

DAYVIGO®

Lemborexant

(lem-bo-rex-ant)

New Zealand Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about DAYVIGO.

It does not contain all the available information about DAYVIGO. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet. You may need to read it again.

WHAT DAYVIGO IS USED FOR

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.

Your doctor may have prescribed DAYVIGO for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. This medicine is available only with a doctor's prescription.

BEFORE YOU TAKE DAYVIGO

When you must not take it

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.

If you are not sure whether you should start using DAYVIGO, talk to your doctor.

Before you start to take it

Tell your doctor if:

- 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.

If any of these affects you, tell your doctor who may wish to stop treatment or reduce the dose.

Taking other medicines

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

Some medicines may interfere with DAYVIGO. These include:

- itraconazole, clarithromycin, fluconazole, and verapamil, which may interact with DAYVIGO. Taking DAYVIGO with these medicines may increase the risk of side effects.
- 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.

Pregnancy and breast feeding

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.

HOW TO USE DAYVIGO

How much to take

- 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 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 take 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.

WHILE YOU ARE USING DAYVIGO

Things you must 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 must 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.

Do not take any other medicines, whether they require a prescription or not, without first telling your doctor or consulting with a pharmacist.

Things to be careful of

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.

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.

IN CASE OF OVERDOSE

If you use too much DAYVIGO

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much DAYVIGO.

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

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using DAYVIGO.

All medicines may have unwanted side effects.

Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits he/she expects it will have for you.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Common side effects (may affect up to 1 in 10 people) are:

- Somnolence
- Headache
- Nightmare or abnormal dreams
- Sleep paralysis: temporary inability to move or talk for up to several minutes while you are going to sleep or waking up

Frequency unknown:

- Temporary weakness in your legs that can happen during the day or at night.
- Complex sleep behaviours

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

AFTER USING DAYVIGO

Storage

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.

Disposal

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.

PRODUCT DESCRIPTION

What it looks like

DAYVIGO 5 mg film coated tablet: pale yellow, round, biconvex, film coated tablets, and debossed with "5" on one side and "LCM" on the other side.

DAYVIGO 10 mg film coated tablet: orange, round, biconvex, film coated tablets, and debossed with "10" on one side and "LCM" on the other side.

Ingredients

Active ingredient:

- Lemborexant

Excipient Ingredients:

- Lactose monohydrate

- Hyprollose
- Magnesium stearate
- Hypromellose
- Purified talc
- Macrogol 8000
- Titanium dioxide
- Iron oxide yellow
- Iron oxide red (10 mg)

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

SPONSOR

DAYVIGO is supplied in New Zealand by:

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Simpson Grierson, Level 27
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