

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **IMOVANE**[®]

Zopiclone tablets

Read this carefully before you start taking **IMOVANE** 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 **IMOVANE**.

Serious Warnings and Precautions

Addiction, Abuse and Misuse: Even if you take **IMOVANE** 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 **IMOVANE** with:

- opioids
- alcohol or
- illicit drugs

Your healthcare professional should:

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

Store **IMOVANE** in a secure place to avoid theft or misuse.

Withdrawal: If you suddenly stop taking **IMOVANE**, 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 doctor before stopping, or lowering your dose of **IMOVANE** or changing your medicine.

IMOVANE with Opioids: Taking **IMOVANE** with opioid medicines can cause:

- severe drowsiness
- decreased awareness
- breathing problems
- coma
- death

Complex Sleep Behaviours:

Taking **IMOVANE** 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 **IMOVANE** right away if you experience any complex sleep behaviours.

What is IMOVANE used for?

- IMOVANE is used in adults (over 18 years of age) for short term (usually not more than 7-10 days) 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. IMOVANE 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 IMOVANE. IMOVANE may not be an effective treatment for you and you may be more sensitive to experiencing side effects.

How does IMOVANE work?

IMOVANE 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 ingredients in IMOVANE?

Medicinal ingredients: zopiclone

Non-medicinal ingredients:

5 mg: corn starch, dicalcium phosphate, hydroxypropyl-methylcellulose, lactose, magnesium stearate, sodium carboxymethyl starch and titanium dioxide.

7.5 mg: calcium phosphate dihydrate dibasic, carnauba wax, croscarmellose sodium, FD&C Blue #1, magnesium stearate, microcrystalline cellulose, Opadry II White and polyethylene glycol.

IMOVANE comes in the following dosage forms:

Tablet: 5 mg, 7.5 mg.

Do not use IMOVANE if:

- you are allergic to zopiclone or to any of the ingredients in IMOVANE
- you have a muscular disease known as myasthenia gravis (muscle weakness)
- you have severe 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.

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

- have ever had a problem with:
 - substance use, including prescribed or illegal drugs (such as opioids), or
 - alcohol
- have ever had seizures or convulsions (violent uncontrollable shaking of the body with or without loss of consciousness)
- drink or plan to drink alcohol. Do not drink alcohol while you take IMOVANE.

- are taking other medications, including central nervous system (CNS) depressants (slow down brain activity)
- have a history or family history of sleepwalking
- 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 liver or kidney problems
- are lactose intolerant or have one of the following diseases:
 - Galactosemia
 - Glucose-galactose malabsorption
- have a history of violent behaviour
- have had an unexpected reaction to sedative medications in the past, including alcohol and benzodiazepines
- have signs of depression or a history of depression
- have or have a history of suicidal thoughts or attempts or mental health problems
- have lung or breathing problems
- are 65 years of age or older
- are planning to become pregnant, if you are pregnant, or if you become pregnant while taking this medication
- are breastfeeding

Other warnings you should know about:

Complex Sleep Behaviours: IMOVANE 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 may occur whether or not you drink alcohol or take other medicines that can make you sleepy, such as medicines used to treat depression or anxiety. 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, having sex and talking on the phone. These behaviours can cause serious injuries, including death.

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

Driving and Using Machines: IMOVANE may make you feel dizzy, drowsy and affect your coordination. DO NOT drive, use machinery, or do activities that require you to be alert:

- if it has not been 12 hours or more since you took IMOVANE, especially if you are elderly or you take the 7.5 mg dose.
- if you do not feel fully awake
- until you know how IMOVANE affects you
- if you are also taking opioid medicine
- if have consumed alcohol
- if you are taking other medications, including central nervous system (CNS) depressants (slow down brain activity)

Memory Problems: IMOVANE can 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 not usually a problem if you take IMOVANE before sleeping. However, if you take IMOVANE to help sleep while travelling, such as during an airplane flight, you may wake up to memory lapse caused by the drug. This has been called “traveller’s amnesia” and can be a problem. **DO NOT** take IMOVANE 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 IMOVANE from your system.

