



Your guide to Eszopiclone[®]

Your doctor has prescribed Eszopiclone, a prescription medicine for the short-term treatment and symptomatic relief of insomnia characterized by difficulty falling asleep, frequent nocturnal awakenings and/or early morning awakenings where disturbed sleep results in impaired daytime functioning.

Read this carefully before you start taking Eszopiclone and each time you get a refill. This brochure is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Eszopiclone.

What is insomnia?

Insomnia is a common sleep problem that can make it hard to fall asleep and stay asleep.

What can you do about insomnia?

The first step in managing your insomnia is to remove anything that may contribute to it, like drinking coffee too late, or using your phone in bed.

These changes might work for some people, but others may still have trouble falling asleep. For them, additional insomnia treatment may involve cognitive behavioral therapy (CBT), or medications.

Some simple tips to help with sleep:

- Learn techniques to relax
- Take some time to unwind before bedtime and maintain good sleep.
- Go to bed only when you are sleepy
- Get out of bed if you can't fall asleep right away and Wake up at the same time every morning even on weekends
- Limit naps during the day

What is Night Calm?

Night Calm is used for a short period of time (usually not exceeding 7–10 days) for: treatment and symptomatic relief of insomnia characterized by difficulty falling asleep, frequent nocturnal awakenings and/or early morning awakenings where disturbed sleep results in impaired daytime functioning. Night Calm is a prescription treatment

How does Eszopiclone work?

Eszopiclone causes a calming effect in your brain and allows you to sleep.


If you are prescribed sleep medications, you should consider both their benefits and risks.

Important Risks and Limitations of Eszopiclone include:

- You may become dependent on Eszopiclone
- Eszopiclone may affect your mental alertness or memory, particularly when not taken as prescribed



How to take Eszopiclone

- ✗ Do not take more than one dose in a single night
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- ✓ Make sure you are able to stay in bed a full night (7–8 hours) before you have to be active again
 - ✓ Take Eszopiclone right before you get into bed, not sooner
 - ✓ The recommended starting dose for Eszopiclone is 1 mg. Depending on your response, your doctor may increase the dose to 2 mg or 3 mg. The maximum daily dose in adults is 3 mg
 - ✗ Do not take a higher dose of Eszopiclone than was prescribed by your healthcare professional
 - ✗ Do not take Eszopiclone if it is not prescribed for you
 - ✗ Do not take Eszopiclone if you drink alcohol
 - ✗ Do not break or crush the Eszopiclone tablets
 - ✗ Eszopiclone is not indicated for patients under 18 years of age. Do not take Eszopiclone if you are under 18 years of age
 - ✓ Eszopiclone may take longer to work if you take it with or right after having a big meal
 - ✗ Treatment with Eszopiclone should usually not go on for more than 7–10 days. Do not take Eszopiclone for more than 7–10 days without first speaking with your doctor



• Dosing Considerations

- The use of hypnotics should be restricted for insomnia where disturbed sleep results in impaired daytime functioning.
- The length of treatment should be for the minimum duration necessary for the patient. Treatment with ESZOPICLONE should usually not exceed 7-10 consecutive days. Use for more than 2-3 consecutive weeks requires complete reevaluation of the patient. Prescriptions for ESZOPICLONE should be written for short-term use (7-10 days) and it should not be prescribed in quantities exceeding a 1-month supply.
- ESZOPICLONE should always be prescribed at the lowest effective dose for the shortest duration possible.

• Discontinuation

- Tapering should be tailored to the specific patient. Special attention should be given to patients with a history of seizure.
- ESZOPICLONE can produce withdrawal signs and symptoms or rebound phenomena following abrupt discontinuation or rapid dose reduction. Abrupt discontinuation should be avoided and treatment - even if only of short duration - should be terminated by gradually tapering the dosage schedule under close monitoring.
- If a patient experiences withdrawal signs and symptoms, consider postponing the taper or raising ESZOPICLONE to the previous dosage prior to proceeding with a gradual taper.

Important safety information about Eszopiclone

Speak to your doctor about your medical conditions and all medicines you are taking before starting with Eszopiclone.

