

PACKAGE LEAFLET

Package leaflet: Information for the patient

Serlieve, soft capsules Lavender oil

Read all of this leaflet carefully before you start taking this medicine because it contains important information for 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 Serlieve is and what it is used for
2. What you need to know before you take Serlieve
3. How to take Serlieve
4. Possible side effects
5. How to store Serlieve
6. Contents of the pack and other information

1. What Serlieve is and what it is used for

Serlieve is a 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.

What you need to know before you take Serlieve

Do not take Serlieve

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 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.

Children and adolescents

Serlieve should not be used in children under the age of 12 years as there are no adequate data available concerning the application of this medicinal product in this age group.

Other medicines and Serlieve

No case of interactions of Serlieve with other medicines has been reported.

In the event of contact with a doctor or other health care 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 Serlieve during pregnancy and lactation is not recommended. Data on fertility are not available.

Driving and using machines

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

Serlieve contains sorbitol.

This medicine contains approx. 12 mg sorbitol in each soft capsule.

2. How to take Serlieve

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 health care practitioner.

Use in children and adolescents

Serlieve should not be taken by persons under the age of 12 years.

If you take more Serlieve than you should

No case of overdose has been reported.

If you forget to take Serlieve

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 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 national notification system mentioned below. By reporting side effects you can help provide more information on the safety of this medicine.

Website: <http://www.infarmed.pt/web/infarmed/submissaoram>
(preferably)

Or through the following contacts:

Direção de Gestão do Risco de Medicamentos

Parque da Saúde de Lisboa, Av. Brasil 53

1749-004 Lisboa

Tel: +351 21 798 73 73

Medicine Line: 800222444 (free)

Email: farmacovigilancia@infarmed.pt

5. How to store Serlieve

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 strip) after Exp. The expiry date refers to the last day of that month.

Do not store at temperatures above 30 °C.

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 Serlieve contains

- The active substance is Lavender oil (*Lavandula angustifolia* Miller, aetheroleum)
1 soft capsule contains 80 mg Lavender oil (*Lavandula angustifolia* Miller, aetheroleum).
- The other ingredients are:
Gelatin succinylated; glycerol 85%; refined rapeseed oil; sorbitol 70% non crystallising; carminic acid aluminium lake (E 120); patent blue V aluminium lake (E 131); titanium dioxide (E171).

What Serlieve looks like and contents of the pack

Serlieve is an oval bluish-violet opaque soft capsule. Capsule dimensions: length approx. 11 mm, width approx. 7 mm.

The soft capsules are packed into blister strips. Serlieve is available in packs with 14, 28 and 56 soft capsules. Not all pack sizes may be marketed.

Registration Holder and Manufacturer

Dr. Willmar Schwabe GmbH & Co. KG
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Lubefar – Produtos Farmacêuticos, Lda.
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