PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine can be sold without a physician's prescription

Lavecalm®
Soft Capsules

The active ingredient and its quantity in a dosage unit:
Each soft capsule contains:
Lavender oil (Silexan®) 80 mg.
For list of all inactive ingredients and allergens in the medicine – see section 6.
For important information about some of the ingredients of the medicine – see section 2.

Read this entire leaflet carefully before using this medicine.
This leaflet contains concise information about this medicine. If you have any further questions, refer to the physician or pharmacist.
Lavecalm® Soft Capsules is intended for adults.
You must take the medicine according to the instructions in the dosage section of this leaflet. Refer to a physician if the symptoms of the disease worsen or do not improve after 14 days of using the medicine.
Consult a pharmacist if you need more information.

1. What is the medicine intended for?
Herbal medicinal product for relief of mild symptoms of mental stress and to aid sleep, in adults.
Therapeutic group: Anxiolytics**.**

2. Before using this medicine:
Do not use this medicine:

- If you suffer from a liver dysfunction (liver failure).
- If you are hypersensitive (allergic) to lavendar 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 (allergic reaction) to Lavecalm®.
- Under 18 years of age.

Special warnings regarding the use of the 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 Lavecalm® and other medicines. No interaction has been found between the active ingredient in Lavecalm® and birth control pills.

Children and adolescents: Do not use Lavecalm® 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 laboratory studies, no fetal toxicity has been observed as a result of using the active ingredient in Lavecalm®. Since no clinical studies on

Lavecalm® use during pregnancy have been conducted, do not use Lavecalm® during pregnancy.
Since the safety of Lavecalm® 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.

Driving and operating machinery: Lavecalm® has no or negligible effect on the ability to drive or use and operate machinery.

3. How to use this medicine?

Check with your physician or pharmacist if you are not sure about the dosage and manner of treatment with the medicine.
The usual recommended dosage in adults (18 years of age and above) is: One capsule once daily.
Do not exceed the recommended dose.

Treatment duration: The treatment duration depends on the disease duration. Consult a physician if the disease symptoms worsen or do not improve after 14 days of using the medicine.

Method of administration: Swallow the medicine whole with a sufficient amount of drinking liquid (preferably a glass of water).
Do not take the capsule while you are lying down.
Crushing/halving/chewing: Do not crush or chew, halve or empty the contents of the capsule.

If you have accidentally taken a higher dose, inform your physician; he will decide if it is necessary to take any action. In case of an overdose, the side effects listed below may be stronger. If a child has accidently swallowed the medicine, proceed immediately to a physician or a hospital emergency room and bring the package of the medicine with you.

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 a pharmacist or physician.

Do not take medicines in the dark! Check the label and dose each time you take the 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 Lavecalm® 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 use or high 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 physician or seek medical attention.

Common side effects that appear 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, worsens, or if you suffer from a side effect not mentioned in the 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 for reporting side effects, 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 email: 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.
Storage conditions: Do not store at a temperature above 30ºC.

6. Additional information

In addition to the active ingredient, the medicine also contains the following inactive ingredients:
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: Lavecalm® is an oval, soft, blue-purple capsule. Capsule length: 11 mm, width: 7 mm. The capsules are packed in plastic trays (blisters), which are packed in carton boxes.
Size of package: Lavecalm® is supplied in carton packages containing plastic trays with 14 soft capsules. The number of plastic trays in each carton package may vary according to the size of the package. The total number of capsules in each package appears on the carton package. Not all pack sizes may be marketed.

Registration holder and importer: Dr. Samuelov Importing and Marketing Ltd., Company ID 512260944, P.O.B 2486, Ra'anana 4365007. Phone: 09-7483769, email address: info@drsamuelov.co.il
Manufacturer: Dr. Willmar Schwabe GmbH & Co. KG, Karlsruhe, Germany.
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Registration number of the medicine in the national drug registry of the Ministry of Health: 173-95-36643-99

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