

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Dorminol Night film coated tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Fixed combination of *Valeriana officinalis* L., radix (Valerian Root Dry Extract) and *Humulus lupulus* L., flos (Hop Cones Dry Extract).

1 film coated tablet contains:
42 mg Hop Cones Dry Extract
187.5 mg Valerian Root Dry Extract

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film coated tablet

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Herbal medicinal product for problems falling asleep and staying asleep, as well as restless sleep) .

4.2 Posology and method of administration

Posology

Adults

-12 film coated tablets should be taken half to one hour before bed time.

Adolescents over 12 years of age

1 film coated tablet should be taken half to one hour before bed time

Elderly

Posology is the same as for adults.1- 2 film coated tablets should be taken half to one hour before bed time.

The use in children below the age of 12 years is not recommended (see section 4.4).

Duration of use

Because of its gradual onset of efficacy Dorminol Night is not suitable for acute interventional treatment of mild nervous tension or sleep disorders. To achieve optimal treatment effect, the continued use over 4 weeks is recommended.

If symptoms persist or worsen after 4 weeks of continued use, a doctor should be consulted.

Method of administration

Oral use.

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

4.3 Contraindication

Hypersensitivity to the active substance(s) or to any of the excipients of Dorminol Night.

4.4 Special warnings and precautions for use

The use of Dorminol Night is not recommended in children below the age of 12 years, due to lack of adequate data.

4.5 Interaction with other medicinal products and other forms of interaction

Only limited data on pharmacological interactions with other medicinal products are available. Clinically relevant interaction with drugs metabolised by the CYP 2D6, CYP 3A4/5, CYP 1A2 or CYP 2E1 pathway has not been observed.

Combination with synthetic sedatives requires medical diagnosis and supervision.

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established. As a precautionary measure, because of lack of data, use during pregnancy and lactation is not recommended.

4.7 Effects on ability to drive and use machines

May impair ability to drive and use machines. Affected patients should not drive or operate machinery.

4.8 Undesirable effects

Very common ($\geq 1/10$)

Common ($\geq 1/100$ to $< 1/10$)

Uncommon ($\geq 1/1'000$ to $< 1/100$)

Rare ($\geq 1/10'000$ to $< 1/1'000$)

Very rare ($< 1/10'000$)

Not known cannot be estimated from available data

Gastrointestinal symptoms (e.g. nausea, vomiting, diarrhea, abdominal pain) may occur after ingestion of valerian root preparations. The frequency of occurrence of these effects is not known.

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 in this medical product.

If other adverse reactions not mentioned above occur, a doctor or a pharmacist should be consulted.

Reporting of side effects

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

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form

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

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

drugsafety@neopharmgroup.com

4.9 Overdose

Valerian root at a dose of approximately 20 g caused benign symptoms (fatigue, abdominal cramp, chest tightness, lightheadedness, hand tremor and mydriasis), which disappeared within 24 hours. If symptoms arise, treatment should be supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Hypnotics and sedatives.

ATC code: N05CM

The sedative effects of preparations of valerian root and hop strobiles have been long recognised empirically and have been confirmed for valerian root preparations in preclinical tests and controlled clinical studies. So far no clinical studies have been conducted with hop extracts alone as active drug for insomnia, but at least four randomized, placebo- or reference-controlled prospective clinical studies have been carried out with fixed combinations of dry extracts prepared from valerian root and hop strobiles with methanol 45% (*m/m*).

Orally administered fixed combinations of these extracts in the recommended dosage have been shown to improve sleep latency and sleep quality. These effects cannot be attributed with certainty to any known constituents. Several mechanisms of action possibly contributing to the clinical effect have been identified for diverse constituents of valerian root (sesquiterpenoids, lignans, flavonoids) and include interactions with the GABA-system, agonism at the A-1 adenosine receptor and binding to the 5-HT_{1A} receptor. Also several mechanisms of action have been identified for diverse constituents of hop strobiles (bitter acids, flavonoids) and

include at the melatonin receptors (ML1 and ML2) and binding to serotonin receptor subtypes (5-HT_{4c}, 5-HT₆ and 5-HT₇).

Whether hop strobile extract acts either as a mild sedative independently or as a synergist for valerian root extract, is not yet known.

5.2 Pharmacokinetic properties

No data are available.

5.3 Preclinical safety data

Extracts with ethanol and the essential oil of valerian root have shown low toxicity in rodents during acute tests and from repeated dose toxicity over periods of 4-8 weeks. Tests on reproductive toxicity, genotoxicity and carcinogenicity of valerian root have not been performed.

Tests on genotoxicity of water/ ethanolic extracts of hop strobiles were negative.

Tests on genotoxicity were not performed for water extracts of hops.

Tests on reproductive toxicity and carcinogenicity of hop preparations have not been performed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container, pack sizes

PVC/PE/PVdC-Al-blisters in paper box, patient information leaflet
Pack sizes: 20 and 60 film-coated tablets
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7. MANUFACTURER

Max Zeller Sohne AG
CH-8590 Romanshorn
Switzerland

8. REGISTRATION HOLDER

Neopharm (Israel) 1996 Ltd.
POB 7063
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Israel



9. REGISTRATION NUMBER

149-40-33542-00.

Revised in August 2023 according to MOHs guidelines

Dorminol Night FCT SPC vr 01A