Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Valerian Complex Stress Relief Oral Drops

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose (20 drops) of oral liquid contains:
263 mg of tincture from *Valeriana officinalis* L., radix (Valerian root), (1:10-11). Extraction solvent ethanol 58 % v/v and
263 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 20 drops contains approximately 280 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

A traditional herbal medicinal product for the relief of symptoms of mild mental stress, exclusively based on long-standing use.

4.2 Posology and method of administration

Posology
Adults and older people: Take 10-20 drops in a little water or fruit juice once or twice a day.
Maximum daily recommended dose is 40 drops.

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

Duration of use:
If symptoms persist, worsen or do not improve after 2 weeks use of Valerian Complex a qualified healthcare 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 Valerian Complex 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 medicinal product contains 62 vol% ethanol (alcohol). This corresponds to:
- 280 mg alcohol, equivalent to 7 ml beer or 2.9 ml wine, per 20 drop dose;
- 140 mg alcohol, equivalent to 3.5 ml beer or 1.5 ml wine, per 10 drop dose.

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 interactions

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.

Additive effects with hypnotics and other sedatives cannot be excluded and therefore comedication 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 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.

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, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

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

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, Valerian Complex did not demonstrate genotoxic activity.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

From tincture:
Ethanol
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, 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, 50 ml

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 REGISTRATION HOLDER

A. Vogel Ireland Limited
48 Upper Drumcondra Road
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8 REGISTRATION NUMBER(S)

TR2309/020/001

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

April 2019
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