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

The opportunity to

START HER DAY WITH A GOOD NIGHT'S SLEEP[1]

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 additional Selected Safety Information throughout this booklet and accompanying full Prescribing Information.

See how at **DAYVIGOhcp.com**

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

Help Patients Fall Asleep Faster and Stay Asleep Longer[1]

At the proven starting dose of 5 mg, and at 10 mg, DAYVIGO was assessed vs placebo across 2 pivotal trials, including nearly 2000 adult patients.[1]

SUNRISE 1

The SUNRISE 1 pivotal trial measured sleep onset and sleep maintenance at Month 1 (sleep labs) in males ≥65 years of age and females ≥55 years of age.[1,2]

SUNRISE 1 (sleep labs)
DAYVIGO reduced time to sleep onset and WASO, as assessed by the primary and secondary endpoints respectively (mean* change from baseline in LPS and WASO, respectively, vs placebo at Month 1).[1]

SUNRISE 2

SUNRISE 2 measured sleep onset and sleep maintenance at Month 6 (patient diaries) in patients ≥18 years of age.[1]

SUNRISE 2 (patient diaries)
DAYVIGO reduced time to sleep onset and sWASO, as assessed by the primary and secondary endpoints respectively (mean* change from baseline in sSOL and sWASO, respectively, vs placebo at Month 6).[1]

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.

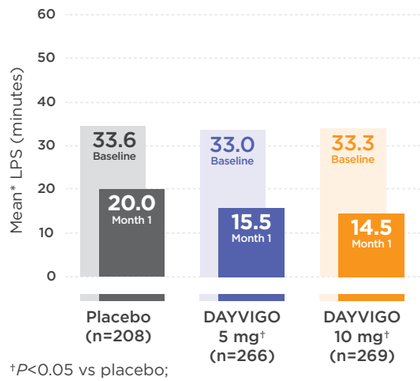
  Use with other classes of CNS depressants (e.g., benzodiazepines, opioids, tricyclic antidepressants, alcohol) increases the risk of CNS depression, which can cause daytime impairment. Dosage adjustments of DAYVIGO and concomitant CNS depressants may be necessary when administered together. Use of DAYVIGO 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.

Please see additional Selected Safety Information throughout this booklet and accompanying full Prescribing Information.

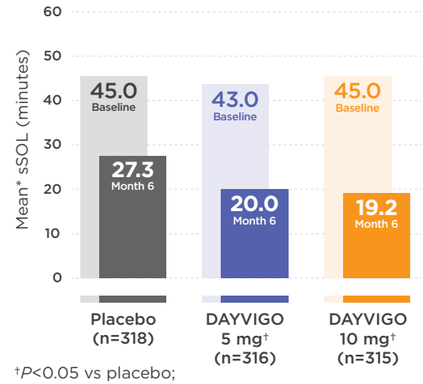
SLEEP ONSET

SLEEP LABS (1 Month)[1,3]



†*P*<0.05 vs placebo;
Treatment effect‡ was 0.8 (5 mg) and 0.7 (10 mg).

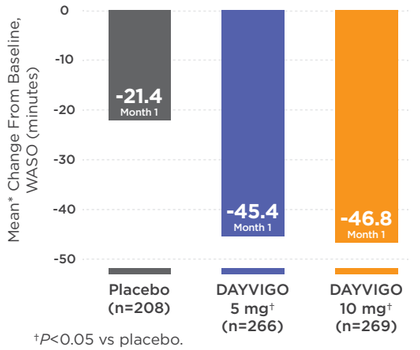
PATIENT DIARIES (6 Months)[1,4]



†*P*<0.05 vs placebo;
Treatment effect‡ was 0.7 (5 mg) and 0.7 (10 mg).

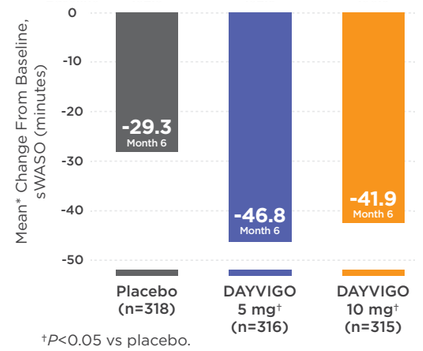
WAKE AFTER SLEEP ONSET (WASO)

SLEEP LABS (1 Month)[1,3]



†*P*<0.05 vs placebo.

PATIENT DIARIES (6 Months)[1,4]



†*P*<0.05 vs placebo.