Dependence: Taking IMOVANE can lead to physical dependence. The risk of dependence is greater when IMOVANE is used for longer than 4 weeks and in patients with a history of mental health problems and/or alcohol or drug abuse.

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.

Your risk of going through withdrawal is higher if you are taking IMOVANE for a long time or at high doses. However, symptoms can still occur if you are taking IMOVANE 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) and experiences of unreality or detachment from one’s mind, self, or body (depersonalisation)
- 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 doctor before stopping or reducing your dose of IMOVANE 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

Falls and Fractures:

Benzodiazepines or other sedative-hypnotic drugs, such as IMOVANE, 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 IMOVANE. Some of these changes include aggressiveness and extroversion that seem out of character, delirium (a sudden and severe change in mental state which includes a combination of confused thinking, disorientation and decreased attention), confusion, strange behaviour, anxiety, restlessness, hallucinations, feeling like you are not yourself, worsening insomnia or depression, which may lead to suicidal thinking. If you develop any unusual thoughts or behaviour while using IMOVANE, 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: Do not take IMOVANE if you are pregnant. IMOVANE 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: IMOVANE passes into breast milk. Do not breastfeed while taking IMOVANE. Talk to your healthcare professional about the best way to feed your baby while you are taking IMOVANE.

Blood Tests: IMOVANE 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 IMOVANE:

Serious Drug Interactions
Taking IMOVANE and opioids may cause:
<ul style="list-style-type: none">• 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 IMOVANE

- alcohol. Do not take IMOVANE 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 medication)
- 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 IMOVANE:

- Always take IMOVANE exactly as your healthcare professional tells you to. Do not change your dose without talking to your healthcare professional.
- Take IMOVANE by mouth just before going to bed. Do not take IMOVANE if a full night's sleep is not possible before you need to become active and functional again.
- Do not consume any alcohol while taking IMOVANE.

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 adult starting dose is 3.75 mg. This is one half of the 7.5 mg tablet.
- Based on your response and tolerability of IMOVANE, 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 doctor'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 IMOVANE, 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 IMOVANE?

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

Side effects may include:

- bitter taste, dry mouth, bad breath
- drowsiness
- dizziness or light-headedness
- difficulty with coordination
- decreased muscle tone
- nausea or vomiting
- anorexia or increased appetite
- constipation or diarrhea
- abnormal weakness or lack of energy
- muscle weakness
- rashes, spots on your skin, or itchy skin
- seeing double
- palpitations
- 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	
UNCOMMON			
Mental and behavioural changes: excitement, agitation, hyperactivity, delirium, hallucination, worsened insomnia, aggression, irritability, rages, psychoses, and violent behaviour symptom	✓		
Severe allergic reactions: swelling of the tongue or throat, trouble breathing, sudden wheeziness, chest pain or tightness, shortness of breath, throat closing, nausea, or vomiting. Other allergic reactions may include rashes, spots on your skin, or itchy skin			✓
RARE			
Amnesia (a type of memory loss): difficulty recalling events that recently happened	✓		
Complex sleep behaviours: getting out of bed while not fully			✓

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	
awake and doing activities you do not remember the day after, including sleep walking, driving, making phone calls, or having sex			
UNKNOWN			
Overdose: 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.			✓
Respiratory Depression: slow, shallow or weak breathing.			✓
Self-harm or Suicide: thoughts or actions about hurting or killing yourself			✓
Withdrawal: Severe symptoms include: Delirium: sudden and severe change in mental state that can cause a combination of confusion, disorientation and/or attention deficit Derealization: experiences of unreality or detachment from one's surroundings Depersonalization: experiences of unreality or detachment from one's mind, self, or body Hallucinations: seeing or hearing things that are not there Hyperacusis: sensitivity to sounds and noise Convulsions: (seizures – including some that do not stop): loss of consciousness with uncontrollable shaking Other symptoms include: Stomach cramps; trouble remembering or concentrating; diarrhea; feeling uneasy or		✓	

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	
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.			

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

Keep in a safe place out of reach and sight of children.

If you want more information about IMOVANE:

- 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>); the manufacturer’s website (www.sanofi.ca), or by calling 1-800-265-7927.

This leaflet was prepared by sanofi-aventis Canada Inc.

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