PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

This medicine is to be supplied upon a physician's prescription only

Dayvigo 5 mg film coated tablets
The active ingredient and its quantity:
Each tablet contains:
Lemborexant 5 mg

Dayvigo 10 mg film coated tablets
The active ingredient and its quantity:
Each tablet contains:
Lemborexant 10 mg

Inactive and allergenic substances in the drug - see Section 6 "Additional Information" and Section 2 "Important Information about some components of the drug".

Read this entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, refer to the physician or pharmacist.
This medicine has been prescribed for the treatment of your illness. Do not pass it on to others. It may harm them, even if you think that their illness is similar to yours.

This medicine is not intended for use in children and adolescents under 18 years of age.

1. What is the medicine intended for?

The medicine is designed to treat adults with insomnia, which is characterised by difficulty sleeping and/or difficulty maintaining sleep (insomnia).

Therapeutic Group:
Orexin receptor antagonist (sleep/hypnotic medicine)

2. Before using the medicine

Do not use the medicine if:

- You are hypersensitive (allergic) to the active substance (lemborexant) or any of the other ingredients the medicine contains (see Section 6 "Further Information").
- You suffer from narcolepsy.

Special warnings relating to use of the medicine
Before using Dayvigo, tell your doctor if:

- You have a history of depression, mental illness, or suicidal thoughts.
- You have a history of addiction or misuse of alcohol, prescription medicines or street drugs.
- You have a history of sudden onset of muscle weakness (cataplexy).
- You have a history of daytime sleepiness.
- You have lung function problems or breathing problems.
- You have problems with your liver function.
- You suffer from severe renal dysfunction.

Additional warnings:
The dosage of the medicine should not be increased without the doctor's instruction. Contact your doctor if insomnia worsens or does not improve within 7 to 10 days of treatment. This may indicate that there is another problem that causes insomnia.

Children and adolescents
This medicine is not intended for use in children and adolescents under the age of 18 years. The safety and efficacy of Dayvigo have not been proven in children and adolescents under 18 years of age.

Drug interactions
If you are taking, or have recently taken, other medications including over-the-counter medications and dietary supplements, tell your doctor or pharmacist about it. Especially if you take:

- itraconazole (for the treatment of fungal infections), clarithromycin (antibiotics), fluconazole (for the treatment of fungal infections), verapamil (for the treatment of hypertension and angina), chlorzoxazone (for muscle relaxation), ranitidine (for the treatment of stomach ulcers) – use of these medicines along with Dayvigo may increase the risk of Dayvigo side effects.
- rifampicin (antibiotic), carbamazepine (for the treatment of epilepsy), St. John's wort (for the treatment of depression), bosentan (for the treatment of pulmonary arterial hypertension), Efavirenz (for the treatment of HIV infection), Etravirine (for the treatment of HIV infection), modafinil (for the treatment of sleepiness) - use of these medicines with Dayvigo may reduce Dayvigo's efficacy.
- bupropion (for treating depression), methadone (for moderate to severe pain relief, aid in the withdrawal of narcotic addiction) – The use of these medicines together with Dayvigo may reduce the effectiveness of these medicines. Your doctor may monitor your response to these medicines and may consider raising the dosage of these medicines.
- Central nervous system depressants (such as benzodiazepines, opioids, tricyclic and antidepressants) – taking these medicines together with Dayvigo increases the risk of central nervous system depression, which can impair alertness during daylight hours. The doctor may need to adjust the dosage of Dayvigo and these medicines when taking them together.
- **Do not take other medications that can make you sleepy unless instructed by your doctor.**

Use of this medicine and food:
If the medicine is taken with or shortly after a meal, the time until the onset of sleep may become longer.

Use of this medicine and alcohol consumption
Do not consume alcohol in conjunction with Dayvigo, as it increases the risk of suffering serious side effects.

Pregnancy, breastfeeding, and fertility
If you are pregnant or planning a pregnancy, consult with your doctor before using the medication. It is not known whether Dayvigo can harm the fetus.
If you are breastfeeding or planning to breastfeed, consult with your doctor before using the medication. It is not known whether Dayvigo passes into the breast milk. Talk to your doctor about the best way to feed your baby during Dayvigo treatment.

Driving and using machines
Do not drive, operate heavy machinery, do dangerous things, or perform activities that require clear thinking, if you are taking Dayvigo and have had less than a full night of sleep (at least 7 hours) or if you have taken a higher dose than the doctor prescribed you.
You may still feel drowsy the next day after taking Dayvigo. **Do not** drive or do other dangerous things until you feel fully awake.

