

Kalms Night 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 the 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.

What is in this leaflet

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

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

Kalms Night is a traditional herbal medicinal product used to aid sleep exclusively based on long standing use.

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

Do not take Kalms Night if you:

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

Other medicines and Kalms Night

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 Night with food, drink and alcohol

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

Pregnancy and breast-feeding

Kalms Night 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 Night is designed to 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 Night

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 30 to 60 minutes before bedtime. If necessary, one additional tablet can be taken earlier in the evening.

Do not exceed the recommended dose.

Not recommended for anyone under 18 years old.

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

If you take more Kalms Night 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 Night

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 Night

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 above 25°C.

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

6. Contents of the pack and other information

What Kalms Night contains

The active substance per tablet is:

385mg of extract (as dry extract) from *Valeriana officinalis* L., radix
(equivalent to 1.54 – 19.25g of Valerian root).

Extraction solvent: Ethanol 60% v/v.

Excipients: Maltodextrin, Colloidal Anhydrous Silica.

The other ingredients are:

Core: Croscarmellose Sodium, Magnesium Stearate, Silicified Microcrystalline Cellulose, Talc and Silicon Dioxide.

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

What Kalms Night looks like and contents of the pack

Kalms Night tablets are off-white ovaloid film-coated tablets. They are available in blister packs of 14, 21, 28, 42 and 56 tablets and 50 tablets stored in bottles. Not all pack sizes may be marketed.

Traditional Herbal Registration Holder

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