone, discuss the matter immediately with your doctor.

Worsening of Side Effects

DO NOT CONSUME ALCOHOL WHILE TAKING Sandoz Zopiclone. Some medicines may also worsen side effects that some patients experience with Sandoz Zopiclone (see **Drug Interactions with this medication**).

Elderly: An increased risk of falls and fractures has been reported in elderly people who take sleeping pills such as Sandoz 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 Sandoz 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 Sandoz Zopiclone** at anytime during pregnancy, it may affect the developing baby.

Use in Nursing Mothers: Sandoz 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 Sandoz 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 Sandoz Zopiclone if you drink alcohol. **Do not use Sandoz Zopiclone** along with other medications, over-the counter medicines or herbal products without first discussing this with your doctor or pharmacist.

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 Sandoz 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

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:

Sandoz Zopiclone should be taken just before retiring for the night.

Adult: The recommended starting dose is 3.75 mg (one half of a 7.5 mg tablet). This can be increased to 5 mg or 7.5 mg if advised by your doctor.

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. The dose in elderly, debilitated patients and/or patients with liver or kidney problems is not to exceed 5 mg.

Follow your doctor's advice about how to take Sandoz 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 Sandoz Zopiclone.

Do not take Sandoz Zopiclone if it is not prescribed for you.

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

Do not take Sandoz Zopiclone if you drink alcohol.

Sandoz Zopiclone is not indicated for patients under 18 years of age. **Do not take Sandoz Zopiclone if you are under 18 years of age.**

Do not take Sandoz 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 (see WARNINGS AND PRECAUTIONS, Patients requiring mental alertness).

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:

Sandoz 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 Sandoz Zopiclone is taste alteration (bitter taste).

Sandoz 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. If you experience excessive drowsiness the next

day that affects your ability to perform tasks in the morning contact your physician as your dose may need to be reduced (see Warnings and Precautions, Patients requiring mental alertness).

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 Sandoz Zopiclone. Do not use sleeping pills along with other medications without first discussing this with your doctor.

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 Sandoz Zopiclone (see **Warnings and Precautions, Drug abuse, dependence and withdrawal**).

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 Sandoz 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)			✓
	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		✓	

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		
Very rare	Thoughts of death or suicide		✓	
Unknown	Trouble breathing		✓	

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

Reporting Side Effects
 You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at [MedEffect](#);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
 Health Canada, Postal Locator 0701E
 Ottawa, ON
 K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

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.

HOW TO STORE IT

Store in a dry place, at room temperature (15° - 30°C). Protect from light. Do not exceed the expiry date indicated on the container.

Keep out of the reach of children.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.sandoz.ca> or by contacting the sponsor, Sandoz Canada Inc., at:
1-800-361-3062

or by written request at:

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Boucherville QC
J4B 7K8

or by e-mail at :

medinfo@sandoz.com

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