

Patient Information Leaflet

Nytol Herbal Simply Sleep and Calm Elixir

Valerian Root Extract

Please read this leaflet carefully before using Nytol Herbal Simply Sleep and Calm Elixir. It contains important information about this medicine.

Keep this leaflet. You may want to read it again. If you need more information or advice, please ask your doctor, pharmacist or qualified healthcare practitioner.

What is in this leaflet

1. What this product is and what it is used for
2. Before you take this product
3. How to take this product
4. Possible side effects
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1. What this product is and what it is used for

Nytol Herbal Simply Sleep and Calm Elixir is a traditional herbal medicinal product used for the temporary relief of symptoms of mild anxiety and to aid sleep, based on traditional use only.

2. Before you take this product

Do not take this product if you:

- are allergic to any of the ingredients (see section 6)
- are pregnant or breastfeeding
- are under 18 years of age
- are already taking a medicine which makes you drowsy.

Tell your doctor if you have an intolerance to any of the ingredients.

This product may cause drowsiness. Affected patients should not drive or operate machines.

Alcohol may increase the effects of this product. Excessive use of alcohol should therefore be avoided.

You should also know:

This product contains approx. 33% (v/v) ethanol (alcohol). Each 5ml of oral liquid contains approx. 1.3g of alcohol, equivalent to 32ml beer or 13ml wine. Harmful for people suffering from alcoholism or liver disease.

This product contains sucrose. If you have been told you have an intolerance to some sugars, contact your doctor before taking this medicinal product. May be harmful to the teeth.

3. How to take this product

Adults and the elderly:

For the symptomatic relief of mild anxiety: Take two 5ml spoonfuls three times a day with water or fruit juice if desired.

To aid sleep: Take two 5ml spoonfuls 30 minutes before bedtime with an earlier dose during the evening if necessary.

The effects of this treatment may not occur immediately, therefore this product should be taken continuously for 2-4 weeks.

Maximum daily dose: Four single doses.

Do not exceed the stated dose.

This formulation is not suitable for children or those under 18.

If you take too much of this product (overdose)

If you take more than the recommended dose, speak to a doctor, pharmacist or healthcare practitioner and take this leaflet with you. Overdose of this product may result in alcohol intoxication and should be treated accordingly (see Section 2 – You should also know).

If you forget to take this product

Continue to take your usual dose at the usual time. It does not matter if you have missed a dose.

If your symptoms of mild anxiety and/or sleeplessness persist for more than 4 weeks after using this product, tell your doctor.

If you have any questions, or are unsure about anything, please ask your doctor, pharmacist or healthcare practitioner.

4. Possible side effects

Like all medicines, this product can have side effects, although not everybody gets them.

These include:

- Nausea
- Abdominal cramps

If these persist or become troublesome stop taking the product.

Tell your doctor or pharmacist if you notice any other side effects.

This product may cause drowsiness. Affected patients should not drive or operate machines.

Reporting side effects:

If you get any side effects talk to your doctor or 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 this product

Do not use after the expiry date shown on the bottle.

Return any out of date medicine to your pharmacist who will dispose of it for you.

This product does not require any special storage conditions. Keep the bottle tightly closed.

Keep all medicines out of the reach and sight of children.

6. Further Information

Nytol Herbal Simply Sleep and Calm Elixir is a brown liquid.

Ingredients: Each 5ml of oral liquid contains 1.5 ml of tincture from dried Valerian (*Valeriana officinalis* L.) root (1:8). Extraction solvent: ethanol 57% v/v.

This product also contains the following ingredients:

Liquorice Liquid Extract, Orange Oil, Lemon Oil, Coriander Oil, Anise Oil, Ethanol (90%), Sucrose, Water.

This product is available in packs of 100ml, 150ml, 200ml and 300ml.

Not all pack sizes may be marketed.

Manufacturer and Traditional Herbal Registration Holder:

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THR No: 28255/0017

Distributed by:

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If you would like further information about this product

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