

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Kiwiherb Valerian Oral Liquid

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains 5ml liquid extract from *Valeriana officinalis* radix (corresponding to 2.5 g of valerian root) DER 1:2. Extraction solvent: ethanol 45% v/v.

A maximum dose of 15ml contains up to 6.75ml ethanol.

For a full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Oral liquid.

A brown liquid.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

Kiwiherb Valerian is a Traditional herbal medicinal product for 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 the elderly:

To aid sleep:

Take two or three 5ml spoonfuls half an hour before bedtime in a small amount of juice or water.

To relieve symptoms of mild mental stress:

Take one 5ml spoonful up to three times a day in a small amount of juice or water.

Maximum daily dose: Three doses per day (total of 15 ml).

This product is not recommended in patients less than 18 years.

Duration of use:

If the condition worsens or symptoms do not improve after 2 weeks, a qualified healthcare professional e.g. a doctor or pharmacist should be consulted

### 4.3 Contraindications

Hypersensitivity to Valerian or any of the excipients.

### 4.4 Special warnings and precautions for use

The use of this product is not recommended in children and adolescents below the age of 18 years because data is not

sufficient and medical advice should be sought.

If the condition worsens or symptoms do not improve after 2 weeks, a qualified healthcare professional e.g. a doctor or pharmacist should be consulted. This product contains alcohol (45% ethanol), i.e. up to 2.25 ml per 5 ml dose, (equivalent to 45 ml beer or 18.8 ml wine), and maybe harmful to those suffering from alcoholism. To be taken into account in pregnant or breastfeeding women, children and high risk groups such as patients with Liver disease or epilepsy.

Do not exceed the stated dose.

#### **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 have not been observed.

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

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

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

#### **4.6 Fertility, pregnancy and lactation**

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

Studies on the effect on fertility have not been performed

#### **4.7 Effects on ability to drive and use machines**

May impair the ability to drive and use machines. Affected patients should not drive or operate machinery.

In addition, this product contains alcohol (see Section 4.4 Special warnings and precautions for use). This may impair your ability to drive and use machines

#### **4.8 Undesirable effects**

Gastrointestinal symptoms (e.g. nausea, abdominal cramps) may occur. The frequency is not known.

If other adverse reactions not mentioned above occur, qualified healthcare professional e.g. 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, Earlsfort Terrace, IRL - Dublin 2; Tel:+353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

#### **4.9 Overdose**

Valerian root at a dose of approximately 20 g (equivalent to 8 doses at the highest end of Kiwiherb Valerian) caused benign symptoms (fatigue, abdominal cramp, chest tightness, lightheadedness, hand tremor and mydriasis), which disappeared within 24 hours.

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 and should be treated accordingly. The amount of alcohol in a full bottle of the product is:

18 g equivalent to 0.75 large glasses of wine in a 50 ml bottle

36 g equivalent to 1.5 large glasses of wine in a 100 ml bottle

## **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.

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

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Purified water  
Ethanol

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

3 years

### **6.4 Special precautions for storage**

Do not store above 30°C. Store in the original container.

### **6.5 Nature and contents of container**

Amber glass bottle with a black olefin, child-resistant sealed screwcap in a cardboard carton.  
50 ml and 100ml.

Clear polyolefin plastic, CE-marked measuring cup (6ml)

Not all pack sizes may be marketed.

### **6.6 Special precautions for disposal**

No special requirements.

**7 REGISTRATION HOLDER**

Phytomed (UK) Ltd.,  
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**8 REGISTRATION NUMBER(S)**

TR1734/006/001

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

Date of first registration: 6th of October 2017.

**10 DATE OF REVISION OF THE TEXT**