Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Holland & Barrett Valerian Hard Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each hard capsule contains 337 mg of extract (as dry extract) from*Valeriana officinalis* L. radix (equivalent to 1683 mg - 2020 mg of valerian root). Extraction solvent: ethanol 70% v/v.

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Hard capsules (capsules)

Two piece clear, hard capsules with grey/brown fill.

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 older people:
For the relief of symptoms of mild mental stress: take 1 capsule 3 times daily. Swallow the whole capsule with water.

To aid sleep: Take one capsule 30 minutes before bedtime with an earlier dose during the evening if necessary.

As the treatment effects of this product may not be apparent immediately, Holland & Barrett Valerian Hard Capsules should be taken for 2 weeks continuously.

Maximum dose: 4 capsules per day.

Do not exceed the stated dose

Duration of use:
If symptoms persist, worsen or do not improve after 2 weeks use of Holland & Barrett Valerian Hard Capsules, a qualified healthcare professional, e.g. a doctor or a pharmacist should be consulted.

Not recommended for children or adolescents under 18 years.

4.3 Contraindications

Do not use in cases of known hypersensitivity to Valerian root or any of the excipients listed in section 6.1

Valerian should not be used in children and adolescents under 18 years because sufficient data is not available and medical advice should be sought.

4.4 Special warnings and precautions for use

Do not exceed 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, CYP1A2 or CYP 2E1 pathway has not been observed. 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.

4.6 Fertility, pregnancy and lactation

Safety 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 the ability to drive and use machines. If affected, patients should not drive or operate machinery.

4.8 Undesirable effects

Gastrointestinal symptoms such as nausea and abdominal cramps may 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, 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 20g (equivalent to approximately 10 capsules of Holland & Barrett Capsules) caused benign symptoms (fatigue, abdominal cramp, chest tightness, light-headedness, 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.

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 and carcinogenicity have not been performed.

An *in vitro* Ames study has shown the quantified dry extract used in Valerian is non-mutagenic.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium stearate
Maltodextrin
Colloidal anhydrous silica
Hypromellose

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25^{o}C.

Keep the bottle tightly closed in order to protect from light and moisture.

6.5 Nature and contents of container

Green polyethylene terephthalate (PET) bottles with a polypropylene cap and an inner seal liner made up of polyester, polymer adhesive layer, polyolefin foam and aluminium foil.

Pack sizes: 30 capsules
60 capsules

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 REGISTRATION HOLDER

Holland & Barrett International Limited
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United Kingdom

8 REGISTRATION NUMBER(S)

TR1563/001/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first registration: 7th September 2012

Date of last renewal: 6th September 2017

10 DATE OF REVISION OF THE TEXT

September 2017