

PACKAGE LEAFLET

Package leaflet: Information for the patient

Lavender oil Medipha soft capsules

Lavender oil

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You should talk to a doctor if you feel worse or if you do not feel better after two weeks.

What is in this leaflet

1. What [Product name] soft capsules is and what it is used for
2. What you need to know before you take [Product name] soft capsules
3. How to take [Product name] soft capsules
4. Possible side effects
5. How to store [Product name] soft capsules
6. Contents of the pack and other information

1. What [Product name] soft capsules is and what it is used for

[Product name] soft capsules is a traditional herbal medicinal product for relief of mild anxiety and to aid sleep.

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

[Product name] is indicated in adults and adolescents from 12 years of age.

2. What you need to know before you take [Product name] , soft capsules

Do not take [Product name] , soft capsules

- if you are allergic to lavender oil or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

If the symptoms worsen during the use of the product, a doctor or a qualified healthcare 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.

Children and adolescents

[Product name], soft capsules should not be used in children under the age of 12 years as there are no adequate data available concerning the use of this medicinal product in this age group.

Other medicines and [Product name] , soft capsules

No case of interactions of [Product name], soft capsules with other medicines has been reported.

In the event of contact with a doctor or other healthcare professional, remember to tell them if you are taking or have recently taken this non-prescriptive medicine.

Pregnancy, breast-feeding and fertility

In the absence of sufficient data, the use of [Product name], soft capsules during pregnancy and lactation is not recommended. Data on fertility are not available.

Driving and using machines

[Product name], soft capsules has no or negligible influence on the ability to drive and use machines.

[Product name] , soft capsules contains sorbitol.

This medicine contains 8,4 mg sorbitol in each soft capsule.

3. How to take [Product name] , soft capsules

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults and adolescents from 12 years of age:

One soft capsule once daily.

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, you should consult your doctor or a qualified healthcare practitioner.

Use in children and adolescents

[Product name], soft capsules should not be taken by children under the age of 12 years.

If you take more [Product name] , soft capsules than you should

No case of overdose has been reported.

If you forget to take [Product name] , soft capsules

Do not take a double dose to make up for a forgotten dose but continue the intake as told by your doctor or pharmacist or as described in this leaflet.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Frequency not known (cannot be estimated from the available data):

- Mild gastrointestinal complaints (e.g. belching);
- Hypersensitivity reactions.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via **the national reporting system**. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store [Product name] soft capsules

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the container (blister). The expiry date refers to the last day of that month.

No specific storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What [Product name], soft capsules contains

- The active substance is lavender oil (*Lavendula angustifolia* Mill. , aetheroleum):
1 soft capsule contains lavender oil (*Lavendula angustifolia* Mill. , aetheroleum).
- The other ingredients are:
Rapeseed oil refined; Gelatin; Glycerol 85% (E422); Sorbitol, liquid (non-crystallising); Carminic Acid (E120); Patent blue V (E131).

What [Product name], soft capsules looks like and contents of the pack

Purple colour round soft capsule containing a clear and yellowish oily solution.

The soft capsules are packed into blister made of PVC/PVDC Aluminium.

[Product name] soft capsules is available in packs with 14, 28 and 56 soft capsules.

Not all pack sizes may be marketed.

Registration Holder

MEDIPHA SANTE
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Manufacturer

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