Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Peace & Calm Oral Liquid

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of oral liquid contains 2 ml of tincture from dried *Valeriana officinalis* L., radix (Valerian root) (DER 1:2). Extraction solvent ethanol 60 % v/v.
Excipients with known effect:
Each 5 ml of oral liquid contains approximately 1.78 g of ethanol (alcohol) and 734 mg of 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

Peace & Calm Oral Liquidis a traditional herbal medicinal product used in adults for the relief of symptoms of mild mental stress and to aid sleep, exclusively based on long-standing use.

4.2 Posology and method of administration

For oral short term use only.

Adults and older people
For the symptomatic relief of symptoms of mild mental stress: take one 5 ml spoonful three times a day with water or fruit juice if desired.

To aid sleep: take one 5 ml spoonful 30 minutes before bed time with an earlier dose during the evening if necessary.

Maximum daily dose: 4 single doses

Duration of use
As treatment effects may not be apparent immediately, this product should be taken for 2 weeks.

If symptoms persist, worsen or do not improve after 2 weeks use of this product, a doctor or pharmacist should be consulted.

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

4.3 Contraindications

Patients with known hypersensitivity to Valerian root or any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Do not exceed the stated dose.
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.
Ethanol warning: This medicine contains 1780 mg of alcohol (ethanol) in each 5 ml dose, which is equivalent to 45 ml beer or 19 ml wine per 5 ml dose. The amount of alcohol in this medicine is not likely to have an effect in adults.

Sucrose warning: This medicine contains 734 mg of sucrose per 5 ml dose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

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 CYP2D6, CYP3A4/5, 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 Fertility, pregnancy and lactation

There are no or limited amount of data from the use of valerian root in pregnant women. Animal studies are insufficient with respect to reproductive toxicity (see section 5.3). Peace & Calm Oral Liquidis not recommended during pregnancy and in women of child bearing potential not using contraception.

There is insufficient information on the excretion of valerian root/metabolites in human milk. A risk to newborns/infants cannot be excluded. Peace & Calm Oral Liquid should not be used during breast-feeding.

4.7 Effects on ability to drive and use machines

This product may cause dizziness and impair the ability to drive or use machinery. Affected patients should not drive or operate machinery. This product contains alcohol (see section 4.4 for details of alcohol content). Over dose of this product may result in alcohol intoxication.

4.8 Undesirable effects

Gastrointestinal symptoms (eg nausea, vomiting, abdominal cramps and diarrhoea) may occur after ingesting Valerian root. 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 pharmacist 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 HPRA Pharmacovigilance, website: www.hpra.ie.

4.9 Overdose

No case of overdose has been reported.

Valerian root at a dose of approximately 20 g (equivalent to 100 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 in take 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.

Overdose of this product may result in alcohol in toxication. One 200 ml bottle of this product contains 71 g ethanol. This is equivalent to 4.5 large glasses of wine and may result in intoxication which 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

Star anise oil
Sweet orange oil
Lemon oil
Coriander oil
Liquorice liquid extract
Liquid Sucrose
Ethanol 96%
Purified 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

The product is presented as a liquid in a 100 ml or 200 ml amber glass bottle with a polypropylene tamper-evident, child-resistant closure.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Irish Botanica
3-5 Charvey Business Park
Rathnew
Co. Wicklow
Ireland

7 REGISTRATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

TR1723/002/001

8 REGISTRATION NUMBER(S)

TR1723/002/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first registration: 27th March 2015
Date of last renewal: 26th March 2020

10 DATE OF REVISION OF THE TEXT

April 2025