

Kalms

Tablets

Hop Strobiles and extracts of Valerian and Gentian

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However you still need to take Kalms tablets carefully to get the best results from them.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor or qualified healthcare practitioner if your symptoms worsen, or do not improve after 4 weeks.
- If any of the side effects become serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Kalms tablets are and what they are used for

Hop Strobiles and extracts of Valerian root and Gentian root. A traditional herbal medicinal product used for the temporary relief of;

- Symptoms associated with stress such as mild anxiety and irritability
- Symptoms associated with menopause such as flushings and cold sweats
- Sleep disturbances

Based on traditional use only.

2. Before you take Kalms tablets

Do not take Kalms tablets if you:

- are allergic to any of the ingredients (see Section 6 for a complete list of ingredients).
- are pregnant or breastfeeding
- are under 18 years old
- are already taking a medicine for sleep or anxiety

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including:

- medicines obtained without a prescription.

Important information about some of the ingredients:

- This medicine contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking this product.
- Driving and using machines: If you feel sleepy, do not drive or operate machines.

Additional information:

The effects of this medicine may be increased by alcohol. Therefore alcohol should be avoided whilst taking this medicine.

3. How to take Kalms tablets

For the temporary relief of:

- symptoms associated with stress such as mild anxiety and irritability or symptoms associated with menopause such as flushings and cold sweats;

Adults and the elderly: Take 2 tablets three times per day with water after meals.

For temporary relief of sleep disturbances;

Adults and the elderly: 2 tablets 30 to 60 minutes before bedtime. One additional tablet can be taken earlier during the evening if necessary.

- For oral short term use only.
- The tablets should be swallowed whole with some water or other liquid.
- The use of this product in children or adolescents under 18 years of age is not recommended because data is not sufficient and medical advice should be sought.
- As treatment effects may not be apparent immediately, this medicine should be taken for 2-4 weeks continuously
- **The maximum daily dose is 6 tablets.**
- **Do not exceed the stated dose.**

Duration of use

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

If you take more Kalms tablets 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 tablets

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

If you are unsure about anything, consult your doctor or qualified healthcare practitioner for advice.

4. Possible side effects

Like all medicines, Kalms tablets can cause side effects, although not everybody gets them.

- Gastrointestinal effects such as nausea, and stomach cramps have been reported with Valerian root preparations. The frequency is not known.
- Gastrointestinal disorders have been observed with Gentian root. The frequency was uncommon. In rare cases, tachycardia and pruritis have been reported. Headache may occur. The frequency is unknown.
- If any of the side effects become serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Kalms tablets

Keep out of the reach and sight of children.

Do not take Kalms tablets after the expiry date which is stated on the packaging. Do not store above 25°C. Store in the original package.

6. Further Information

What Kalms Tablets contain:

The active substance per coated tablet is:

- 45mg of Hop Strobiles (*Humulus lupulus* L.)
- 33.75mg of extract (as dry extract) from Valerian root (*Valeriana officinalis* L.) (equivalent to 135 to 167mg of Valerian root) Extraction solvent: Ethanol 60%v/v
- 22.5mg of extract (as dry extract) from Gentian root (*Gentiana lutea* L.) (equivalent to 90mg of Gentian root) Extraction solvent: Ethanol 50% v/v

Each coated tablet contains 247mg sucrose.

The other ingredients are:

- Extract: Maltodextrin, Silicon Dioxide
- Core: Acacia (Spray-dried), Icing Sugar, Magnesium Stearate, Maize Starch, Silicon Dioxide, Sodium Starch Glycolate, Stearic Acid.
- Coating: Acacia (Spray-dried), Calcium Carbonate (Light), Carnauba Wax, Mastercote White SP0950G, Talc, Shellac Varnish, Sucrose, Titanium Dioxide E171, Yellow Beeswax.

What Kalms tablets look like and contents of the pack

Kalms tablets are white, circular, sugar coated tablets. They are available in amber glass bottles containing 100 or 200 tablets. Kalms tablets are also available in blister packs containing 84 tablets. Not all pack sizes may be marketed.

Traditional Herbal Registration holder & manufacturer

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For a large print, Braille or audio versions of this leaflet please telephone: 01452 524012.