

Consumer Medicine Information

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:

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