

Kalms Day Film-Coated Tablets Valerian Root Extract

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 or pharmacist 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to your doctor if you do not feel better or if you feel worse after 2 weeks.

In this leaflet

1. What Kalms Day is and what it is used for
2. What you need to know before you take Kalms Day
3. How to take Kalms Day
4. Possible side effects
5. How to store Kalms Day
6. Contents of the pack and other information

1. What Kalms Day is and what it is used for

Kalms Day is a traditional herbal medicinal product for the relief of symptoms of mild mental stress exclusively based on long standing use.

Kalms Day contains extracts of Valerian root.

2. What you need to know before you take Kalms Day

Do not take Kalms Day if you:

- are allergic to Valerian root extract, hops strobile, or any of the other ingredients of this medicine (listed in section 6).

Other medicines and Kalms Day

Tell your doctor or pharmacist if you are taking, have recently taken, or might take other medicines, including:

- medicines which make you drowsy
- medicines obtained without a prescription including herbal medicines

Kalms Day with food, drink and alcohol

Alcohol may increase the sedative effect of Kalms Day. Therefore, excessive alcohol consumption should be avoided whilst you are taking Kalms Day.

Pregnancy and breast-feeding

Kalms Day is not recommended for use during pregnancy or when breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Kalms Day may make you feel sleepy or dizzy. If affected do not drive or operate any tools or machinery.

Excipients warnings

This medicine contains less than 1mmol sodium (23mg) per tablet, that is to say essentially “sodium-free”.

3. How to take Kalms Day

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.

For oral short-term use only.

The recommended dose is one tablet three times a day.

Do not exceed the recommended dose.

Not recommended for anyone under 18 years old.

As the effects of this product may not occur immediately, this tablet should be taken continuously for 2 weeks.

If you take more Kalms Day than you should

If you take more than the recommended dose, see a doctor or pharmacist and take this leaflet with you.

If you forget to take Kalms Day

Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

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

The following side effects have been reported:

- Nausea (feeling sick)
- Vomiting
- Abdominal Cramps
- Abdominal Pain
- Diarrhoea
- Dizziness
- Headache
- Nightmares or vivid dreams

The frequency is not known. If these persist for more than a few days or become troublesome, stop taking this product.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse.

This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, Dublin 2 Tel: +353 1 6764971 Fax: +353 1 6762517 Website: www.hpra.ie. E-mail: medsafety@hpra.ie. E-mail: medsafety@hpra.ie or by the HPRA Pharmacovigilance website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Kalms Day

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

Do not take this medicine after the expiry date which is stated on the packaging.

Do not store about 25°C.

Do not use if the cap seal is broken or foil strip is damaged.

Store in the original packaging to protect from moisture and light.

6. Contents of the pack and other information

What Kalms Day contains

The active substance per tablet is:

52mg of extract (as dry extract) from *Valeriana officinalis* L., radix
(equivalent to 208 to 260mg of Valerian root).

Extraction solvent: Ethanol 60% V/V.

Excipients: Maltodextrin, Colloidal Anhydrous Silica.

The other ingredients are:

Core: Hops Extract,-Croscarmellose Sodium, Magnesium Stearate, Microcrystalline Cellulose,
Pregelitinised Starch, Stearic Acid and Silicon Dioxide.

Coating: Hypromellose, Talc, Titanium Dioxide, Macrogol, Saccharin Sodium.

What Kalms Day looks like and contents of the pack

Kalms Day tablets are off-white circular biconvex film-coated tablets. They are available in blister packs of 21, 42 or 84 tablets and bottles containing 100 tablets. Not all pack sizes may be marketed.

Traditional Herbal Registration Holder

LanesHealth (Ireland) Limited,
Suite 7, The Courtyard, Carmanhall Road,
Sandyford, Dublin 18, D18 NW62, Ireland.
Email: kalmsday@laneshealth.com

Manufacturer (EU QP Release Site)

Elara Pharmaservices Europe Limited,
Regus Block 1, Blanchardstown Corporate Pak, Ballycoolin Road,
Blanchardstown, Dublin. D15 AKK1. Ireland

This leaflet was last revised in December 2024.