Physicians Prescribing Information

1. NAME OF THE MEDICINAL PRODUCT

Lasea®

80 mg / soft capsule

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 soft capsule contains:
Active substance: 80 mg lavender oil (Silexan®)
Contains 12 mg sorbitol. For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Soft capsule

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Treatment of Anxiety, in adults

4.2. Posology and method of administration

Adults from 18 years of age take one soft capsule once daily (corresponding to 80 mg lavender oil per day).

The soft capsules are to be taken in whole, unchewed with sufficient liquid (preferably a glass of water). The soft capsule should not be cut or emptied. Lasea® should not be taken in a lying position.

Children and adolescents
Lasea® is contraindicated for persons under the age of 18 years as there are no adequate data available concerning the application of this pharmaceutical product in this age group.

Mode of application
If the symptoms persist unchanged or deteriorate after two weeks of treatment, you should consult your doctor.

4.3. Contraindications

Lasea® is not to be taken:

- In case of liver dysfunction (hepatic failure)
- Hypersensitivity to lavender oil or one of the other constituents of the pharmaceutical product.
- In case a hypersensitivity reaction was developed to Lasea in previous use.
- By children and adolescents under 18 years of age.

4.4. Specials warnings and precautions for use

Please take note to 4.3 and 4.6

4.5. Interactions with other medicinal products and other forms of interaction

None known

4.6. Pregnancy and lactation

No impairment of fertility and embryo-foetal development due to Lasea® was shown in reproductive toxicity studies in rats and rabbits (see section 5.3). Clinical data on the use of lavender oil during pregnancy are not available. Lasea® should therefore not be used during pregnancy.
The safety of the use of Lasea® during lactation has not yet been investigated. It is not known whether constituents of lavender oil or their metabolites are excreted in breast milk. Nursing women should therefore not take Lasea®.

4.7. Effects on ability to drive and use machines

None known

4.8. Undesirable effects

Adverse reactions are listed based on the following information about their frequency:

Very common: affects at least 1 out of 10 treated persons	**Common:** affects at least one and fewer than 10 of 100 treated persons
Uncommon: affects at least one and fewer than 10 of 1,000 treated persons	**Rare:** affects at least one and fewer than 10 of 10,000 treated persons
Very rare: affects fewer than 1 in 10,000 treated persons	**Not known:** Cannot be estimated from the available data

Immune system disorders:
Frequency not known: In individual cases, severe hypersensitivity reactions with swelling, circulatory complaints and / or respiratory complaints have been reported. In such cases, a doctor must be informed immediately.
If hypersensitivity reactions occur, Lasea® must be discontinued.

Diseases of the gastrointestinal tract:
Common: eructation
Frequency not known: other gastrointestinal complaints.

Skin and subcutaneous tissue disorders:
Frequency not known: allergic skin reactions.

The following note for the patient is included in the information leaflet:
"Please inform your doctor or pharmacist if you are considerably impaired by one of these side effects."

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il Or directly to Dr. Samuelov's drug safety department at: drugsafety@drsamuelov.co.il

4.9. Overdose

No cases of overdose are known up to date.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

In animal experiments carried out with lavender oil (Silexan®) contained in Lasea®, anxiolytic, antidepressive and sedative properties could be demonstrated after oral application. With regards to the mechanism of action of lavender oil, in vitro investigations indicated an effect on the $GABA_A$ receptors via potentiation of the response of $GABA_A$ receptors to GABA.
Spasmolytic effects of lavender oil could be demonstrated in vitro.

5.2. Pharmacokinetic properties

Published investigations on pharmacokinetics of lavender oil after oral application are not available.

5.3. Preclinical safety data

In mice, no symptoms of systemic toxicity were found after oral administration of WS® 1265 at doses of up to 2000 mg/kg; orally administered doses between 2700 mg/kg and 4000 mg/kg of WS® 1265 led to a dose-dependent mild to moderate inhibition of motility, ataxia and dyspnoea.
In pharmacological safety studies, WS® 1265 was not observed to affect cardiovascular parameters (NOEL* ≥ 450 mg/kg orally, dog), behaviour or body temperature (NOEL* ≥ 450 mg/kg orally, rat); in rats, 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 rats and dogs (30, 100 or 300 mg/kg WS® 1265 orally administered) for a duration of 26 weeks (rats) and 39 weeks (dogs). In both studies, the NOAEL** was 300 mg/kg BW.
Studies on reproductive toxicity were carried out in rats (combined segment I and segment II study, segment III study) and in rabbits (segment II) with doses of 30, 100 and 300 mg/kg WS® 1265 administered orally. In rabbits, complete foetal resorption in

the early post-implantation phase was observed in one animal of the low dose group (N=21) and in two animals respectively of the medium (N=22) and high dose groups (N=21). No embryotoxic effects were found in rats. The NOEL test was above 300 mg/kg/day.Mutagenicity tests with WS® 1265 (Ames test, test with cultivated human lymphocytes, micronucleus test) showed no evidence of mutagenic properties of WS® 1265. Studies on carcinogenicity are not available.

** NOEL = No observed effect level*
*** NOAEL = No observed adverse effect level*

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Gelatin succinylated; glycerol 85%; refined rapeseed oil; sorbitol solution 70%; carmine lacquer (E 120); patent blue V; aluminium lacquer (E 131); titanium dioxide (E 171).

6.2. Incompatibilities

None known

6.3. Shelf-life

The expiry date is printed on both pack and container (blister strip). Lasea® should not be used after expiry of shelf life.

6.4. Special precautions for storage

Do not store at temperatures above 30 °C.

6.5. Nature and contents of container

The container (blister pack) is made of PVC/PVDC foil and aluminium foil. Each blister pack contains 14 soft capsules.

6.6. Special precautions for disposal / handling of the product

No special requirements

7. PHARMACEUTICAL COMPANY AND MANUFACTURER

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

8. ISRAELI MARKETING AUTHORIZATION HOLDER

Dr. Samuelov Importing & Marketing Ltd
13 Hasadna st, POB 2486
Ra'anana 4365007, Israel
Phone: 09 7483769

9. MARKETING AUTHORIZATION NUMBER

155-33-34385-00

10. DATE OF FIRST AUTHORIZATION/RENEWAL OF AUTHORIZATION

01/2016

11. DATE OF REVISION OF THE TEXT

Revised in August 2021 according to MOHs guidelines.

LASEA-SPC-06/2021