



5. How to store Kalms Night

Keep out of the sight and reach of children.

Do not take Kalms Night after the expiry date which is stated on the label and carton.

Do not store above 25°C.

Store in the original package.

6. Contents of the pack and other information

What Kalms Night contains

The active substance per film-coated tablet is:

- 96mg of extract (as dry extract) from Valerian root (*Valeriana officinalis* L.) equivalent to 384–480mg of Valerian root. Extraction solvent: Ethanol 60% v/v.

The other ingredients are:

- **Extract excipients:** Maltodextrin, Colloidal anhydrous silica.
- **Core:** Croscarmellose Sodium, Magnesium Stearate, Prosolv SMCC50 (Silicified Microcrystalline Cellulose) Talc, Silicon Dioxide.
- **Coating:** Opadry TM White 07F28588 (Hypromellose, Titanium Dioxide, Polyethylene Glycol (PEG) 3350, Saccharin, Sodium).

What Kalms Night looks like and the contents of the pack

Kalms Night tablets are white circular film coated tablets. They are available in bottles containing 50, 56, 100 and 200 tablets. Not all pack sizes may be marketed.

Traditional Herbal Registration holder and Manufacturer

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Certification Mark



For a large print, Braille or audio version of this leaflet please telephone 01452 524012

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 symptoms worsen, or do not improve after 4 weeks, a doctor or a qualified healthcare practitioner should be consulted.
- 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.

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

3008-04, Kalms Night PIL

Date: 25-07-23

Amends author: EHG

Brief Description:

Hybrid

Size: 163mm x 140mm

Colours:

K Pantone 2593





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

Kalms Night is a traditional herbal medicinal product containing Valerian root extract, used for the temporary relief of sleep disturbances, based on traditional use only.

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

Do not take Kalms Night if you are:

- allergic to Valerian or any of the other ingredients of this medicine (listed in section 6)
- pregnant or breastfeeding
- under 18 years of age
- already taking a medicine that makes you sleepy
- taking a medicine for stress or anxiety

Warnings and precautions

Talk to your doctor or pharmacist if symptoms worsen, or do not improve after 4 weeks of taking Kalms Night.

Other medicines and Kalms Night

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

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

Taking Kalms Night with food and drink

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

Driving and using machines

Kalms Night may make you feel sleepy or dizzy. If affected, do not drive or operate machines.

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.

The recommended dose is:

Take 4 tablets 30 to 60 minutes before bedtime. If necessary, on subsequent evenings, 4 additional tablets may be taken earlier during the evening.

Not recommended for anyone under 18 years old.

Do not take more tablets than the leaflet/label tells you to. As the effects of this product may not occur immediately, the tablets should be taken continuously for 2-4 weeks.

If you take more Kalms Night than you should

If you take too many tablets, consult your doctor or qualified healthcare practitioner as soon as possible.

Take this leaflet to show them.

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 product can have 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

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 qualified healthcare practitioner. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.