SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Lavendelolja Silexan soft capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 soft capsule contains:
80 mg *Lavandula angustifolia* Miller, aetheroleum (lavender oil).

Excipient with known effect: Sorbitol, approx. 12 mg/soft capsule.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Soft capsule
Oval transparent colourless soft capsule.

Capsule dimensions: length approx. 11 mm, width approx. 7 mm.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Traditional herbal medicinal product for relief of mild anxiety and to aid sleep.

The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.

Lavendelolja Silexan is indicated in adults and adolescents from 12 years of age.

4.2 Posology and method of administration

Posology

Adults and adolescents from 12 years of age: One soft capsule once daily (corresponding to 80 mg lavender oil per day).

Paediatric population

Lavendelolja Silexan should not be used in children under the age of 12 years (see section 4.4).

Method of administration

Oral use. The soft capsules are to be swallowed whole with sufficient liquid (preferably a glass of water).

Duration of use
If the symptoms persist after two weeks use of the product, a doctor or a qualified health care practitioner should be consulted.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

The use in children under 12 years of age has not been established due to lack of adequate data.
If the symptoms worsen during the use of the product, a doctor or a qualified health care practitioner should be consulted.
The use in patients with impairment of hepatic function is not recommended as components of lavender oil are largely eliminated by metabolism in the liver.

4.5 Interaction with other medicinal products and other forms of interaction

Published data show that lavender oil (160 mg/day) has no clinically relevant inhibitory or inducing effects on the CYP 1A2, 2C9, 2C19, 2D6 and 3A4 enzymes in human. In addition, no relevant clinical impact of lavender oil on the contraceptive efficacy of combined oral contraceptive was found.

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. Data on fertility are not available.

4.7 Effects on ability to drive and use machines

Lavendelolja Silexan has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Gastrointestinal disorders
Mild gastrointestinal complaints (e.g. eructation). The frequency is not known.

Skin and subcutaneous tissue disorders / Immune system disorders
Hypersensitivity reactions. The frequency is not known.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the safety of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in …[To be completed nationally]

4.9 Overdose

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other anxiolytics, ATC code: N05BX05

5.2 Pharmacokinetic properties

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5.3 Preclinical safety data

In vitro and *in vivo* genotoxicity tests performed with lavender oil contained in Lavendelolja Silexan did not show any genotoxic potential. Adequate tests on carcinogenicity and reproductive toxicity of lavender oil have not been performed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule content:
rapeseed oil, refined

Capsule shell:
gelatin succinylated
glycerol 85%
sorbitol 70%, non crystallising

6.2 Incompatibilities

None known

6.3 Shelf life

5 years

6.4 Special precautions for storage

Do not store at temperatures above 30 °C.

6.5 Nature and contents of container

The container (blister) is made of PVC/PVDC/Al foil.
Packs with 14, 28 and 56 soft capsules.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements

7. REGISTRATION HOLDER

Dr. Willmar Schwabe GmbH & Co. KG
Willmar-Schwabe-Str. 4
76227 Karlsruhe
Germany

8. REGISTRATION NUMBER(S)

<[To be completed nationally]>

9. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

<[To be completed nationally]>

10. DATE OF REVISION OF THE TEXT

2024-06-25