



PATIENT MEDICATION INFORMATION

Pr DAYVIGO™

Lemborexant Tablet
Tablet, 5 mg, 10 mg, Oral
Hypnotic

Eisai Limited
6925 Century Avenue, Suite 701
Mississauga, Ontario
L5N 7K2

Date of Revision:
NOV-03-2020

DAYVIGO™ is a trademark of Eisai R&D Management Co., Ltd. and is licensed to Eisai Inc.

Submission Control No: 231286

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

Pr**DAYVIGO™** **Lemborexant Tablets**

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

What is DAYVIGO™ used for?

DAYVIGO is used in adults who have trouble falling asleep and/or staying asleep (insomnia). DAYVIGO is not for use in children under the age of 18 years.

How does DAYVIGO work?

Orexins are chemicals that bind to certain receptors in your brain to keep you awake. DAYVIGO temporarily blocks these receptors. This may help you fall asleep and stay asleep.

What are the ingredients in DAYVIGO?

Medicinal ingredients: lemborexant

Non-medicinal ingredients: hydroxypropyl cellulose, lactose monohydrate, low-substituted hydroxypropyl cellulose and magnesium stearate.

The film coating contains the following non-medicinal ingredients: hypromellose 2910, talc, polyethylene glycol 8000, titanium dioxide, and

- for the 5 mg tablet: ferric oxide yellow
- for the 10 mg tablet: ferric oxide yellow and ferric oxide red

DAYVIGO comes in the following dosage forms:

Film-coated tablet: 5 mg and 10 mg

Do not use DAYVIGO if you:

- are allergic to lemborexant, or any of the other ingredients of DAYVIGO (see **What are the ingredients in DAYVIGO?**).
- have narcolepsy (a sleep disorder that causes excessive daytime sleepiness and causes you to fall asleep often at unexpected times).

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

- have a history of drug or alcohol abuse or addiction.
- have a history of falling asleep often at unexpected times (narcolepsy) or feeling sleepy during the day.
- have breathing problems (such as sleep apnea).
- have liver problems.
- are pregnant or plan to become pregnant. It is not known if DAYVIGO can harm your unborn baby. Your doctor will decide whether prescribing DAYVIGO to you outweighs the risk to your unborn baby.

- are breastfeeding or plan to breastfeed. It is not known if DAYVIGO passes into your breast milk.
- are lactose intolerant

Other warnings you should know about:

Need to check for other existing medical conditions: Sleep problems can be a sign of many physical and mental disorders. Your doctor will need to check your medical history before you start taking DAYVIGO.

Talk to your doctor if after 7 to 10 days of taking DAYVIGO your sleep problems:

- do not stop or do not get better
- get worse or you develop new abnormal thinking or behaviour

This may mean that there is another condition such as a physical or mental illness causing your sleep problems.

Abnormal thinking and behavioural changes: When using hypnotics such as DAYVIGO you may experience abnormal thinking and changes to your behaviour. These can include:

- memory loss (amnesia) for events that occur when you are not fully awake
- anxiety
- seeing or hearing things that are not there (hallucinations) when falling asleep or waking up

Complex sleep-related behaviours: While taking hypnotic medicines such as DAYVIGO, you may get out of bed while not being fully awake and do activities that you do not know you are doing, such as:

- sleep-walking
- driving a car ("sleep-driving")
- eating
- making phone calls
- having sex

The next morning you may not remember what you did during the night. If someone tells you about events you do not remember doing, or you think you may have done things in your sleep you do not remember doing, stop taking DAYVIGO and **call your doctor**.

You increase your risk of doing activities while not fully awake if you:

- drink alcohol
- take other medicines that make you feel sleepy
- have other conditions that affect your sleep that can cause you to wake up often during the night (such as sleep apnea, Periodic Limb Movement Disorder or Restless Leg Syndrome)

Worsening depression and thoughts of suicide: Thoughts of suicide have been reported in people taking DAYVIGO. Some people with depression who took hypnotic medicines saw their depression get worse. They also had increased thoughts of suicide and actions. If you, your caregiver or your family members notice that your depression is getting worse or that you are having thoughts of suicide **call your doctor right away**.

Sleep paralysis, muscle weakness (cataplexy) and hallucinations: You may experience the following when taking DAYVIGO:

- you are not able to move or talk for up to several minutes while you are going to sleep or waking up (“sleep paralysis”)
- have sudden muscle weakness, commonly in the legs, that can last a few seconds to a few minutes (cataplexy-like symptoms). This can happen during the day or at night and may not be associated with an identified triggering event (e.g. laughter or surprise)
- seeing or hearing things that are not there (hallucinations) while falling asleep or when you wake up

If you experience any of these, talk to your doctor.

