

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

SleepEezy Valerian tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains 150mg of extract (as dry extract) from Valerian root (*Valeriana officinalis* L). Equivalent to 750mg - 900mg of Valerian root.)

Extraction solvent: ethanol 70% v/v.

DER (native) 5-6:1, DER (final) 3.7-4.5:1

Each tablet contains dextrose (glucose) 1.8mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet, film-coated.

A brown circular convex coated tablet

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A traditional herbal medicinal product used for the temporary relief of sleep disturbances due to symptoms of mild anxiety based on traditional use only.

4.2 Posology and method of administration

For oral use only.

Adults and the elderly: take 1 – 2 tablets half an hour before bedtime. If necessary, an additional tablet can be taken earlier in the evening.

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

As treatment effects may not be apparent immediately, the tablets should be taken continuously for 2 – 4 weeks.

Duration of use:

If symptoms worsen or do not improve after 4 weeks a doctor or qualified healthcare practitioner should be consulted.

4.3 Contraindications

Hypersensitivity to Valerian or any of the excipients.

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 not sufficient and medical advice should be sought.

If symptoms worsen, or do not improve after 4 weeks, a doctor or qualified healthcare practitioner should be consulted.

Each tablet contains dextrose (glucose) 1.8mg (see section 6.1); Patients with rare hereditary problems of glucose-galactose malabsorption 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 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.

4.6 Fertility, pregnancy and lactation

The safety of the product during pregnancy has not been established. In the absence of sufficient data, the 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 cause dizziness and impair ability to drive and use machines. If affected, patients should not drive or operate machinery.

4.8 Undesirable effects

Gastrointestinal symptoms, such as nausea, vomiting, abdominal cramps and diarrhoea may occur. 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 qualified healthcare practitioner 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 of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Valerian root at a dose of 20g (equivalent to 22 – 27 tablets) 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 intake of very high doses of valerian root over several years (daily consumption corresponding to approximately 10g 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

Extract

Maltodextrin

Silica colloidal anhydrous

Tablet core

Calcium hydrogen phosphate anhydrous

Cellulose microcrystalline

Silica colloidal hydrated

Croscarmellose sodium

Magnesium stearate

Tablet coating

Croscarmellose sodium

Lecithin

Dextrose monohydrate (glucose)

Sodium citrate

Dextrin

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 25⁰C

Store in the original package.

6.5 Nature and contents of container

Ph Eur type III glass bottles with polypropylene closure incorporating an induction heat seal liner. Printed outer carton containing Patient Information Leaflet.

Pack sizes: 30, 60, 90 tablets. Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Natures Aid Ltd

St Georges Park

Kirkham

Preston

Lancashire PR4 2DQ

Tel: 01772 686231

Fax: 01772 671688

email: sales@naturesaid.co.uk

8 MARKETING AUTHORISATION NUMBER(S)

THR 33336/0006

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12/01/2012

10 DATE OF REVISION OF THE TEXT

14/08/2023

11 DOSIMETRY (IF APPLICABLE)

**12 INSTRUCTIONS FOR PREPARATION OF
RADIOPHARMACEUTICALS (IF APPLICABLE)**