

Lemborexant 5mg and 10mg

What is in this leaflet

1. What Dayvigo is used for
2. How Dayvigo works
3. Before you use Dayvigo
4. How to use Dayvigo
5. While you are using it
6. Side effects
7. Storage and Disposal of Dayvigo
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial number

What Dayvigo is used for

Dayvigo is intended for adults who have trouble falling or staying asleep (insomnia)

How Dayvigo works

Dayvigo acts through blocking of orexin receptors (a type of receptor in the brain). Orexin transmitter signaling system plays a role in wakefulness. Blocking the binding of wake-promoting transmitters orexin A and orexin B to its receptors is thought to suppress wake drive.

Before you use Dayvigo

- When you must not use it

Do not take Dayvigo if you have a history of hypersensitivity to any ingredients of Dayvigo.

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

Pregnancy and lactation

Do not take Dayvigo if you are pregnant or think you may be pregnant unless the expected therapeutic benefits are evaluated to outweigh the possible risk of treatment.

Do not take Dayvigo if you are breast-feeding or plan to breast-feed. Dayvigo passes into your breastmilk. Consult your doctor about the best way to feed your baby during treatment with Dayvigo.

Dayvigo is not recommended for children under the age of 18 years.

- Before you start use it

Consult your doctor before using Dayvigo if you have:

- History of depression, mental illness, or suicidal thoughts
- History of drug or alcohol abuse or addiction
- History of a sudden onset of muscle weakness (cataplexy)
- History of daytime sleepiness
- Lung problems or breathing problems
- Liver problems

- Taking other medicines

Tell your doctor if you are taking 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 doctor tells you to.

How to use Dayvigo

- How much to use

Take Dayvigo exactly as directed by your doctor. Only take Dayvigo one time each night, right before going to bed and when you can stay in bed for a full night (at least 7 hours).

Your doctor will ensure you take the lowest effective dose for as short a duration as necessary.

Dayvigo may take longer to work if you take it with or soon after a meal. Do not increase your dose of Dayvigo without consulting your doctor. Call your doctor 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.

- When to use it

Use only as directed by your physician.

- How long to use it

Continue taking Dayvigo for as long as your doctor recommends.

- If you forget to use it

Wait until the next dose to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not take any new medicines without consulting your doctor.

- Things to be careful of *Driving and using machines*

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 doctor.

You may still feel drowsy the next day after taking Dayvigo. Do not drive or do other dangerous activities until you feel fully awake.

Dayvigo has the potential for abuse or dependence (habit forming). Keep it in a safe place to prevent misuse and abuse.

Alcohol

Do not drink alcohol while taking Dayvigo. It can increase your chances of getting serious side effects.

DAYVIGO[®] TABLET

Consumer Medication Information Leaflet (RiMUP)

Lemborexant 5mg and 10mg

Side effects

In the event of the following symptoms, treatment should be discontinued and visit your doctor or pharmacist immediately.

- Temporary inability to move or talk (sleep paralysis) for up to several minutes while you are going to sleep or waking up.
- Sleepiness
- Tiredness
- Urinary tract infection

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Dayvigo

- Storage

Stored below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Dayvigo is a round film-coated tablet debossed with a “LCM” on one side. The 5 mg tablet is pale yellow in colour debossed with a “5” on the otherside. The 10 mg tablet is orange in colour debossed with a “10” on the other side.

- Ingredients

- Active ingredient

- Lemborexant

- Inactive ingredients

- Hydroxypropyl cellulose
- Lactose monohydrate
- Low-substituted hydroxypropyl cellulose
- Magnesium stearate
- Hypromellose 2910
- Polyethylene glycol 8000
- Talc
- Titanium dioxide

- Ferric oxide yellow (for 5 mg tablet)
- Ferric oxide yellow and ferric oxide red (for 10 mg tablet)

- MAL number:

MAL22066114AZ

MAL22066113AZ

Manufacturer

Eisai Manufacturing Limited,
European Knowledge Centre,
Mosquito Way
Hatfield, Hertfordshire AL10 9SN,
United Kingdom

Product Registration Holder

Eisai (Malaysia) Sdn Bhd
Unit 701D, Level 7, Tower D, Uptown 5,
No. 5, Jalan SS21/39, Damansara
Uptown,
47400 Petaling Jaya,
Selangor, Malaysia

Date of revision

27/4/2023

Serial number

NPRA (R1/1) 20102023/179