DAYVIGO is Available for the Treatment of Adult Patients With Insomnia

DAYVIGO (lemborexant) CIV 5mg, 10mg tablets

DAYVIGO™ (lemborexant) CIV is available for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

DAYVIGO is supplied as 5-mg and 10-mg tablets

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

Storage and Handling

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).

Dosing and Administration

- The recommended dosage of DAYVIGO is 5 mg taken no more than once per night, immediately before going to bed, with at least 7 hours remaining before the planned time of awakening. Time to sleep onset may be delayed if taken with or soon after a meal.
- The dose may be increased to the maximum recommended dose of 10 mg based on clinical response and tolerability.
- 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.
- Avoid concomitant use of DAYVIGO with strong or moderate CYP3A inhibitors or inducers. The maximum recommended dosage of DAYVIGO is 5 mg no more than once per night when co-administered with weak CYP3A inhibitors.

Efficacy and Safety

- The approval of DAYVIGO was based on efficacy and safety data established in 2 pivotal phase 3 clinical trials, which included nearly 2000 patients with insomnia.
- Study 1 was a 6-month, randomized, double-blind, placebo-controlled study in adult patients age 18 or older who met DSM-5* criteria for insomnia disorder, that subjectively assessed ability to fall asleep and stay asleep based on patient self-reports (sleep diaries).
- Study 2 was a 1-month, randomized, double-blind, placebo- and active-controlled, multi-center, parallel-group clinical trial in adult female patients age 55 and older and male patients 65 years and older who met DSM-5 criteria for insomnia disorder, that objectively assessed sleep parameters (time to sleep onset, sleep efficiency, and wake after sleep onset).
- The most common adverse reaction (reported in 5% or more of patients treated with DAYVIGO and at least twice the rate of placebo) was somnolence (10% for DAYVIGO 10 mg, 7% for DAYVIGO 5 mg, 1% for placebo).

DAYVIGO Instant Savings Card

With the DAYVIGO Instant Savings Card, eligible patients with prescription coverage will pay as little as $30. Restrictions apply. Not available to patients enrolled in federal or state healthcare programs, including Medicare, Medicaid, Medigap, VA, DoD, or TRICARE. Call 1-866-4DAYVIGO or visit EisaiReimbursement.com for more information.

SELECTED SAFETY INFORMATION

CONTRAINDICATIONS

- DAYVIGO is contraindicated in patients with narcolepsy.

Please see additional Selected Safety Information on the reverse side and click here for full Prescribing Information.

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

Eisai

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.
- **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).
- **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).
- **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. 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.
  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.

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.

Please see additional Selected Safety Information on the previous page and click here for full Prescribing Information for DAYVIGO.

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

Reference: DAYVIGO (lemborexant) [prescribing information]. Woodcliff Lake, NJ: Eisai Inc.

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