Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Kalms Day film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 52 mg of extract (as dry extract) from *Valeriana officinalis* L., radix (equivalent to 208 mg – 260 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, circular, biconvex film-coated tablet

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Kalms Day is a traditional herbal medicinal product for the relief of symptoms of mild mental stress 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 3 times a day.
As treatment effects may not be apparent immediately, Kalms Day should be taken for 2 weeks continuously.

Duration of use:
If symptoms persist, worsen or do not improve after 2 weeks use of Kalms Day 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 Kalms Day.

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

4.4 Special warnings and precautions for use

This medicine contains less than 1 mmol sodium (23mg) per tablet, that is to say essentially "sodium free".

4.5 Interaction with other medicinal products and other forms of interaction

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

4.6 Fertility, pregnancy and lactation

The safety of Kalms Day 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 Day may cause dizziness and impair ability to drive and use machines.
Patients who are affected 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 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 the HPRA Pharmacovigilance Website: www.hpra.ie.

4.9 Overdose

Valerian root at a dose of approximately 20 g (equivalent to 77 to 96 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

Pharmacotherapeutic group: Other hypnotics and sedatives, ATC code: N05CM

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

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
Hops extract
Croscarmellose Sodium
Microcrystalline Cellulose
Magnesium Stearate
Pregelatinised Starch
Silicon Dioxide
Stearic Acid

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

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

30 months

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

21 or 42 tablets stored in PVC/Aclar® -aluminium/polyethylene laminate blister packs – pocketpack format with sliding blisters attached to the carton.

21, 42 or 84 tablets stored in PVC/Aclar® -aluminium/polyethylene laminate blister packs.
100 tablets stored in 60ml 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)

TR22702/002/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first registration: 10th May 2013

Date of last renewal: 9th May 2018

10 DATE OF REVISION OF THE TEXT

December 2024