

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

English Herbal Medicines Valerian Relaxisleep

Herbs Hands Healing ValRelax

Brooke Green Valerian Elixir

Swiss Herbal Remedies Valerian Elixir

Nytol Herbal Simply Sleep & Calm Elixir

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml of oral liquid contains 1.5 ml of tincture from dried Valerian (*Valeriana officinalis* L.) root (1:8). Extraction solvent: Ethanol 57% v/v.

Excipients with known effect

5 ml of oral liquid contains approximately 1.25g Ethanol (alcohol), equivalent to 32 ml of beer or 13 ml of wine and 734 mg sucrose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral Liquid. Dark brown liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A traditional herbal medicinal product used for the temporary relief of symptoms of mild anxiety and to aid sleep, based on traditional use only.

4.2 Posology and method of administration

Posology

For oral short term use only.

Adults and Elderly:

For the symptomatic relief of symptoms of mild anxiety: Take two 5ml spoonfuls three times a day with water or fruit juice if desired.

To aid sleep: Take two 5ml spoonfuls 30 minutes before bedtime with an earlier dose during the evening if necessary.

The effects of this treatment may not occur immediately, therefore the product should be taken continuously for 2-4 weeks.

Maximum daily dose: Four single doses (40mls).

Duration of use:

If symptoms persist, worsen or do not improve after 4 weeks during the use of this product, a doctor or qualified healthcare practitioner should be consulted.

Paediatric population

The use of this product is not recommended in children and adolescents below the age of 18 years (see also 4.4 Special warnings and precautions for use).

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Do not exceed the stated dose.

Contains alcohol - contains 1300 mg of alcohol (ethanol) in each 5ml which is equivalent to 260 mg/ml (33% v/v). The amount in 5ml of this medicine is equivalent to 32ml beer or 13ml wine.

Patients with epilepsy or liver problems should consult their doctor or pharmacist before taking this medicine.

Patients addicted to alcohol should consult their doctor or pharmacist before taking this medicine.

Contains sucrose – Patients who have been told by their doctor that they have an intolerance to some sugars, should contact their doctor before taking this medicinal product. May be harmful to the teeth.

Paediatric population

The use of this product is not recommended in children and adolescents below the age of 18 years because data are insufficient and medical advice should be sought.

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 metabolised 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 co-medication is not recommended.

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

The effect of Valerian may be potentiated by alcohol. Excessive concomitant consumption of alcohol should therefore be avoided.

4.6 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

This product 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 2).

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.

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

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 the Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

No case of overdose has been reported.

Valerian root at a dose of approximately 20g (equivalent to 533 ml of this product) 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 30g of the drug) withdrawal symptoms (delirium) have been reported.

Overdose of this product may result in alcohol intoxication: the amount in a full bottle: (25.2g in 100ml, 37.9g in 150ml, 50.5g in 200ml and 75.6g in 300ml: equivalent to 1.5, 2.3, 3 and 4.5 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

Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquorice Liquid Extract

Orange Oil

Lemon Oil

Coriander Oil

Anise Oil

Ethanol (90%)

Sucrose

Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Three years.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Glass bottle with polypropylene screwcap: 100ml, 150ml, 200ml and 300ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Rutland Biodynamics Ltd, Town Park Farm, Brooke, Rutland, LE15 8DG.

8 MARKETING AUTHORISATION NUMBER(S)

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

29/06/2010

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AUTHORISATION**

Date of first authorisation: 29.06.2010

Date of latest renewal: 09.03.2020

10 DATE OF REVISION OF THE TEXT

13/10/2023