

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Dormeasan Valerian-Hops oral drops

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of oral liquid contains:

0.5 ml of tincture from Valerian root (*Valeriana officinalis* L.) (1:10-11). Extraction solvent:
Ethanol 58% V/V.

and

0.5 ml of tincture from Hop strobile (*Humulus lupulus* L.) (1:12-13). Extraction solvent:
Ethanol 65% V/V.

1 ml is equivalent to 35 drops.

For full list of excipients see Section 6.1

3 PHARMACEUTICAL FORM

Oral liquid.

Green to brown, clear liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A traditional herbal medicinal product used for the temporary relief of sleep disturbances caused by the symptoms of mild anxiety based on traditional use only.

4.2 Posology and method of administration

For oral short term use only.

Adults and the elderly:

To aid sleep:

Take 30 drops half an hour before bedtime.

For relief of symptoms of mild anxiety:

During daytime: Take 10-20 drops once or twice a day.

As treatment effects may not be apparent immediately, the product should be taken for 2-4 weeks continuously.

If symptoms worsen or do not improve after 4 weeks a doctor or qualified healthcare practitioner should be consulted.

Not for children or adolescents under 18 years.

4.3 Contraindications

Hypersensitivity to Valerian, Hops or any of the excipients in the product.

This product should not be used in children or adolescents under 18 years.

4.4 Special warnings and precautions for use

Do not exceed stated dose.

If symptoms worsen or do not improve after 4 weeks a doctor or qualified healthcare practitioner should be consulted.

This product contains 62 vol% ethanol (alcohol).

This corresponds to:

- 420 mg alcohol equivalent to 10.6 ml beer or 4.4 ml wine (30 drops)
- 140 mg alcohol equivalent to 3.5 ml beer or 1.5 ml wine (10 drops)

Harmful for those suffering from alcoholism. To be taken into account in pregnant, or breast-feeding women, children and high-risk groups such as patients with liver disease or epilepsy.

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 interactions with drugs metabolized by the CYP 2D6, CYP 3A4/5, CYP 1A2 or CYP 2E1 pathway has not been observed.

Combination with synthetic sedatives is not recommended.

Contains alcohol and should be avoided in patients taking other medicines known to interact with alcohol (e.g. metronidazole).

4.6 Pregnancy and lactation

The safety of this product during pregnancy and lactation has not been established, therefore the use of this product 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. If affected do not drive or operate machinery. This product contains alcohol (See Section 4.4 for details of alcohol content).

4.8 Undesirable effects

Gastrointestinal symptoms such as nausea, abdominal cramps may occur. The frequency is not known.

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

4.9 Overdose

Valerian root at a dose of approximately 20 g (equivalent to 93 doses) 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.

After intake of very high doses of Valerian root over several years (daily consumption corresponding to approximately 30 g of the drug) withdrawal symptoms (delirium) have been reported.

No cases of overdose have been reported for Hops.

Overdose of this product may result in alcohol intoxication: the amount of alcohol in a full bottle (24.8 g in 50 ml: 49.6 g in 100 ml: equivalent to 1 or 2 large glasses of wine, respectively) may result in intoxication and should be treated accordingly.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended

5.2 Pharmacokinetic properties

Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended

5.3 Preclinical safety data

Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended, unless necessary for the safe use of the product.

The preclinical toxicology data available are limited. Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

From tincture:

Ethanol

Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Brown glass dropper bottles (Type III glass) with a twist-off cap.

Pack sizes: 50 ml

100 ml

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

THR 13668/0017

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19/02/2009

10 DATE OF REVISION OF THE TEXT

19/02/2009