

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

### 1. Why am I using DAYVIGO?

DAYVIGO contains the active ingredient lemborexant. DAYVIGO is used to treat insomnia

For more information, see Section [1. Why am I using DAYVIGO?](#) in the full CMI.

### 2. What should I know before I use DAYVIGO?

Do not use if you have ever had an allergic reaction to DAYVIGO or any of the ingredients listed at the end of the CMI.

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

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use DAYVIGO?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with DAYVIGO and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use DAYVIGO?

- The recommended starting dose is one 5 mg tablet once daily right before going to bed. If more help with your sleep problem (insomnia) is needed, your doctor may increase the dose to one 10 mg tablet once daily.

More instructions can be found in Section [4. How do I use DAYVIGO?](#) in the full CMI.

### 5. What should I know while using DAYVIGO?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using DAYVIGO.</li><li>• Call your doctor if your sleep problem (insomnia) worsens or is not better within 7 to 10 days of taking DAYVIGO.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not give DAYVIGO to anyone else, even if they have the same sleep problem as you.</li><li>• Do not take DAYVIGO if you have less than 7 hours available to sleep.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful driving, operating machinery or doing other activities that require complete alertness until you know how DAYVIGO affects you.</li><li>• DAYVIGO may cause drowsiness in some people the day after taking it.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Do not drink alcohol while taking DAYVIGO.</li><li>• Alcohol can increase your chances of getting serious side effects with DAYVIGO.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep DAYVIGO in a cool dry place where the temperature stays below 30°C.</li><li>• Keep DAYVIGO in the blister pack until it is time to take the tablet.</li></ul>

For more information, see Section [5. What should I know while using DAYVIGO?](#) in the full CMI.

### 6. Are there any side effects?

- Common (may affect up to 1 user in 10) are: sleepiness, headaches, nightmares or abnormal dreams and sleep paralysis.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

# DAYVIGO\*

(daye-vi<sup>1</sup>-goe)

Active ingredient(s): *lemborexant*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using DAYVIGO. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using DAYVIGO.**

Where to find information in this leaflet:

- [1. Why am I using DAYVIGO?](#)
- [2. What should I know before I use DAYVIGO?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use DAYVIGO?](#)
- [5. What should I know while using DAYVIGO?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I using DAYVIGO?

**DAYVIGO contains the active ingredient lemborexant.**

DAYVIGO is a medicine called a dual orexin receptor antagonist.

**DAYVIGO is used to treat insomnia. Insomnia is a condition in which patients may have one or more of the following symptoms:**

- Difficulty falling asleep
- Difficulty staying asleep (waking too often or for too long during the night)
- Waking up too early and then not being able to fall back asleep
- Poor sleep quality

DAYVIGO is thought to help you fall asleep and stay asleep by temporarily blocking wakefulness, allowing sleep to occur.

### 2. What should I know before I use DAYVIGO?

#### Warnings

**Do not use DAYVIGO if:**

- You often fall asleep at unexpected times (narcolepsy).
- You are allergic to lemborexant, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

#### Check with your doctor if you:

- have a history of depression, mental illness, or suicidal thoughts.
- have a history of drug or alcohol abuse or addiction.
- have a history of a sudden onset of muscle weakness (cataplexy).
- have a history of daytime sleepiness.
- have lung problems or breathing problems, including sleep apnoea.
- have liver problems.

Some medicines can cause dependence, especially when they are used regularly for longer than a few weeks. People who have been dependent on alcohol or other drugs in the past may have a higher chance of becoming addicted to sleep medicines. If you have been addicted to alcohol or drugs in the past, it is important to tell your doctor before starting DAYVIGO.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

#### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. It is not known if DAYVIGO can harm your unborn baby.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

- You should not take medicines such as itraconazole, clarithromycin, fluconazole, and verapamil, which may interact with DAYVIGO. Taking DAYVIGO with these medicines may increase the risk of side effects.
- You should not take medicines such as bosentan, efavirenz, etravirine, modafinil, rifampin, carbamazepine, and St. John's wort which may interact with DAYVIGO. These medicines may reduce the effect of DAYVIGO.
- DAYVIGO may reduce the effect of medicines such as methadone and bupropion. Your doctor may need to adjust your treatment.

