SUMMARY OF PRODCUT 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) and *Humulus lupulus* L., flos (hop strobile).

1 film coated tablet contains:
250 mg of Valerian root dry extract (DER 4-6:1, methanol 45% *m/m*)
60 mg of Hop strobile dry extract (DER 5-7:1, methanol 45% *m/m*)

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 (≥ 1/10)
Common (≥ 1/100 to < 1/10)
Uncommon (≥ 1/1’000 to < 1/100)
Rare (≥ 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 is not known.
If other adverse reactions not mentioned above occur, a doctor or a pharmacist should be consulted.

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-HT1A 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_{4e}, 5-HT_{6} and 5-HT_{7}).
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
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8. REGISTRATION HOLDER

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9. REGISTRATION NUMBER

149-40-33542-00.

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