

Patient package insert in accordance with the pharmacists' regulations (preparations) - 1986

The dispensing of this medicine does not require a physician's prescription

Dorminol Night film coated tablets

Composition:

Each tablet contains:

Valerian root dry extract 187.5 mg

Hop cones dry extract 42 mg

Non active ingredients and Allergens: see paragraph 6: "Further Information".

Read this package insert carefully in its entirety before using this medicine. This insert is a synopsis of the product information. In case you have any additional questions, please ask a doctor or a pharmacist.

This medicine is intended for use in adolescents and adults over the age of 12 years.

You should use the drug according to the instructions in the dosage section of this leaflet. Consult a pharmacist in case you need farther information. You should refer to the physician in case your sleeping disorder gets worse or do not get better following a period of one month.

1. What this medicine is used for?

Inducing sleep in cases of problems falling asleep and staying asleep, as well as in cases of sleep disorders and restless sleep.

Therapeutic Group:

Sleep-inducing substances.

2. Before using the medicine

This medicine should not be used if:

- | |
|---|
| <ul style="list-style-type: none">- You are hypersensitive (allergic) to the active ingredients or to any of the other ingredients of Dorminol Night (listed in section 6). |
|---|

Special warning related to the medicine use:

Do not use this medicine without consulting a doctor before starting treatment:

- if you suffer from other illnesses
- If you are sensitive to any type of food or medicine
- if you take other medication
- if you are pregnant or breast-feeding

Drug-drug interactions

If you are taking or were taking lately other medicines including medicines that can be bought without a prescription and food supplements, tell a doctor or a pharmacist.

You should consult your doctor if you are taking other medications to induce sleep.

Pregnancy and lactation:

There is not enough data available considering the use of the medicine in pregnancy and lactation, therefore it is recommended to avoid using this medicine. If you are pregnant or breast-feeding you should consult your doctor or pharmacist before taking this medicine.

Driving and using machines:

Do not drive or operate dangerous machines when taking the medicine, since it may damage your alertness.

As for adolescents, keep them from riding a bicycle or playing by the road etc.

3. **How to use this medicine?**

You should check with a doctor or a pharmacist in case you are not sure regarding the dosage and method of treatment of the drug.

Dosage and instructions to use:

The usual dose is:

- Adults: 1- 2 film-coated tablets with some water half to one hour before going to bed.
- Adolescents aged 12 and over: 1 tablet with some water half to one hour before going to bed.
- This medicine is not intended for the use of children below the age of 12 years.

Do not exceed the recommended dosage.

Swallow the tablet with some water.

Crushing of the tablets is permissible, but it may be difficult to crush the film coating.

If you think that the effect of the medicinal product is too weak or too strong, consult your physician.

If you have mistakenly taken an overdose, or if a child accidentally swallowed this medicine, you must refer immediately to a hospital emergency room and bring the medicine package with you. The signs of overdose may include: fatigue, abdominal cramp, chest tightness, lightheadedness, hand tremor and dilated pupils.

Do not induce vomiting unless explicitly being instructed to do so by a physician! If symptoms of overdose arise, you should turn to a medical staff and receive supportive treatment.

How can you contribute to the success of the treatment?

When experiencing sleep problems, consumption of stimulating beverages (coffee, black tea), nicotine, as well as heavy meals in the evening should be avoided. Get used to a regular sleep rhythm. A short walk in the fresh air, a soothing bath or reading a book in a relaxed atmosphere enhance the readiness to sleep. Bear in mind that physiological sleep duration differs from person to person and decreases with age.

In case your sleeping disorder lasts longer than a month, you should consult a physician.

Do not take medicines in the dark! Check the label and the dose every time you take this medicine. Wear glasses if you need them.

If you have any more questions regarding the use of this medicine, consult your doctor or pharmacist.

4. **Side Effects**

Like all medicines Dorminol Night can cause side effects in some of the users. Don't be alarmed by the list of side effects. It may be that you won't experience any of them.

Gastrointestinal symptoms (e.g. nausea, vomiting, diarrhea, abdominal pain) may occur after ingestion of valerian root preparations. The frequency of occurrence of these symptoms is yet unknown.

The following very rare (may affect up to 1 in 10,000 patients) side effects can occur during the course of treatment: skin reactions, due to the excipients used.

If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please consult your doctor.

Reporting of side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" that appears on the homepage of the Ministry of Health's website

(www.health.gov.il) which links to an online form for reporting side effects, or by the following link:

<https://sideeffects.health.gov.il/>

and by emailing the Registration Holder's Patient Safety Unit at:

drugsafety@neopharmgroup.com

5. How this medicine should be stored?

Avoid Poisoning! This medicine and all other medicines must be stored in a safe place out of the reach of children and/ or infants to avoid poisoning.

Do not store different medications in the same package.

Do not use the medicine after the expiry date (exp. date) which is stated on the carton.

The expiry date refers to the last day of that month.

In any case of doubt, consult a pharmacist who dispensed the medicine to you.

This medicine should be stored below 25°C.

Store in the original package.

6. Further information

In addition to the active ingredients, the medicine contains:

Cellulose microcrystalline, Maltodextrin, Castor oil hydrogenated, Soy polysaccharide, Hypromellose, Titanium dioxide (E 171), Macrogol 6,000, Magnesium stearate, Silica colloidal anhydrous, Macrogol 400, Propylene Glycol, Macrogol 20,000, Vanilla aroma, Indigo carmine aluminium lake (E 132, CI 73,015).

Description and Content of a pack:

Pale blue, round, biconvex film-coated tablets. The tablets are packaged in an aluminium blister tray which contains 20 or 60 film coated tablets.

Name and address of the manufacturer: Max Zeller Sohne AG, Seeblickstrasse 4, CH-8590 Romanshorn, Switzerland

Name and address of the registration holder: Neopharm (Israel) 1996 Ltd, P.O.Box 7063, Petach- Tiqva 4917001

Revised in August 2022 according to MOHs guidelines.

The license number of the medicine in the pharmaceuticals registrar of the MOH: 149-40-33542

Dorminol Night FCT PIL vr 01A