

MEDICATION GUIDE
DAYVIGO™ (daye-vi'-goe)
(lemborexant)
tablets, for oral use, CIV

What is the most important information I should know about DAYVIGO?

DAYVIGO may cause serious side effects including:

- **Decreased awareness and alertness.** The morning after you take DAYVIGO, your ability to drive safely and think clearly may be decreased. You may also have sleepiness during the day.
 - Do not take more DAYVIGO than prescribed.
 - Do not take DAYVIGO unless you are able to stay in bed for a full night (at least 7 hours) before you must be active again.
 - Take DAYVIGO right before going to bed.

See “**What are the possible side effects of DAYVIGO?**” for more information about side effects.

What is DAYVIGO?

- DAYVIGO is a prescription medicine for adults who have trouble falling or staying asleep (insomnia).
- It is not known if DAYVIGO is safe and effective in children under the age of 18 years.

DAYVIGO is a federally controlled substance (CIV) because it can be abused or cause dependence. Keep DAYVIGO in a safe place to prevent misuse and abuse. Selling or giving away DAYVIGO may harm others and is against the law. Tell your doctor if you have ever abused or have been dependent on alcohol, prescription medicines or street drugs.

Who should not take DAYVIGO?

Do not take DAYVIGO if you fall asleep often at unexpected times (narcolepsy).

Before taking DAYVIGO, tell your healthcare provider about all of your medical conditions, including if you:

- have a history of depression, mental illness, or suicidal thoughts.
- have a history of drug or alcohol abuse or addiction.
- have a history of a sudden onset of muscle weakness (cataplexy).
- have a history of daytime sleepiness.
- have lung problems or breathing problems, including sleep apnea.
- have liver problems.
- are pregnant or plan to become pregnant. It is not known if DAYVIGO can harm your unborn baby.
Pregnancy Registry: There is a pregnancy registry for women who are exposed to DAYVIGO during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. For more information or to participate in the registry, call 1-888-274-2378. Talk with your healthcare provider about the risk to your unborn baby if you take DAYVIGO during pregnancy.
- are breastfeeding or plan to breastfeed. It is not known if DAYVIGO passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with DAYVIGO.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

- Taking DAYVIGO with certain other medicines can cause serious side effects. DAYVIGO may affect the way other medicines work and other medicines may affect the way DAYVIGO works.
- **Do not take DAYVIGO with other medicines that can make you sleepy unless your healthcare provider tells you to.**
- 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 should I take DAYVIGO?

- Take DAYVIGO exactly as your healthcare provider tells you to take it.
- Only take DAYVIGO one time each night, right before going to bed.
- Only take DAYVIGO when you can stay in bed for a full night (at least 7 hours).
- DAYVIGO may take longer to work if you take it with or soon after a meal.
- Do not increase your dose of DAYVIGO without talking to your healthcare provider first. Call your healthcare provider if your insomnia (sleep problem) worsens or is not improved within 7 to 10 days. This may mean that there is another condition causing your sleep problem.
- If you take too much DAYVIGO, call your healthcare provider or go to the nearest hospital emergency room right away.

What should I avoid while taking DAYVIGO?

- **Do not drink alcohol** while taking DAYVIGO. It can increase your chances of getting serious side effects.
- **Do not drive**, operate heavy machinery, do anything dangerous, or do other activities that require clear thinking if you take DAYVIGO and have had less than a full night of sleep (at least 7 hours) or if you have taken more DAYVIGO than prescribed by your healthcare provider.
- You may still feel drowsy the next day after taking DAYVIGO. **Do not** drive or do other dangerous activities until you feel fully awake.

What are the possible side effects of DAYVIGO? See “What is the most important information I should know about DAYVIGO?”

DAYVIGO may cause serious side effects, including:

- **temporary inability to move or talk (sleep paralysis) for up to several minutes while you are going to sleep or waking up.**
- **temporary weakness in your legs that can happen during the day or at night.**
- **complex sleep behaviors** such as sleep-walking, sleep-driving, preparing and eating food, making phone calls, having sex or doing other activities while not fully awake that you may not remember the next morning. Call your healthcare provider right away if you experience a complex sleep behavior.
- **worsening depression and suicidal thoughts have happened during treatment with DAYVIGO. Call your healthcare provider right away if you have any worsening depression or thoughts of suicide or dying.**

The most common side effect of DAYVIGO is sleepiness.

These are not all of the possible side effects of DAYVIGO. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store DAYVIGO?

- Store DAYVIGO at room temperature between 68°F to 77°F (20°C to 25°C).
- **Keep DAYVIGO and all medicines out of the reach of children.**

General information about the safe and effective use of DAYVIGO.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use DAYVIGO for a condition for which it was not prescribed. Do not give DAYVIGO to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about DAYVIGO that is written for healthcare professionals.

What are the ingredients in DAYVIGO?

Active ingredient: lemborexant

Inactive ingredients: hydroxypropyl cellulose, lactose monohydrate, low-substituted hydroxypropyl cellulose, and magnesium stearate. The tablet film coating contains: hypromellose 2910, polyethylene glycol 8000, talc, titanium dioxide, and either ferric oxide yellow for the 5 mg tablet; or both ferric oxide yellow and ferric oxide red for the 10 mg tablet.

Distributed by:

Eisai Inc.
Woodcliff Lake, NJ 07677

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

© 2020 Eisai Inc.

For more information, go to www.DAYVIGO.com or call 1-888-274-2378

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Issued: 04/2020