

**Patient package insert according to Pharmacists' Regulation (Preparations)-
1986**

This medicine can be sold with a physician's prescription only.

Lasea®

Soft capsules

Name of the medicine, its form and strength

Name of the medicine: Lasea®

Form: Soft capsules

The active ingredient and its quantity in a dosage unit:

Each soft capsule contains Lavender oil (Silexan®) 80 mg.

For list of excipients and allergens in the medicine - see section 6.

Read this entire leaflet carefully before using this medicine.

This leaflet contains concise information about the medicine. If you have any further questions, ask the physician or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that their medical condition is similar.

The medicine is intended for adults above 18 years of age.

1. What is the medicine intended for?

The medicine Lasea® is intended for adults, for treatment of anxiety.

Therapeutic group: Anxiolytics.

2. Before using this medicine:

Do not use the medicine:

- If you suffer from liver dysfunction (liver failure).
- If you are hypersensitive (allergic) to lavender or to any of the other ingredients this medicine contains. The active ingredient appears in section 1 and the other ingredients are listed in section 6.
- If you have previously developed hypersensitivity (an allergic reaction) to Lasea®
- Under 18 years of age.

Special warnings regarding the use of this medicine:

Drug interactions: If you are taking or have recently taken any other medicines, including non-prescription drugs and nutrition supplements, tell your physician or pharmacist.

As of now there are no known interactions between Lasea® and other medicines.

Children and adolescents:

Do not use Lasea® in children and adolescents under 18 years of age since there is not enough information regarding use of the medicine in this age group.

Pregnancy and breast-feeding:

In experimental studies, no fetal toxicity has been observed as a result of using the active ingredient in Lasea®, Since clinical data on the use during pregnancy have not been carried out, do not use the Lasea® during pregnancy.

Since the safety of Lasea® during breast-feeding has not yet been tested, do not use the medicine while breast-feeding.

Important information about some of the ingredients of the medicine:

Each soft capsule contains 12 mg sorbitol. Consult your physician before using this medicine if you have an intolerance to sugars.

3. How to use this medicine

Always use according to your physician's instructions. Check with your physician or pharmacist if you are not sure. The dosage and manner of treatment will be determined by your physician only.

The usual recommended dosage in adults (above 18 years of age) is:

One capsule of Lasea® once daily.

Swallow the medicine whole with a sufficient amount of drinking liquid (preferably a glass of water).

Do not chew the capsule, do not cut or empty the contents of the capsule.

Do not take the capsule while you are lying down.

Do not exceed the recommended dose.

Treatment duration with the medicine:

Your physician will decide on the treatment duration according to your condition.

Consult your physician if you feel that the effect of the medicine is too strong or too weak or if your condition worsens. If after two weeks of treatment with the medicine you do not feel any improvement or betterment or if your symptoms get worse, consult the attending physician.

If you have accidentally taken an overdose or if a child swallowed the medicine, proceed immediately to a physician or a hospital emergency room and bring the package of the medicine with you. If you have taken an overdose, the side effects of using the medicine may be stronger. No cases of overdose have been reported so far.

If you forgot to take the medicine at the designated time, do not take a double dose. Take the next dose at the usual time and consult your physician.

Continue with the treatment as recommended by your physician. Even if there is an improvement in your health, do not discontinue treatment with this medicine without consulting your physician.

Do not take medicines in the dark! Check the label and dose each time you take a medicine. Wear glasses if you need them. If you have any further questions regarding the use of this medicine, consult your physician or pharmacist.

4. Side effects

Like any medicine, the use of Lasea® may cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.

The list of side effects listed below includes all the side effects reported as a result of using lavender oil, including cases of long-term treatment or higher dosage.

Side effects that were reported in individual cases:

Hypersensitivity (an allergic reaction) accompanied by swelling, blood circulation and/or respiratory disorders were reported in individual cases. In these cases, proceed immediately to a doctor or seek medical attention.

Common side effect that appears in 1-10 users out of 100:

Belching

Side effects whose frequency is unknown (side effects whose frequency has not yet been determined):

Allergic skin reactions, other gastrointestinal disorders.

If a side effect appears, if one side effect gets worse or if you suffer from a side effect which not mentioned in this leaflet, consult your physician.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" that can be found on the home page of the Ministry of Health's website (www.health.gov.il), directing to the online form side effects reporting or by clicking on the following link: <https://sideeffects.health.gov.il>

In addition, side effects can be reported to Dr. Samuelov Importing and Marketing Ltd. via the e-mail: drugsafety@drsamuelov.co.il

5. How to store the medicine

Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.

Do not use the medicine after the expiry date (exp. date) stated on the carton package or blister. The expiry date refers to the last day of that month.

Storing conditions: Do not store at a temperature above 30°C.

6. Additional information

In addition to the active ingredient, the medicine also contains:

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).

What the medicine looks like and contents of the package:

Lasea® is an oval, soft, blue-purple capsule. The capsules are packed in blisters, which are packed in carton boxes.

Size of package: Lasea® is supplied in carton packages containing plastic tray/s with 14 soft capsules. The number of plastic trays in each carton package may vary according to the size of the package. Not all package sizes may be marketed.

Registration holder and importer: Dr. Samuelov Importing and Marketing Ltd., Company ID 512260944 P.O.B 2486, Ra'anana 4365007.

Manufacturer: Dr. Willmar Schwabe GmbH & Co. KG, Karlsruhe, Germany. Revised in August 2021 according to MOH guidelines.

Registration number of the medicine at the national drug registry of the Ministry of Health: 155-33-34385-00

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