DAYVIGO®
(lemborexant) Ⓒ IV 5mg, 10mg tablets

Patients Who Are Struggling to Fall or Stay Asleep May Find Relief **With DAYVIGO**

INDICATION

DAYVIGO (lemborexant) is an orexin receptor antagonist indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

SELECTED SAFETY INFORMATION

CONTRAINDICATIONS

- DAYVIGO is contraindicated in patients with narcolepsy.

Please see Selected Safety Information throughout and click here for full Prescribing Information.

Introduction to Insomnia

- Insomnia is characterized by patients experiencing difficulty falling asleep, staying asleep, or both, despite having adequate opportunity to sleep[1]
- Insomnia is the most prevalent sleep disorder; approximately 10-20% of adults in the primary care setting complain of significant insomnia symptoms[2]
- Insomnia can be diagnosed alongside comorbid psychiatric and/or medical conditions[3]

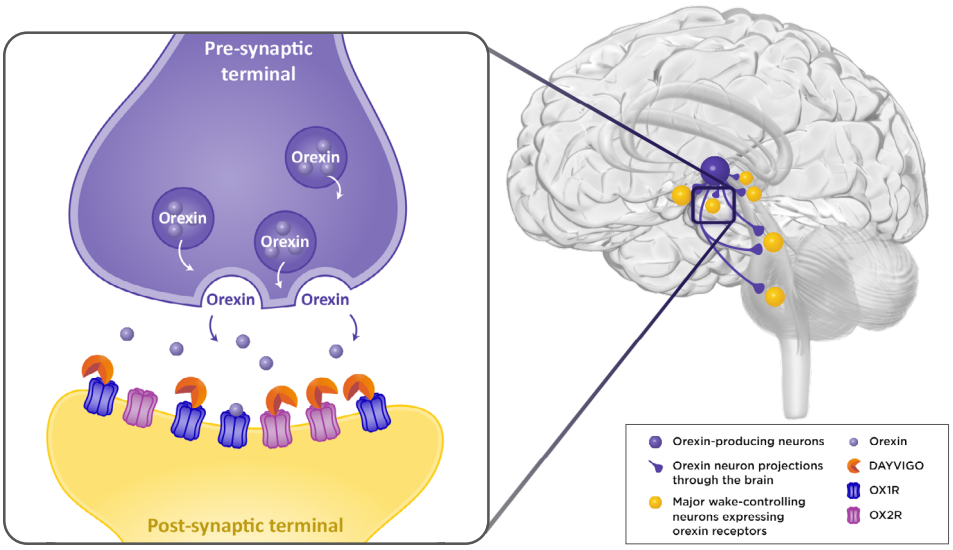
DAYVIGO Mechanism of Action[4]

DAYVIGO is a **D**ual **O**rexin **R**eceptor **A**ntagonist

DAYVIGO is thought to treat insomnia by blocking orexin signals in the brain that are believed to play a role in wakefulness[4]

DAYVIGO binds to orexin receptors OX1R and OX2R and acts as a competitive antagonist.[4]

DAYVIGO Blocks the Orexin Pathway



DAYVIGO is believed to help patients fall asleep and stay asleep throughout the night by blocking the orexin pathway, which is thought to suppress the wake drive[4]

SELECTED SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Central Nervous System (CNS) Depressant Effects and Daytime Impairment:

DAYVIGO can impair daytime wakefulness. CNS depressant effects may persist in some patients up to several days after discontinuing DAYVIGO. Prescribers should advise patients about the potential for next-day somnolence.

Driving ability was impaired in some subjects taking DAYVIGO 10 mg. Risk of daytime impairment is increased if DAYVIGO is taken with less than a full night of sleep remaining or at a higher than recommended dose. If taken in these circumstances, patients should not drive or engage in activities requiring mental alertness.

Use with other classes of CNS depressants (e.g., benzodiazepines, opioids, tricyclic antidepressants, alcohol) increases the risk of CNS depression, which can cause daytime impairment. Dosage adjustments of DAYVIGO and concomitant CNS depressants may be necessary when administered together. Use of DAYVIGO with other insomnia drugs is not recommended. Patients should be advised not to consume alcohol in combination with DAYVIGO.

