Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Dormeasan Sleep Valerian-Hops oral drops

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose (30 drops) of oral liquid contains:
394 mg of tincture from *Valeriana officinalis* L., radix (Valerian root) (1:10-11). Extraction solvent: ethanol 58% v/v and 394 mg of tincture from *Humulus lupulus* L. (Hop strobile) (1:12-13). Extraction solvent: ethanol 65% v/v.

Ethanol content: 62% v/v (54.1% m/m)

1 ml is equivalent to 35 drops.

Excipients with known effect:
A maximum dose of 30 drops contains approximately 420 mg of ethanol (alcohol).

For the full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral drops, solution (Oral drops)
Green to brown, clear liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Traditional herbal medicinal product to aid sleep exclusively based on long standing use.

This product is indicated for use in adults.

4.2 Posology and method of administration

Posology
Adults and older people:
Take 30 drops in a little water or fruit juice half an hour before bedtime.

As treatment effects may not be apparent immediately, Dormeasan Sleep should be taken for 2 weeks continuously.

Duration of use:
If symptoms persist, worsen or do not improve after 2 weeks use of Dormeasan Sleep a qualified health care professional e.g. a doctor or pharmacist should be consulted.

Not recommended for children or adolescents under 18 years (see Section 4.4 Special warnings and precautions for use).

Method of administration
For oral short-term use only.

4.3 Contraindications

Hypersensitivity to Valerian, Hops or any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Do not exceed stated dose.

If symptoms persist, worsen or do not improve after 2 weeks use of Dormeasan Sleep a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

The use of this product is not recommended in children or adolescents under 18 years because data are not sufficient and medical advice should be sought.

This medicine contains 420 mg of alcohol (ethanol) in each 30 drop dose, equivalent to 490 mg/ml. The amount in each 30 drop dose of this medicine is equivalent to less than 11 ml beer or 5 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

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 CYP2D6, CYP3A4/5, CYP1A2 or CYP2E1 pathway has not been observed.

Additive effects with hypnotics and other sedatives cannot be excluded and therefore co-medication is not recommended.

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

4.6 Fertility, pregnancy and lactation

The safety of this product during pregnancy and lactation has not been established. Due to the lack of data, use during pregnancy and lactation is not recommended.

4.7 Effects on ability to drive and use machines

May cause dizziness and impair ability to drive and use machines. If affected, patients should 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, vomiting, abdominal cramps and diarrhoea may occur. Dizziness, headaches and nightmares or vivid dreams may also occur. The frequency is not known.

Reporting of suspected adverse reactions
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. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance. Website: http://www.hpra.ie

4.9 Overdose

Valerian root at a dose of approximately 20g (equivalent to 93 doses) caused benign symptoms (fatigue, abdominal cramp, chest tightness, light headedness, 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 equivalent to 1 large glass of wine) 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 Article16c (1) (a) (iii) of Directive 2001/83/EC as amended.

5.3 Preclinical safety data

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

In an Ames test for the detection of gene mutation, Dormeasan Sleep Valerian-Hops oral drops did not demonstrate genotoxic activity.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.
Use within 5 months of opening.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Amber glass bottles (type III conforming to Ph. Eur. standards) with a polyolefine two part dropper/dispenser cap.
Pack sizes: 15 ml, 30 ml and 50 ml

Amber glass bottles (type III conforming to Ph. Eur. standards) with a two part dropper (PE-LD)/child-resistant closure (PP/PE-HD or HDPE/HDPE).
Pack sizes: 15 ml, 30 ml and 50 ml

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 REGISTRATION HOLDER

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8 REGISTRATION NUMBER(S)

TR2309/005/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first registration: 2nd May 2014
Date of last renewal: 1st May 2019

10 DATE OF REVISION OF THE TEXT

October 2024