Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lamberts Valerian Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains dry extract of *Valeriana officinalis* radix (valerian root) 300 mg, equivalent to 1500 -1800 mg of valerian root.
Extraction solvent: ethanol 70 % v/v

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet
Brown speckled, film-coated tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

A traditional herbal medicinal product used for the relief of symptoms of mild mental stress and to aid sleep, exclusively based upon long-standing use.

4.2 Posology and method of administration

For oral short term use only.

Adults and the elderly.

For the relief of symptoms of mild mental stress: Take one tablet twice a day.

To aid sleep: Take 1 tablet half to one hour before bedtime with an earlier dose during the evening if necessary to aid sleep
Do not exceed the stated dose (4 tablets per day).

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

Tablets should be swallowed whole with some water or other liquid. The tablets should not be chewed.

As treatment effects may not be apparent immediately, tablets should be taken for at least 2 weeks continuously.

Maximum dose: 4 tablets per day.

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

4.3 Contraindications

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.
If the condition worsens during the use of the product consult a doctor or qualified healthcare professional.

The use of this product is not recommended in children and adolescents below the age of 18years because data are not sufficient 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. Additive effects with hypnotics and other sedative drugs cannot be excluded and therefore co-medication is not recommended as a general precaution.

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

Clinically relevant interaction with drugs metabolised by the CYP 2D6, CYP 3A4/5, CYP 1A2 or CYP 2E1 pathway has not been observed.

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established.
In the absence of sufficient data the use in pregnancy and lactation is not recommended.

Studies on the effects 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. If affected, do not drive or operate machines.

4.8 Undesirable effects

Gastrointestinal symptoms, such as nausea, abdominal cramps, may occur. The frequency is not known.

If other adverse reactions not mentioned above occur, a doctor or a 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; Email: medsafety@hpra.ie.

4.9 Overdose

Valerian root at a dose of approximately 20 g (equivalent to 11 tablets) 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.

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

Herbal Preparation
Maltodextrin
Colloidal anhydrous silica

Tablet Core
Maltodextrin
Microcrystalline cellulose
Sodium croscarmellose
Stearic acid
Colloidal anhydrous silica
Magnesium stearate

Tablet Coating
Hypromellose
Glycerol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C. Store in the original packaging.

6.5 Nature and contents of container

Tablets are packed into a PVC/PVDC blister strip and packed into a carton in the following pack sizes: 30, 60 and 90 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Lamberts Healthcare Limited,
1 Lamberts Road,
Tunbridge Wells,
Kent, TN2 3EH,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER

TR2029/001/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first registration: 23rd of December 2016.

10 DATE OF REVISION OF THE TEXT