Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Valdrian hard capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each hard capsule contains 400 mg of *Valeriana officinalis* L., radix minutata (Cut valerian root).

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Hard capsule (capsule)

Clear size 0 hard capsule containing a light brown powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Valdrian 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: For the relief of symptoms of mild mental stress, take one capsule 3 times daily swallowed with water. To aid sleep, take one capsule 30 minutes before bedtime with an earlier dose during the evening if necessary.

As treatment effects may not be apparent immediately, VALDRIAN should be taken for 2 weeks continuously. Maximum daily dose:- 4 single doses.

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

Not recommended for children or adolescents under 18 years.

4.3 Contraindications

Patients with known hypersensitivity to Valerian root or to any of the other ingredients of this product should not use VALDRIAN.

Valdrian should not be used in children and adolescents under 18 years.

4.4 Special warnings and precautions for use

None.

4.5 Interaction with other medicinal products and other forms of interactions

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 comedication is not recommended as a general precaution.

The effect of Valdrian may be increased by alcohol, excessive use of alcohol should therefore be avoided.

4.6 Fertility, pregnancy and lactation

The safety of VALDRIAN 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

VALDRIAN may impair ability to drive and use machines. Patients who are affected should not drive or operate machinery.

4.8 Undesirable effects

Gastrointestinal symptoms (eg nausea, abdominal cramps) may occur after ingesting VALDRIAN (valerian root). 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 medical product is important. it allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517 . Website: ww.hpra.ie; Email: medsafety@hpra.ie

4.9 Overdose

Valerian root at a dose of approximately 20g (equivalent to 50 VALDRIAN capsules) caused benign symptoms (fatigue, abdominal cramps, 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.

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

Extracts with ethanol and the essential oil of Valerian root have shown low toxicity in rodents during acute tests and from repeated dose toxicity over periods of 4-8 weeks. Tests on reproductive toxicity and carcinogenicity have not been performed.

An in vitro bacterial reverse assay has demonstrated Valdrian to be non-muntegenic up to a dose of 5000 mcg/plate.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule shell
Hypromellose

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 package in order to protect from light.

6.5 Nature and contents of container

HDPE plastic container and tamper-evident threaded HDPE cap.
Each pack contains 60 capsules.

6.6 Special precautions for disposal

No special requirements.

7 REGISTRATION HOLDER

Bio-H Europe Limited
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8 REGISTRATION NUMBER(S)

TR22719/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd September 2011
Date of last renewal: 22nd September 2016

10 DATE OF REVISION OF THE TEXT

March 2020