Because DAYVIGO can cause drowsiness, patients, particularly the elderly, are at a higher risk of falls.

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DAYVIGO® (lemborexant) CIV 5mg, 10mg tablets

DAYVIGO Is Supplied as 5-mg and 10-mg Tablets[4]

Strength	Package Size	NDC
5 mg	30-count bottle	62856-405-30
10 mg	30-count bottle	62856-410-30

Storage and Handling[4]

Store DAYVIGO at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F)

Efficacy and Safety Profile of DAYVIGO[4]

The approval of DAYVIGO was based on efficacy and safety data vs placebo established in 2 pivotal phase 3 clinical trials, which included nearly 2000 adult patients with insomnia who met DSM-5* criteria

- DAYVIGO helped people with insomnia fall asleep faster and stay asleep longer
- These studies, SUNRISE 1 and SUNRISE 2, measured sleep onset and maintenance at Month 1 (sleep labs) and Month 6 (patient diaries), respectively
- The effects of DAYVIGO at first use were generally consistent with later timepoints

In a special safety study of adults without insomnia, there was no significant impairment in driving performance the morning after taking DAYVIGO. Impairment was seen in some patients taking DAYVIGO 10 mg. Patients using the 10 mg dose should be cautioned about the potential for next-morning driving impairment because there is individual variation in sensitivity to DAYVIGO

- The most common adverse reaction (reported in 5% or more of patients treated with DAYVIGO and at least twice the rate of placebo) in SUNRISE 1 and SUNRISE 2 (the first 30 days) was somnolence (10% for DAYVIGO 10 mg, 7% for DAYVIGO 5 mg, 1% for placebo)
- No suggested physical dependence with chronic use or association with rebound insomnia upon discontinuation
- At either dose of DAYVIGO, there was no evidence of withdrawal effects upon drug discontinuation through 1 year of use, suggesting no physical dependence
- DAYVIGO contains lemborexant, a Schedule IV-controlled substance
  - Individuals with a history of abuse or addiction to alcohol or other drugs may be at an increased risk for abuse and addiction to DAYVIGO—follow such patients carefully

For patients requesting information regarding DAYVIGO in other languages, visit DAYVIGO.com

Dosing and Administration[4]

The recommended starting dose of DAYVIGO is 5 mg

- The dose may be increased to the maximum recommended dose of 10 mg, based on clinical response and tolerability
- There is no need for dose adjustment based on age, sex, BMI, and renal impairment
- Patients aged 65 years or older should use caution when taking DAYVIGO 10 mg
- Patients with severe renal impairment may experience an increased risk of somnolence

For patients with moderate hepatic impairment, the maximum recommended dose is 5 mg once per night

- DAYVIGO is not recommended for patients with severe hepatic impairment
- Patients with mild hepatic impairment may experience an increased risk of somnolence

Advise patients to avoid concomitant use of DAYVIGO with strong or moderate CYP3A inhibitors and inducers

- The maximum recommended dose of DAYVIGO is 5 mg no more than once per night when co-administered with weak CYP3A inhibitors

Administration instructions for patients:

- Advise patients to take DAYVIGO only when preparing for or getting into bed and only if they can stay in bed for a full night (at least 7 hours) before the planned time of awakening
- Advise patients that the effect of DAYVIGO may be delayed if taken with or soon after a meal

* DSM-5=Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (American Psychiatric Association).

SELECTED SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- **Sleep Paralysis, Hypnagogic/Hypnopompic Hallucinations, and Cataplexy-Like Symptoms:** Sleep paralysis, an inability to move or speak for up to several minutes during sleep-wake transitions, hypnagogic/hypnopompic hallucinations, including vivid and disturbing perceptions can occur with DAYVIGO. Prescribers should explain these events to patients.

  Symptoms similar to mild cataplexy can occur with DAYVIGO and can include periods of leg weakness lasting from seconds to a few minutes, can occur either at night or during the day, and may not be associated with identified triggering event (e.g., laughter or surprise).