Important information about some of the ingredients of the medicine
Dayvigo contains lactose. If you have previously been told by a doctor that you have an intolerance to certain sugars, consult your doctor before taking this medication.

3. How to use this medicine

Dayvigo should always be used according to the doctor's instructions. You should speak with your doctor or pharmacist if you are unsure about the dosage and method of administration.
The dosage and method of administration will be determined by the doctor only. The generally accepted dose is:
No more than one tablet a day of Dayvigo near bedtime in the evening, when the scheduled time left to wake up is at least 7 hours.
Do not exceed the recommended dose.

How to take
There is no information regarding the crushing/breaking/chewing of the tablet.

If you have accidentally taken a higher dosage If you have taken an overdose or if a child accidentally ingested the medicine, contact your doctor or hospital emergency room immediately and bring the medicine package with you.

In case you stop taking the medicine
This treatment should be followed as recommended by the doctor.
Even if your health has improved, you should not stop treatment without consulting a doctor.

Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.

If you have any further questions regarding the use of this medicine, consult the physician or pharmacist.

4. Side Effects

As with any medicine, the use of Dayvigo can cause side effects in some patients. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.
The medicine can cause serious side effects, including:

- **Temporary inability to move or speak (sleep paralysis) for several minutes when you go to sleep or wake up,** and hallucinations while you fall asleep at night or wake up in the morning, including disturbing and vivid perceptions and a sudden and transient onset of muscle weakness.
- **Temporary weakness in the legs can occur during the day or at night**.
- **Complex sleep behaviours** such as sleepwalking, sleep driving, preparing and eating food, making phone calls, having sex, or performing other activities while you are not fully awake, activities you may not remember the next morning. If you experience complex sleep behaviour, contact your doctor immediately.
- **During treatment with the medicine, cases of worsening depression and suicidal thoughts/ behaviours occurred. If you are suffering from any worsening depression or thoughts of suicide or death, contact your doctor immediately.**

The most common side effect of the medicine (appearing in 1-10 users out of 100) is sleepiness or fatigue.

Additional Side Effects

- Dayvigo can impair alertness during daylight hours. This effect of central nervous system depression may persist in some patients for several days after discontinuation of treatment. In some patients who took 10 mg, their driving ability was impaired (see section 2 "Driving and using machines"). Since Dayvigo can cause sleepiness, patients, especially the elderly, are at greater risk of falls.
- Headache
- nightmare or unusual dreams

If any of the side effects appears, if any of the side effects worsen or if you experience any side effect not mentioned in this leaflet, consult the physician or pharmacist.

Reporting side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" that appears on the homepage of the Ministry of Health's website (www.health.gov.il) which links to an online form for reporting side effects, or by the following link: https://sideeffects.health.gov.il

5. How to store the medicine

- Prevent poisoning! This medicine and any other medication should be kept in a closed place out of the reach and sight of children and/or infants and doing so will prevent poisoning. Do not induce vomiting without explicit instruction from the doctor.
- The medicine should not be used after the expiration date (exp.) that appears on the packaging. The expiration date refers to the last day of that month.
- **Storage Conditions:** Store below 30°C in the original cardboard packaging.
- Do not dispose of medicines into the sewer or household trash. Ask the pharmacist how to discard unused medicines. These measures will help protect the environment.

6. Additional information

- **In addition to the active ingredient, the medicine also contains:**

Hydroxypropyl cellulose, lactose monohydrate, low-substituted hydroxypropyl cellulose, magnesium stearate.
The tablets coating contains:
hypromellose 2910, polyethylene glycol 8000, talc, titanium dioxide, iron oxide yellow.
Additionally, Dayvigo 10 mg also contains iron oxide red.

- **What the medicine looks like and content of the pack:**
  Dayvigo 5 mg: A convex tablet on both sides, round, bright yellow, with "5" imprinted on one side and "LEM" on the other.
  Dayvigo 10 mg: A convex, round, orange-coloured tablet with "10" imprinted on one side and an "LEM" on the other.
  The tablets are marketed in aluminum foil blisters in cartons of 28 tablets.
- **Marketing authorisation holder and importer:** Eisai Israel Ltd., PO Box 3393, Petah Tikva, 4951600, Israel
- Revised in May 2023 in accordance with Ministry of Health guidelines.

Drug registration numbers at the national medicines registry of the Ministry of Health:
5 mg- 172-64-37068-99
10 mg- 172-65-37069-99