SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Kalms Lavender One-a-Day capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each soft capsule contains:

80 mg of oil from flowering tops of Lavender (*Lavandula angustifolia* Miller, aetheroleum).

Each soft capsule also contains: up to 13 mg of sorbitol (see 'Section 4.4 Special warnings and precautions for use'.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oval transparent colourless to pale yellow soft capsule

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A traditional herbal medicinal product used for the temporary relief of the symptoms of mild anxiety such as stress and nervousness based on traditional use only.

4.2 Posology and method of administration

For oral use only. The capsules should be swallowed with a full glass of water. The capsules should not be chewed.

Adults and the elderly. Take one soft capsule once daily.

The use of this product in children and adolescents under 18 years of age is not recommended (see Section 4.4. Special warnings and precautions for use. ').

If the symptoms worsen, or do not improve after 2 weeks, a doctor or qualified healthcare practitioner should be consulted.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1. Hepatic impairment

4.4 Special warnings and precautions for use

Do not exceed the stated dose.

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

If the symptoms worsen, or do not improve after 2 weeks, a doctor or qualified healthcare practitioner should be consulted.

Should not be taken with other medicines for sleep or anxiety.

This product is intended for the relief of symptoms of mild anxiety such as stress and nervousness. Patients with signs and symptoms of depression should seek medical advice for appropriate treatment.

4.5 Interaction with other medicinal products and other forms of interaction

None reported.

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

No impairment of fertility with Lavender oil was shown in reproductive toxicity studies in rats and rabbits (see section 5.3).

4.7 Effects on ability to drive and use machines

May impair ability to drive and use machines. Affected patients should not drive or operate machinery.

4.8 Undesirable effects

The evaluation of adverse reactions is based on the following information on frequency:

Very common (≥1/10)

Common (≥1/100 to <1/10)

Uncommon (≥1/1,000 to <100)

Rare (≥1/10,000 to <1/1,000)

Very rare (<1/10,000)

not known (cannot be estimated from the available data)

Gastrointestinal disorders
Common: eructation

Skin and subcutaneous tissue disorders / Immune system disorders
Frequency not known: hypersensitivity reactions
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 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

No case of overdose has been reported.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not required as per Article 16c(1)8a)(iii) of Directive 2001/83/EC as amended.

5.2 Pharmacokinetic properties

Not required as per Article 16c(1)8a)(iii) of Directive 2001/83/EC as amended.

5.3 Preclinical safety data

In the mouse, no symptoms of systemic toxicity were found after oral administration of Lavender oil at single doses of up to 2000 mg/kg. The administration of doses of 2700 mg/kg up to 4000 mg/kg of Lavender oil by oral route led in a dose-dependent manner to a mild to moderate inhibition of motility, ataxia and dyspnoea.

In safety-pharmacological investigations, no effect of Lavender oil on cardiovascular para¬meters (NOEL* ≥ 450 mg/kg orally, dog), behaviour and body temperature (NOEL* ≥ 450 mg/kg orally, rat) was observed; in the rat, a dose of 450 mg/kg orally led to a short-term respiration-stimulating effect (NOEL* 150 mg/kg orally).

Chronic toxicity was investigated in the rat and dog (30, 100 or 300 mg/kg Lavender oil by oral route) for a duration of 26 weeks (rat) and 39 weeks (dog). In both studies, the NOAEL** was 300 mg/kg BW.

Studies on reproductive toxicity were carried out in the rat (combined segment I and segment II study, segment III study) and in the rabbit (segment II study) with doses ranging from 30 to 300 mg/kg Lavender oil by oral route. No effect on fertility, embryo-fetal as well as peri- and postnatal development was observed.

No mutagenicity was observed in tests (AMES test, test with cultivated human lymphocytes, micronucleus test) conducted with Lavender oil.

Studies on carcinogenicity have not been performed.

* NOEL = No observed effect level

** NOAEL = No observed adverse effect level

6.1 List of excipients

Gelatin succinylated

Glycerol 85%

Refined rapeseed oil

Sorbitol (E 420)

6.2 Incompatibilities

None known

6.3 Shelf life

5 years

6.4 Special precautions for storage

Do not store above 30 °C. Store in the original packaging.

6.5 Nature and contents of container

Original packages containing 14, 28 and 56 soft capsules.

The soft capsules are packed in PVC/PVDC blisters and inserted into a carton together with the package leaflet.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

Dr. Willmar Schwabe GmbH & Co. KG
Willmar-Schwabe-Str. 4
76227 Karlsruhe
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8 MARKETING AUTHORISATION NUMBER(S)

THR 05332/0008

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30/11/2015

10 DATE OF REVISION OF THE TEXT

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