Do not use Eszopiclone if you:

- Have a known allergy to eszopiclone, zopiclone, or to any ingredients in the formulation or components of the container
- Have myasthenia gravis, a condition where the muscles easily tire and become weak
- Have severe breathing problems and/or sleep apnea where you stop breathing for short periods while you sleep
- Are elderly and taking certain antifungals or antibiotics (such as ketoconazole) or you have severe liver problems
- Have ever experienced a complex sleep-related behavior (such as driving a car, making and eating food, talking on the phone or having sex while not fully awake) after taking Eszopiclone or any other medication

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Eszopiclone. Talk about any health conditions you might have including if you:

- Have a history of depression, mental illness, and/or suicidal thoughts or attempts
- Have a history of drug or alcohol abuse or addiction
- Have had unexpected reactions to alcohol or sedative medications in the past
- Have liver or kidney problems
- Have a lung disease or breathing problem
- Have had episodes of sleepwalking in the past, or have a family history of sleepwalking
- Have a condition that affects your sleep, such as Periodic Limb Movement Disorder or Restless Legs Syndrome
- Consume alcohol
- Are taking opioid medicines or other central nervous system depressants such as sedatives or hypnotics, as well as if you are taking any other medicines, including over-the-counter medicines and herbal products
- Are pregnant or planning to become pregnant

- Taking other drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

Other warnings you should know about:

- **Mental Alertness:** Eszopiclone may affect your ability to be alert the next day. DO NOT DRIVE A CAR or operate potentially dangerous machinery if you do not feel fully awake or if it has not been at least 12 hours since taking Eszopiclone.
- **Memory Problems:** Eszopiclone may cause a special type of memory loss (amnesia); you may not recall events that occurred during some period of time, usually several hours, after taking the drug.
- **Dependence and Abuse:** All prescription sleeping pills can cause dependence (addiction), especially when they are used regularly for more than a few weeks or at higher doses. When sleep drugs are used nightly for more than a few weeks, they may not work as well to help sleep problems. This is known as tolerance. Only use sleep drugs for a short time. If sleep problems last, call the doctor.
- **Addiction, Abuse and Misuse:** The use of benzodiazepines, or other sedative-hypnotic drugs, such as eszopiclone, can lead to abuse, misuse, addiction, and physical dependence and withdrawal reactions. Abuse and misuse can result in overdose or death, especially when benzodiazepines, or other sedative-hypnotic drugs, such as eszopiclone, are combined with other medicines, such as opioids, alcohol or illicit drugs.
- Assess each patient's risk prior to prescribing ESZOPICLONE.
- Monitor all patients regularly for the development of these behaviors or conditions.
- ESZOPICLONE should be stored securely to avoid theft or misuse.
- **Withdrawal:** Benzodiazepines, or other sedative-hypnotic drugs, such as eszopiclone, can produce 'severe or life-threatening withdrawal symptoms. Although uncommon, withdrawal symptoms (including stomach pain, headache, increased appetite and insomnia) have been reported after Eszopiclone treatment is stopped.
- Avoid abrupt discontinuation or rapid dose reduction of ESZOPICLONE.
- Terminate treatment with ESZOPICLONE by gradually tapering the dosage schedule under close monitoring
- **Mental and Behavioral Changes:** A variety of abnormal thinking and behavioral changes may occur when you use prescription sleeping pills. Some of these changes include aggressiveness and extroversion which seem out of character. If you develop any unusual, disturbing thoughts or behavior while

using Eszopiclone, discuss the matter immediately with your healthcare professional.

- **Worsening of Side Effects:** DO NOT CONSUME ALCOHOL WHILE TAKING ESZOPICLONE. Some medicines may also worsen the side effects that some patients experience with Eszopiclone.

- **Suicidal ideation/suicide attempt/suicide and depression:** Some studies have shown an increased risk of suicidal ideation, suicide attempt and suicide in patients taking certain sedatives and hypnotics, including this medicine. However, it has not been established whether this is caused by the medicine or if there may be other reasons. If you have suicidal thoughts, contact your doctor as soon as possible for further medical advice.

General drug facts

If your symptoms or health problems do not get better or if they become worse, call your doctor.

Do not share your drugs with others and do not take anyone else's drugs.

Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.

If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

For more information:

- Talk to your doctor or healthcare professional
- See the Patient Information leaflet included with Night Calm

Call for reporting

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Please remember that any suspected adverse events should be reported to EPVC.

The Egyptian Pharmaceutical Vigilance Center is reminding HCP and public to report any safety information regarding human medicinal products including adverse drug reactions, medications errors, lack of efficacy and other medicine related problems through the following contacts:

Address: 21 Abd El Aziz Al Soud Street, El-Manial, Cairo, Egypt,
PO box: 11451

Telephone: (+2)02 25354100, Extension: 1470

Fax: +202-23610497

Email for reporting: pv.followup@edaegypt.gov.eg

Website for reporting: <https://primaryreporting.who-umc.org/EG>

Hotline: 15301

(For Physicians) QR code:



(For Patients) QR code:



And/ Or:

Medizen Pharmaceutical Industries-Pharmacovigilance directorate

Address: 426 El-Horeya Avenue, Roushdy, Alexandria

Tel: 03-5448585 / 01225659000

E-mail: medizen.pv@gmail.com

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