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Sleep and Waking Discussion Points for Your Patients With Insomnia

Ask your patients:

- If they take any medications before bedtime
- If they currently are taking or have tried any medications to help them sleep
- How much time elapses between eating their last meal and drink of the day before going to bed
- If they have trouble falling asleep, staying asleep, or both
- How long they have been experiencing insomnia symptoms

Encourage your patients to:

- Stick to a sleep schedule with the same bedtime and wake-up time, even on weekends
- Create a relaxing ritual and prepare their bedroom: turn off lights, remove their phone or laptop, and keep the room cool (between 60° and 70°F)
- Regular daily exercise to keep their body healthy
- Avoid caffeine in the evening
- Avoid cigarettes, alcohol, and late evening meals for at least 2 to 3 hours before they plan to go to bed. Avoid alcohol use on days they plan on taking DAYVIGO. DAYVIGO also may take longer to work if they take it with or soon after a meal

DAYVIGO Savings Card

Instant Savings Card

Eligible patients may save on their prescriptions for DAYVIGO

Eligible commercially insured patients may **pay as little as $10 on out-of-pocket expenses** for DAYVIGO

Instructions to Activate Card

1. Patients can download or activate a card at www.dayvigosavings.com
2. Click "DOWNLOAD OR ACTIVATE A SAVINGS CARD"
3. Click "ACTIVATE A CARD"
4. Choose how the patient would like to receive a card and fill out the required fields
5. Click "SUBMIT"
   - Or activate card by calling 1-866-4DAYVIGO, or texting ENROLL to 630-87

Instructions to Process Card

1. Obtain the activated savings card from the patient
2. Process the savings card by inputting the required fields
   - *Please note that the primary insurance may need to be billed first in order to process the savings card*

* DAYVIGO Instant Savings Card Terms and Conditions: Good toward the purchase of DAYVIGO prescriptions. Most commercially insured patients will pay as little as $10 of out-of-pocket expenses. Instant Savings Card benefit is limited to twelve uses annually. Patients could have additional financial responsibility for any amounts over Eisai's maximum liability. No substitutions permitted. Save the Instant Savings Card to reuse with each prescription. Not available to patients enrolled in federal or state healthcare programs, including Medicare, Medicaid, Medigap, VA, DoD, or TRICARE. Patients must have commercial insurance. Cash paying patients are excluded. Not valid for DAYVIGO prescription reimbursed in full by any third-party payer. May not be combined with any other discount or offer. Federal law prohibits the selling, purchasing, trading, or counterfeiting of this card. Void outside the USA and where prohibited by law. Eisai Inc. reserves the right to rescind, revoke, or amend this offer without notice at any time. You must be 18 years or older to use the card. Patients and pharmacies are responsible for disclosing to insurance carriers the redemption and value of the Instant Savings Card and complying with any other conditions.

For assistance activating or processing an Instant Savings Card, call **1-866-4DAYVIGO**.

SELECTED SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- **Complex Sleep Behaviors:**
  Complex sleep behaviors, including sleep-walking, sleep-driving, and engaging in other activities while not fully awake (e.g., preparing and eating food, making phone calls, having sex), have been reported to occur with the use of hypnotics such as DAYVIGO. Events can occur in hypnotic-naïve and hypnotic-experienced persons. Patients usually do not remember these events. Complex sleep behaviors may occur following the first or any subsequent use of DAYVIGO, with or without the concomitant use of alcohol and other CNS depressants. Discontinue DAYVIGO immediately if a patient experiences a complex sleep behavior.

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Programs in Support of DAYVIGO Patient Access and Education

Electronic Prior Authorization

- Eisai subscribes to CoverMyMeds. CoverMyMeds is an online platform through which prescribers and pharmacies can submit electronic prior authorization forms
- For more information, please visit eisaireimbursement.com

DAYVIGO Patient Assistance Program

- The DAYVIGO Patient Assistance Program provides DAYVIGO at no cost to financially needy patients who meet eligibility criteria
- Patients can call the DAYVIGO Patient Assistance Program at 1-866-349-3026. Hours of operation are Monday to Friday 8 AM to 8 PM (ET)

Patient Trial Offer

- Eligible patients with a valid prescription may obtain a free 10-day trial of DAYVIGO 5 mg when their Rx is accompanied by a voucher that the patient downloaded online or a physical voucher provided by the prescriber

Additional Information

- Visit www.Eisaireimbursement.com for additional information on patient support, commercial coverage, billing, coding, and applicable forms

