Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Kalms Night Film-Coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 385mg of extract (as dry extract) from *Valeriana officinalis* L., radix (equivalent to 1540 mg – 1925 mg of Valerian root).

Extraction solvent: Ethanol 60% v/v.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.
Off-white, ovaloid film-coated tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Kalms Night is a traditional herbal medicinal product used 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: One tablet to be taken 30-60 minutes before bedtime.
One additional tablet can be taken earlier in the evening if necessary

As treatment effects may not be apparent immediately, Kalms Night should be taken for 2 weeks continuously.

Duration of use:
If symptoms worsen or do not improve after 2 weeks, 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

Hypersensitivity to the active substances or to any of the excipients.

4.4 Special warnings and precautions for use

Do not exceed stated dose

The use of this product in children or adolescents under 18 years of age is not recommended because data are not sufficient and medical advice should be sought.

If symptoms persist or worsen after 2 weeks of using the medicinal product, a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

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 Kalms Night may be increased by alcohol. Excessive concomitant consumption of alcohol should therefore be avoided.

4.6 Fertility, pregnancy and lactation

The safety of Kalms Night 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

Kalms Night may impair ability to drive and use machines.

Patients who are affected should not drive or operate machinery.

4.8 Undesirable effects

Gastrointestinal symptoms (e.g. nausea, abdominal cramps) may occur. The frequency is not known.

If other adverse reactions not mentioned above occur, a qualified 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 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; E-mail: medsafety@hpra.ie.

4.9 Overdose

Valerian root at a dose of approximately 20 g (equivalent to 10 to 13 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 10 g of the drug) withdrawal symptoms (delirium) have been reported.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not required as per Article 16 c (1) (a) (iii) of Directive 2001/83/EC as amended.

5.2 Pharmacokinetic properties

Not required as per Article 16 c (1) (a) (iii) of Directive 2001/83/EC as amended.

5.3 Preclinical safety data

Genotoxicity testing has been performed on the product. Reverse mutation assays (Ames test) on bacteria indicated that the product was not mutagenic in Salmonella typhimurium (strains TA 98, TA 100, TA 102, TA 1535 and TA 1537) mutation assays with or without metabolic activation.

Tests on reproductive toxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Extract excipients
Maltodextrin
Colloidal anhydrous silica

Tablet Core
Croscarmellose sodium
Microcrystalline cellulose
Magnesium Stearate
Silicon Dioxide
Talc

Tablet Coating
Opadry 07F28588 White (hypromellose, talc, titanium dioxide, macrogol and saccharin sodium.)

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 moisture and light.

6.5 Nature and contents of container

14, 21, 28, 42 or 56 tablets stored in PVC/Aclar® -aluminium/polyethylene laminate blister packs. 50 tablets stored in amber glass bottles (Ph. Eur. Type III glass) fitted with white HDPE tamper evident caps.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 REGISTRATION HOLDER

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8 REGISTRATION NUMBER(S)

TR22702/001/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first registration: 3rd May 2013

Date of last renewal: 2nd May 2018

10 DATE OF REVISION OF THE TEXT

March 2024