The effects of DAYVIGO at first use were generally consistent with later timepoints.[1] Evaluation across subgroups by age, race, sex, and BMI suggested no differences in response to DAYVIGO.[1,5]

BMI=body mass index; LPS=latency to persistent sleep; sSOL=subjective sleep onset latency; sWASO=subjective wake after sleep onset; WASO=wake after sleep onset. *For the sleep onset endpoints (LPS, sSOL), the mean refers to least squares geometric mean, which was used due to the approximately log normal distribution of the outcomes; for the sleep maintenance endpoints (WASO, sWASO), the mean refers to least squares mean. ‡Treatment effect refers to the ratio of [Day 29/30 LPS / Baseline LPS] or [Month 6 sSOL / Baseline sSOL] for DAYVIGO vs placebo, such that a smaller ratio corresponds to a greater improvement.

SELECTED SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

- **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).

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

The Safety Profile of DAYVIGO

The safety of DAYVIGO was assessed in patients with insomnia.[1]

SUNRISE 1 and SUNRISE 2 evaluated the safety of DAYVIGO

Adverse reactions reported in ≥2% of DAYVIGO-treated patients and at a greater frequency than placebo-treated patients during the first 30 days.[1]

*Combines preferred terms: somnolence, lethargy, fatigue, and sluggishness.

Adverse Reactions,%	Placebo (n=528)	DAYVIGO 5 mg (n=580)	DAYVIGO 10 mg (n=582)
Somnolence or fatigue*	1.3%	6.9%	9.6%
Headache	3.4%	5.9%	4.5%
Nightmares or abnormal dreams	0.9%	0.9%	2.2%

Studies suggested that chronic DAYVIGO use did not produce physical dependence.[1]

- 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

Most common discontinuation rates due to adverse reactions in SUNRISE 1 and SUNRISE 2 (the first 30 days)[1]

Discontinuation Due to:	Placebo	DAYVIGO 5 mg	DAYVIGO 10 mg
Adverse Reactions	1.5%	1.4%	2.6%
Somnolence	0.4%	0.7%	1.0%
Nightmares	0.0%	0.3%	0.3%

Most common discontinuation rates due to adverse reactions in SUNRISE 2 (the first 6 months)[1]

Discontinuation Due to:	Placebo	DAYVIGO 5 mg	DAYVIGO 10 mg
Adverse Reactions	3.8%	4.1%	8.3%
Somnolence	0.6%	1.0%	2.9%
Nightmares	0.0%	0.3%	1.3%
Palpitations	0.0%	0.0%	0.6%

Analyses suggested DAYVIGO was not associated with rebound insomnia when discontinued.[1]

SELECTED SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

- **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.
- **Patients with Compromised Respiratory Function:** The effect of DAYVIGO on respiratory function should be considered for patients with compromised respiratory function. DAYVIGO has not been studied in patients with moderate to severe obstructive sleep apnea (OSA) or chronic obstructive pulmonary disease (COPD).

Please see additional Selected Safety Information throughout this booklet and accompanying full Prescribing Information.

SELECTED SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

- **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.
- **Need to Evaluate for Comorbid Diagnoses:** Treatment of insomnia should be initiated only after careful evaluation of the patient. Re-evaluate 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.

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Special Safety Studies

MORNING

In 2 randomized, placebo- and active-controlled trials in healthy subjects and patients with insomnia ≥55 years of age[1]:

Next-day postural stability[1]
No meaningful differences were observed between DAYVIGO (5 mg or 10 mg) and placebo

Next-day memory[1]
No meaningful differences were observed between DAYVIGO (5 mg or 10 mg) and placebo

In a randomized, double-blind, placebo- and active-controlled, 4-period crossover study[1]:

Next-morning driving[1]
DAYVIGO (5 mg or 10 mg) did not significantly impair the morning driving performance of healthy volunteers vs those taking placebo (N=48)

Patients using the DAYVIGO 10 mg dose should be cautioned about the potential for next-morning driving impairment because there is individual variation in sensitivity to DAYVIGO.[1]

MIDDLE OF THE NIGHT

In a randomized, placebo- and active-controlled trial in healthy female subjects ≥55 years or male subjects ≥65 years[1]:

Postural stability[1]
Both DAYVIGO doses (5 mg and 10 mg) impaired balance (measured by body sway) at 4 hours postdose compared with placebo

Attention and memory[1]
DAYVIGO was associated with dose-dependent worsening 4 hours postdose on measures of attention and memory compared with placebo