Mental alertness, driving and using machines: DAYVIGO may affect your ability to be alert the next day.

It may affect how well you drive and you may be at an increased risk of falling asleep while you drive. **Do NOT** drive or use dangerous machinery until you know how taking DAYVIGO affects you the next day.

You can feel less alert:

- even if you take DAYVIGO as exactly as prescribed
- for several days after you stop taking it

You increase the risk of being less alert the next day if:

- you do NOT get a full night of sleep (**at least** 7 hours)
- take DAYVIGO with other medicines that make you sleepy
- are taking a higher dose

If you notice that you are feeling more sleepy or drowsy during the day and it is affecting your ability to do tasks that require clear thinking or attention, talk to your doctor.

Falls: Since DAYVIGO can cause you to feel drowsy, patients, especially the elderly, may be at a higher risk of falls.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Do NOT:

- **drink alcohol while taking DAYVIGO. It can increase your chances of getting serious side effects or**
- **take other medicines that can make you sleepy (sedatives).** Examples of these types of medicines are:
 - prescription and over the counter sleep products
 - opioids (used to treat pain)
 - certain antidepressants (used to treat depression)

You should not take the following medications which may interact with DAYVIGO:

- itraconazole, ketoconazole and posaconazole (used to treat fungal infections)
- clarithromycin, telithromycin (used to treat bacterial infections)
- bocepravir, telaprevir (used to treat Hepatitis C Virus (HCV))

- fluconazole (used to treat fungal and yeast infections)
- diltiazem and verapamil (to treat high blood pressure and chest pain/angina)
- digoxin (used to treat heart failure)
- aprepitant (used to treat nausea and vomiting caused by certain anti-cancer medicines)
- imatinib (used to treat certain types of cancer)
- nefazodone (used to treat depression)
- conivaptan (used to treat low sodium levels)
- rifampin (used to treat bacterial infections)
- carbamazepine and phenytoin (used to treat convulsions and seizures)
- St. John's wort (used to treat depression)
- grapefruit juice

Know the medicines you take. Keep a list of your medicines with you to show your healthcare provider and pharmacist each time you get a new medicine.

How to take DAYVIGO:

Take DAYVIGO:

- exactly as your doctor has told you to take it
- once a day at night within a few minutes before going to bed
- only when you can get a full night of sleep (**at least 7 hours**)

DAYVIGO may take longer to work if you take it with or soon after eating a meal.

Usual dose:

The recommended daily dose: 5 mg once a day (within a few minutes of going to bed, and with at least 7 hours remaining before you plan to wake up).

The maximum recommended dose: 10 mg once a day (within a few minutes of going to bed and with at least 7 hours remaining before you plan to wake up).

Do NOT take more than 10 mg a day.

Your doctor may change your dose depending on how you respond to DAYVIGO

Overdose:

If you think you have taken too much **DAYVIGO**, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

- If you miss a dose and you do have time to sleep for at least 7 hours before you must wake up again, take your dose as usual.
- If you do not have time to sleep for at least 7 hours before you must wake up again:
Do NOT take your dose. Take it the next night.

What are possible side effects from using DAYVIGO?

These are not all the possible side effects you may feel when taking **DAYVIGO**. If you experience any side effects not listed here, contact your healthcare professional.

The most common side effect of DAYVIGO includes:

- Sleepiness during the day.

Other possible side effects of DAYVIGO may include:

- Headache
- Nasopharyngitis
- Fatigue
- Urinary tract infection
- Nausea
- Upper respiratory tract infection
- Back pain
- Nightmare
- Abnormal dreams

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	
COMMON Excessive sleepiness during the day		✓	
Sleep paralysis: Temporary inability to move or talk for up to several minutes while you are going to sleep or waking up. It may be accompanied by hallucinations or vivid and disturbing perceptions		✓	
UNCOMMON Temporary weakness in the legs that can happen during the day or night		✓	
Abnormal thoughts and behaviour. Symptoms may include more outgoing or aggressive behaviour than normal, confusion, agitation, hallucinations, anxiety, memory loss.	✓		
Worsening of depression		✓	
VERY RARE “Sleep-walking” or doing other activities when you are asleep like eating, talking, having sex, or driving a car			✓
NOT KNOWN Thoughts of suicide or actions			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to 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

- at room temperature (15°C - 30°C).
- in the original bottle with the child-resistant closure.
- Do not use this medicine after the expiry date on the bottle.

Keep out of reach and sight of children.

If you want more information about DAYVIGO

- 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://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website [eisai.ca](https://www.eisai.ca), or by calling 1-877-873-4724.



This leaflet was prepared by Eisai Limited

DAYVIGO™ is a trademark of Eisai R&D Management Co., Ltd. and is licensed to Eisai Inc.

Last Revised NOV-03-2020