Visit DAYVIGOHCP.com for available resources and more information

SELECTED SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- **Patients with Compromised Respiratory Function:**
  DAYVIGO has been studied in mild to severe Obstructive Sleep Apnea (OSA) and moderate to severe Chronic Obstructive Pulmonary Disease (COPD) in short-term clinical trials. The effect of DAYVIGO on respiratory function should be considered for patients with compromised respiratory function.
- **Worsening of Depression/Suicidal Ideation:**
  Incidence of suicidal ideation or suicidal behavior, as assessed by questionnaire, was higher in patients receiving DAYVIGO than placebo (0.3% for DAYVIGO 10 mg, 0.4% for DAYVIGO 5 mg, and 0.2% for placebo).

  In primarily depressed patients treated with hypnotics, worsening of depression and suicidal thoughts and actions (including completed suicides) have been reported. Suicidal tendencies may be present in such patients and protective measures may be required. Intentional overdose is more common in this group of patients; therefore, the lowest number of tablets that is feasible should be prescribed at any one time.

  The emergence of any new behavioral sign or symptom of concern requires careful and immediate evaluation.

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Important Safety Information

WARNINGS AND PRECAUTIONS

- **Need to Evaluate for Comorbid Diagnoses:**
  Treatment of insomnia should be initiated only after careful evaluation of the patient. Reevaluate for comorbid conditions if insomnia persists or worsens after 7 to 10 days of treatment. Worsening of insomnia or the emergence of new cognitive or behavioral abnormalities may be the result of an unrecognized underlying psychiatric or medical disorder and can emerge during the course of treatment with sleep-promoting drugs such as DAYVIGO.

ADVERSE REACTIONS

- The most common adverse reaction (reported in 5% of patients treated with DAYVIGO and at least twice the rate of placebo) with DAYVIGO was somnolence (10% for DAYVIGO 10 mg, 7% for DAYVIGO 5 mg, 1% for placebo).

DRUG INTERACTIONS

- **CYP3A Inhibitors:** The maximum recommended dose of DAYVIGO is 5 mg no more than once per night when co-administered with weak CYP3A inhibitors. Avoid concomitant use of DAYVIGO with strong or moderate CYP3A inhibitors.
- **CYP3A Inducers:** Avoid concomitant use of DAYVIGO with moderate or strong CYP3A inducers.

USE IN SPECIFIC POPULATIONS

- **Pregnancy and Lactation:** There is a pregnancy exposure registry that monitors pregnancy outcomes in women who are exposed to DAYVIGO during pregnancy. Healthcare providers are encouraged to register patients in the DAYVIGO pregnancy registry by calling 1-888-274-2378. There are no available data on DAYVIGO use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes.

  Data supports that transfer of lemborexant into breastmilk is low. There are no data on the effects of lemborexant on the breastfed infant, or the effects on milk production. Infants exposed to DAYVIGO through breastmilk should be monitored for excess sedation.
- **Geriatric Use:** Exercise caution when using doses higher than 5 mg in patients ≥65 years old.
- **Renal Impairment:** Patients with severe renal impairment may experience an increased risk of somnolence.
- **Hepatic Impairment:** The maximum recommended dose of DAYVIGO is 5 mg in patients with moderate hepatic impairment. DAYVIGO is not recommended in patients with severe hepatic impairment. Patients with mild hepatic impairment may experience an increased risk of somnolence.

DRUG ABUSE AND DEPENDENCE

- DAYVIGO is a Schedule IV-controlled substance.
- Because individuals with a history of abuse or addiction to alcohol or other drugs may be at increased risk for abuse and addiction to DAYVIGO, follow such patients carefully.

For more information about DAYVIGO, click here to see full Prescribing Information.

Price disclosure information for prescribers available here: https://us.eisai.com/RequiredPriceDisclosures

References: 1. Institute of Medicine. Sleep disorders and sleep deprivation: an unmet public health problem. Washington, DC: National Academies Press; 2006. **2.** American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*. 5th ed. Washington, DC: American Psychiatric Association; 2013. **3.** Taylor DJ, et al. *Sleep*. 2007;30(2):213-218. **4.** Dayvigo. Prescribing information. Eisai Inc. https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/212028s000lbl.pdf

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