

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

DAYVIGO 5, Film-coated tablets

DAYVIGO 10, Film-coated tablets

Lemborexant

DAYVIGO 5 contains 93,88 mg lactose monohydrate per tablet.

DAYVIGO 10 contains 88,88 mg lactose monohydrate per tablet.

Read all of this leaflet carefully before you start taking DAYVIGO

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- DAYVIGO has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What DAYVIGO is and what it is used for
2. What you need to know before you take DAYVIGO
3. How to take DAYVIGO
4. Possible side effects

5. How to store DAYVIGO

6. Contents of the pack and other information

1. What DAYVIGO is and what it is used for

DAYVIGO contains lemborexant which is part of the sleep promoting and sedatives medicine group.

DAYVIGO is a medicine used in adults who have trouble falling or staying asleep (insomnia).

2. What you need to know before you take DAYVIGO

Do not take DAYVIGO

- if you are hypersensitive (allergic) to lemborexant or any of the other ingredients of DAYVIGO (listed in section 6).
- if you suffer from a condition characterized by an extreme tendency to fall asleep whenever in relaxing surroundings (narcolepsy)

Warnings and precautions

Special care should be taken with DAYVIGO:

- Decreased awareness and alertness. The morning after you take DAYVIGO, your ability to drive safely and think clearly may be decreased. You may also have sleepiness during the day.
- Do not take DAYVIGO unless you are able to stay in bed for a full night (at least 7 hours) before you must be active again.
- If you have a history of depression, mental illness, or suicidal thoughts.
- If you have a history of medicine, drug or alcohol abuse or addiction.
- If you have a history of a sudden onset of muscle weakness (cataplexy).

- If you have a history of daytime sleepiness.
- If you have lung problems or breathing problems, including sleep apnoea.
- If you have liver problems.

Children and adolescents

Do not give DAYVIGO to children under 18 years of age

Other medicines and DAYVIGO

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

You should not take medicines such as

- itraconazole, fluconazole (antifungal medicine)
- clarithromycin (antibacterial medicine)
- ranitidine (stomach ulcer medicine)
- verapamil (blood pressure medicine)

which may interact with DAYVIGO. Taking DAYVIGO with these medicines may increase the risk of side effects.

You should not take medicines such as

- efavirenz (antiretroviral medicine)
- modafinil (treatment of extreme sleepiness)
- rifampin (antibacterial medicine)
- carbamazepine (antiepileptic medicine)

- St. John's wort (herbal medicine used in the treatment of mood disorders)

which may interact with DAYVIGO. These medicines may reduce the effect of DAYVIGO.

DAYVIGO may reduce the effect of medicines such as methadone (treatment of drug addiction) and bupropion (antidepressant medicine). Your doctor may need to adjust your treatment.

Co-administration with other medicine classified as sedatives, tranquilisers and hypnotics (e.g., benzodiazepines, opioids, tricyclic antidepressants, alcohol) can cause daytime impairment. Dosage adjustments may be necessary.

The use of DAYVIGO with other medicines used to treat sleep disorder in which you have trouble falling and/or staying asleep (insomnia), is not recommended.

DAYVIGO with food and alcohol

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

DAYVIGO may take longer to work if you take it with or soon after a meal.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Safety during pregnancy and breastfeeding has not been established.

Driving and using machines

It is not always possible to predict to what extent DAYVIGO may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which DAYVIGO affects you.

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 healthcare provider.

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 contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking DAYVIGO.

3. How to take DAYVIGO

Do not share medicines prescribed for you with any other person.

Always take DAYVIGO exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is DAYVIGO 5 taken once per night, right before going to bed.

Only take DAYVIGO when you can stay in bed for a full night (at least 7 hours).

Do not increase your dose of DAYVIGO without talking to your doctor first. Your dose may be increased to DAYVIGO 10 once per night by your doctor.

Your doctor will tell you how long your treatment with DAYVIGO will last.

Talk to 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.

If you have the impression that the effect of DAYVIGO is too strong or too weak, tell your doctor or pharmacist.

If you take more DAYVIGO than you should

In the event of overdosage, consult your doctor or pharmacist immediately. If neither is available, go to the nearest hospital or poison centre right away.

If you forget to take DAYVIGO

Do not take a double dose to make up for forgotten individual doses. Only take DAYVIGO when you can stay in bed for a full night (at least 7 hours).

4. Possible side effects

DAYVIGO can have side effects.

Not all side effects reported for DAYVIGO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DAYVIGO, please consult your health care provider for advice.

If any of the following happens, stop taking DAYVIGO and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty

in swallowing or breathing

- rash or itching
- fainting

These are all very serious side effects. If you have them, you may have had a serious reaction to DAYVIGO. You may need urgent medical attention or hospitalisation.

Common side effect

- Sleepiness or tiredness
- Headache
- Nightmare or abnormal dreams
- Temporary inability to move or talk for up to several minutes while you are going to sleep or waking up (sleep paralysis)

Uncommon side effects

- Hallucinations as a person is falling asleep
- Palpitations (feels like your heart is beating too hard or too fast)
- Complex sleep behaviours such as sleepwalking, sleep-driving, preparing and eating food, making phone calls, having sex or doing other activities while not fully awake that you may not remember the next morning. Call your doctor right away if you experience a complex sleep behaviour.
- Worsening depression and suicidal thoughts have happened during treatment with DAYVIGO. Call your doctor right away if you have any worsening depression or thoughts of suicide or dying.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of DAYVIGO.

5. How to store DAYVIGO

Store all medicines out of reach of children.

Store at or below 30 °C.

Store tablets in the original package until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label / carton / bottle.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DAYVIGO contains

- The active substance is lemborexant. Each film-coated tablet contains lemborexant 5 mg or 10 mg respectively.
- The other ingredients are:

Core tablet: hydroxypropyl cellulose, lactose monohydrate, low-substituted hydroxypropyl cellulose, magnesium stearate.

Film-coating:

Dayvigo 5: Opadry 03F42222 Yellow consisting of hypromellose 2910, talc, polyethylene glycol 800, titanium dioxide, ferric oxide yellow.

Dayvigo 10: Opadry 03F43101 Orange consisting of hypromellose 2910, talc, polyethylene glycol 800, titanium dioxide, ferric oxide yellow, ferric oxide red.

What DAYVIGO looks like and contents of the pack

DAYVIGO 5: Pale yellow, round, biconvex film-coated tablets debossed “LEM” on one side and “5” on the other side.

DAYVIGO 10: Orange, round, biconvex film-coated tablets debossed “LEM” on one side and “10” on the other side

Polyvinyl chloride (PVC) film/aluminium foil blister strips in outer cardboard carton.

Pack sizes: 30 or 90 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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