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Educational brochure on "Drug dependence and suicidal behavior "

What is Night Calm?

NIGHT CALM (eszopiclone) is indicated for short-term (usually not exceeding 7-10 days) use 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.

The effects of eszopiclone are due to modulation of gamma-aminobutyric acid (GABA)-A-receptor macromolecular complexes, containing alpha-1, alpha-2, alpha-3 and alpha-5 sub-units. GABA-evoked chloride conductance is increased resulting in neuronal hyper polarization and thereby inhibiting neuronal transmission and causing sleep.

Dosage and administration

Administration

- ESZOPICLONE should be taken orally immediately before retiring or when in bed.

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 -

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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.

Warnings and precautions the physician and/or pharmacist should inform patient about:

Dependence/Tolerance

- Use of benzodiazepines or other sedative-hypnotic drugs, such as eszopiclone, can lead to abuse, misuse, addiction, physical dependence (including tolerance) 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.
- The risk of dependence increases with higher doses and longer-term use but can occur with short-term use at recommended therapeutic doses. Cases of dependence have been reported more frequently in patients treated with sedative-hypnotic drugs, such as eszopiclone, for longer than 4 weeks. The risk of dependence is greater in patients with a history of psychiatric disorders and/or substance (including alcohol) use disorder. Interdose daytime anxiety and rebound anxiety may increase the risk of dependency in ESZOPICLONE treated patients.
- Discuss the risks of treatment with ESZOPICLONE with the patient, considering alternative (including non-drug) treatment options.
- Carefully evaluate each patient's risk of abuse, misuse and addiction, considering their medical condition and concomitant drug use, prior to prescribing ESZOPICLONE. In individuals prone to substance use disorder, ESZOPICLONE should only be administered if deemed medically necessary, employing extreme caution and close supervision.
- ESZOPICLONE should always be prescribed at the lowest effective dose for the shortest duration possible.
- All patients receiving benzodiazepines or other sedative-hypnotic drugs, such as eszopiclone, should be routinely monitored for signs and symptoms of misuse and abuse. If a substance use disorder is suspected, evaluate the patient and refer them for substance abuse treatment, as appropriate.
- Once physical dependence has developed, abrupt termination of treatment will be

accompanied by withdrawal symptoms.

- Development of physical dependence and withdrawal following discontinuation of therapy has been observed with benzodiazepines or other sedative -hypnotic drugs, such as eszopiclone. Severe and life-threatening symptoms have been reported.

➢ **Tolerance:** In clinical studies with eszopiclone, no development of tolerance to any median parameter of sleep measurements was observed during treatment periods of up to 12 months. Development of tolerance in some patients cannot be excluded.

Withdrawal:

- Benzodiazepines or other sedative-hypnotic drugs, such as eszopiclone,
- can produce withdrawal signs and symptoms, ranging from mild to severe and even life threatening, following abrupt discontinuation or rapid dose reduction. The risk of withdrawal is higher with higher dosages and/or prolonged use, but can occur with short-term use at recommended therapeutic doses. Patients given therapeutic dosages for as few as 1 -2 weeks can also have withdrawal symptoms including daytime anxiety between nightly doses.
- Since symptoms of withdrawal are often similar to those for which the patient is being treated, it may be difficult to distinguish from a relapse of the patient's condition.
- Severe or life-threatening signs and symptoms of withdrawal include delirium, de-realization, depersonalization, hallucinations, hyperacusis, seizures (including status epilepticus).
- Other withdrawal signs and symptoms, similar in character to those noted with barbiturates and alcohol, include abdominal and muscle cramps, cognitive impairment, convulsions, diarrhea, dysphoria, extreme anxiety, headache, hypersensitivity to light, noise and physical contact, insomnia, irritability, muscle pain or stiffness, paresthesia, perceptual disturbances, restlessness, sweating, tension, tremors and vomiting. There is also a possibility of rebound anxiety or rebound insomnia.
- 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.
- Tapering should be tailored to the specific patient. Special attention should be given to patients with a history of seizure.

- If a patient experiences withdrawal symptoms, consider postponing the taper or

raising the ESZOPICLONE dose to the previous dosage prior to proceeding with a gradual taper.

- Inform patients of risk of discontinuing abruptly, reducing dosage rapidly or switching medications.
- As with all hypnotics, repeat prescriptions should be limited to those who are under medical supervision.
- Stress the importance of consulting with their health care professional in order to discontinue safely.
- It may be useful to inform the patient when treatment is started that it will be of limited duration and to explain precisely how the dosage will be progressively decreased.
- Patients experiencing withdrawal symptoms should seek immediate medical attention.

Depression

- In primary depressed patients, worsening of depression, including suicidal thoughts and actions (including completed suicides), have been reported in association with the use of sedative/hypnotics. Benzodiazepines and benzodiazepine - like agents are not to be used alone to treat patients with depression or anxiety associated with depression (suicide may be precipitated in such patients). These agents should be administered with caution to patients exhibiting signs and symptoms of depression. Intentional overdose is more common in this group of patients and the least amount of drug that is feasible should be prescribed for the patient at any one time

References:

1. Latest Lunesta SPC
https://pdf.hres.ca/dpd_pm/00067708.PDF
2. Current approved leaflet for Night Calm film coated tablets

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:

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