Awakening to sound[1]
Neither DAYVIGO dose demonstrated any meaningful differences in patients' ability to awaken to sound compared with placebo

Patients should be cautioned about the potential for middle of the night postural instability as well as attention and memory impairment.[1]

DAYVIGO Dosing and Administration

DAYVIGO features convenient dosing, once nightly right before bed.[1]

Recommended dosage[1,5]

- 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
- No need for dose adjustment based on age, sex, BMI, and renal impairment
  - Exercise caution when using 10 mg in patients ≥65 years of age
  - 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

Administration[1]

- DAYVIGO should be taken immediately before going to bed and with at least 7 hours remaining before the planned time of awakening
- DAYVIGO should not be taken more than once per night
- Time to sleep onset may be delayed if taken with, or soon after, a meal

Use with CYP3A inhibitors or CYP3A inducers[1]

- Avoid concomitant use of DAYVIGO with strong or moderate CYP3A inhibitors and inducers
- When coadministered with weak CYP3A inhibitors, the maximum recommended dose of DAYVIGO is 5 mg, no more than once per night

Recommend an appropriate trial period

- Your patients may feel differently when they fall asleep while taking DAYVIGO than their previous experience or expectations. It's important to give DAYVIGO an appropriate trial period

Dosage strengths[1]

- DAYVIGO tablets are available in 2 strengths:
  - 5 mg tablets: pale yellow, round, biconvex, film-coated tablets, and debossed with "5" on one side and "LEM" on the other side
  - 10 mg tablets: orange, round, biconvex, film-coated tablets, and debossed with "10" on one side and "LEM" on the other side

SELECTED SAFETY INFORMATION

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.

Please see additional Selected Safety Information throughout this booklet and accompanying full Prescribing Information.

SELECTED SAFETY INFORMATION

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.

  There are no data on the presence of lemborexant in human milk, the effects 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.

GO FOR DAYVIGO®

Scan this QR code to access patient resources online

Get Your Patients Started on DAYVIGO With These Resources

DAYVIGO Free Trial Offer

For eligible patients, Eisai offers a 10-day free trial for a valid prescription of DAYVIGO 5 mg. One voucher redemption per patient.

Instant Savings Card

Help eligible patients save on their prescriptions

- Eligible commercially insured patients may pay as little as $30 for out-of-pocket expenses*
- Instant Savings Card benefit is limited to 12 uses annually
- Restrictions apply. Please see full terms, conditions, and eligibility criteria

DAYVIGO® Patient Assistance Program*

Eisai has created the DAYVIGO® Patient Assistance Program for eligible patients who need assistance paying for DAYVIGO. This program provides DAYVIGO at no cost to financially needy patients who meet program eligibility criteria. Healthcare providers and 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 (Eastern Time).

*Not available to patients enrolled in federal or state healthcare programs, including Medicare, Medicaid, Medigap, VA, DoD, or Tricare.

Electronic Prior Authorization (ePA)

Visit EisaiReimbursement.com for more information on ePA.

Support Your Patients With Educational Resources

Patient Brochure

A resource for patients to learn more about insomnia and how DAYVIGO may help.

Sleep Tracker

Give your patients a tool to help keep track of sleep habits and understand how DAYVIGO may be working.

DAYVIGO® Together

DAYVIGO Together is a support program for patients with insomnia, living with the challenges that come with poor sleep. Patients can sign up to get access to tools and educational resources to help them navigate their personal insomnia challenges by calling 1-866-4DAYVIGO.

SELECTED SAFETY INFORMATION

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, see full Prescribing Information.

References: 1. DAYVIGO (lemborexant) [Prescribing Information]. Woodcliff Lake, NJ: Eisai Inc. **2.** Rosenberg R, Murphy P, Zammit G, et al. Comparison of lemborexant with placebo and zolpidem tartrate extended release for the treatment of older adults with insomnia disorder: a phase 3 randomized clinical trial. *JAMA Netw Open*. 2019;2(12):e1918254. doi:10.1001/jamanetworkopen.2019.18254. **3.** Data on file. CSR 304 Supplemental Tables. Eisai Inc., Woodcliff Lake, NJ. **4.** Data on file. CSR 303 Supplemental Tables. Eisai Inc., Woodcliff Lake, NJ. **5.** Data on file. ISE. Eisai Inc., Woodcliff Lake, NJ.

Learn more at DAYVIGOhcp.com