Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Natures Aid Sleepeeze Valerian Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains 150mg of extract (as dry extract) from *Valeriana officinalis* L. radix (Valerian root) (equivalent to 750mg - 900mg of Valerian root).
Extraction solvent: ethanol 70 %v/v.
Excipients with known effect:
Each tablet contains glucose (dextrose) 2.4mg
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet (tablet).
A brown circular convex film-coated tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A traditional herbal medicinal product used for the relief of mild symptoms of 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 relief of mild symptoms of mental stress one to two tablets to be taken daily.
To aid sleep, one tablet to be taken 30-60 minutes before bedtime. One additional tablet can be taken earlier in the evening if necessary.
Not recommended for children or adolescents under 18 years (see Section 4.4).
Maximum dose: 3 tablets per day
Duration of use:
As treatment effects may not be apparent immediately, the tablets should be taken continuously for 2 weeks.
If symptoms worsen, persist or do not improve after 2 weeks, a qualified healthcare professional e.g. a doctor or a pharmacist should be consulted.

4.3 Contraindications

Hypersensitivity to Valerian root or to any of the excipients listed in section 6.1.

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, persist or do not improve after 2 weeks, a qualified healthcare professional e.g. doctor or pharmacistshould be consulted.
Each tablet contains glucose 2.4mg. Patients with rare 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 the ability to drive and use machines. 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 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 of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the:
HPRA Pharmacovigilance
Website: www.hpra.ie

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

In vitro tests for detection of genetic mutation (Ames test) with Valerian root dry extract did not demonstrate mutagenic activity.
Test of reproductive toxicity and carcinogenicity have not been performed with Valerian root dry extract.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Extract
Maltodextrin
Silica, colloidal anhydrous

Tablet core
Calcium hydrogen phosphate
Cellulose, microcrystalline
Silica, colloidal hydrated
Croscarmellose sodium
Magnesium stearate

Tablet coating
Croscarmellose sodium
Lecithin
Glucose monohydrate
Sodium citrate
Dextrin

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 25^0C
Store in the original package.

6.5 Nature and contents of container

Ph Eur type III amber glass bottles with polypropylene closure incorporating an induction heat seal liner. Printed outer carton containing Patient Information Leaflet.
Pack sizes: 30, 60 or 90 film coated tablets. Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 REGISTRATION HOLDER

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8 REGISTRATION NUMBER(S)

TR0126/316/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th August 2022

10 DATE OF REVISION OF THE TEXT

November 2024