Some medicines may interfere with DAYVIGO and affect how it works. DAYVIGO should not be taken with other medicines that can make you sleepy (sedatives).

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DAYVIGO.

## 4. How do I use DAYVIGO?

### How much to take / use

- The recommended starting dose is one 5 mg tablet once daily.
- If more help with your sleep problem (insomnia) is needed, your doctor may increase the dose to one 10 mg tablet once daily.
- Follow the instructions provided and use DAYVIGO until your doctor tells you to stop. Your doctor will ensure you take the lowest effective dose for as short a duration as necessary.

### When to take / use DAYVIGO

- Only take DAYVIGO one time each night, right before going to bed.
- Only take DAYVIGO when you can stay in bed for a full night (at least 7 hours).

### If you forget to use DAYVIGO

DAYVIGO should be used regularly at the same time right before bedtime. If you miss your dose at the usual time, do not take DAYVIGO unless you have the opportunity to get a full night of sleep (at least 7 hours) before you must be active again. You may continue with your usual dose the following night at bedtime.

**Do not take a double dose to make up for the dose you missed.**

### If you use too much DAYVIGO

If you think that you have used too much DAYVIGO, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (by calling **13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using DAYVIGO?

### Things you should do

#### Call your doctor straight away if:

- Your sleep problem (insomnia) worsens or is not better within 7 to 10 days of taking DAYVIGO. This may mean that there is another condition causing your sleep problem.
- you become pregnant while taking DAYVIGO.
- you experience abnormal thoughts or behaviours, as well as worsening of depression or suicidal thoughts or actions.
- you are experiencing complex sleep behaviours (such as sleep-walking, sleep driving and engaging in other activities while not fully awake).

Remind any doctor, dentist or pharmacist you visit that you are using DAYVIGO.

### Things you should not do

- Do not give DAYVIGO to anyone else, even if they have the same sleep problem as you.
- Do not take DAYVIGO if you have less than 7 hours available to sleep.
- Do not change the dosage of DAYVIGO without checking with your doctor.
- Do not take DAYVIGO in larger amounts, or for longer than prescribed.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how DAYVIGO affects you.**

As with other medicines used to treat insomnia, DAYVIGO may cause drowsiness in some people the day after taking it.

Do not drive or do other dangerous activities until you feel fully awake.

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

Do not drink alcohol while taking DAYVIGO. Alcohol can increase your chances of getting serious side effects with DAYVIGO.

### Looking after your medicine

Keep your medicine in the blister pack until it is time to take the tablet. If you take it out of its blister pack, it may not keep well.

Keep DAYVIGO in a cool dry place where the temperature stays below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or

- in the car or on window sills.

Keep it where young children cannot reach it.

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• sleepiness</li> <li>• sleep paralysis: temporary inability to move or talk for up to several minutes while you are going to sleep or waking up.</li> <li>• cataplexy: temporary weakness in your legs that can happen during the day or at night.</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What DAYVIGO contains

<b>Active ingredient (main ingredient)</b>	lemborexant
<b>Other ingredients (inactive ingredients)</b>	lactose monohydrate hypromellose magnesium stearate

	purified talc macrogol 8000 titanium dioxide iron oxide yellow iron oxide red (10 mg)
<b>Potential allergens</b>	none

**Do not take this medicine if you are allergic to any of these ingredients.**

### What DAYVIGO looks like

DAYVIGO 5 mg film coated tablet: pale yellow, round, biconvex, film coated tablets, and debossed with "5" on one side and "LEM" on the other side. (Aust R 338631).

DAYVIGO 10 mg film coated tablet: orange, round, biconvex, film coated tablets, and debossed with "10" on one side and "LEM" on the other side. (Aust R 338645).

### Who distributes DAYVIGO

Eisai Australia Pty Ltd

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Melbourne, VIC, 3004

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