

Valerian Relaxisleep

Therapeutic indication:

Valerian Relaxisleep 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.

Components:

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

Dosage:

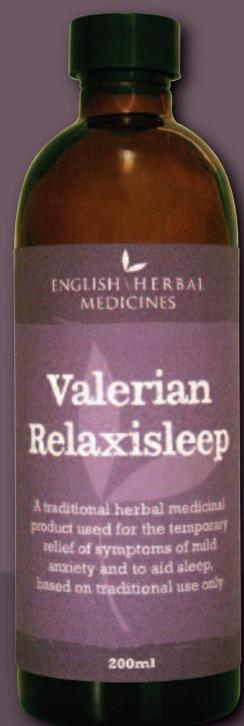
For the symptomatic relief of symptoms of mild anxiety take two 5ml spoonfuls three times a day with water or fruit juice if desired. To aid sleep take two 5ml spoonfuls 30 minutes before bedtime with an earlier dose during the evening if necessary.

Enviro Friendly Label and Packaging:

Almost zero new paper packaging is produced for the manufacture of this product. The Patient Information Leaflet is found behind the peel-and-reseal front label. There is no bottle box and product is re-delivered in the same outer card wrapping that the empty bottles are received in by the final dosage form manufacturers (subject to quality checks).

Pack Size:

Available in 200ml amber glass bottle with 20mm screw top. Supplied in boxes of 10 bottles. Nominal weight per box of 10 is 4.4 kg.



THR 28255/0017

valerian

“Throughout the history of western medicine, valerian (*Valeriana officinalis* L.) has been one of the best-known herbal remedies of all time. Since the 1600s it has been known as one of the greatest sedative and restorative remedies for the nervous system. It is probably the most common herbal remedy recommended by herbalists, naturopathic doctors, and chiropractors for mild forms of insomnia and tension.”³

“The common valerian...helps in nervous complaints, headaches, trembling, palpitations, vapours &c (Nicholas Culpeper 1616 - 1654)”⁴

“Columna (1567-1650) saith that Valerian be renowned as the capital remedy in nervous disorders”⁵

“The rhizome and rootlets collected in autumn, the English valerian is superior to that of Europe.”⁶

“The three main areas of use for valerian are for nervous excitement, nervous sleeplessness, and nervous palpitations.”⁷

“Valerian produced a significant improvement in sleep quality: the latter was most notable amongst people who considered themselves poor or irregular sleepers, smokers, and people who thought they normally had long sleep latencies. Night awakenings, dream recall and somnolence the next morning were relatively unaffected by valerian.”⁸

“Valerenic acid inhibits the the enzyme system responsible for the central catabolism of GABA [Riedel, E: 1982], and the valerian extract releases [³H]GABA by reversal of the GABA carrier, which is Na(+)-dependent and Ca(2+)-independent [Santos, M.S. et al.: 1994]. This increase in [³H]GABA release appears to be independent from Na(+)-K(+)-ATPase activity and the membrane potential. Valerenic acid has also been shown to depress the central nervous system (CNS) activity [Hendricks, H. et al.: 1985].”⁹

“Valerian extracts prepared with ethanol are used for the relief of mild nervous tension and sleep disorders.”¹⁰

Professional herbalists use the alcohol-based liquid tincture because it make a more complete extract of the herb and, when taken by mouth, unlike powders and tablets, almost all the extract is absorbed and used by the body. The liquid extract and tincture has been the basis of the official herbal medicine of the British (and later European) Pharmacopoeia for over a century.¹¹

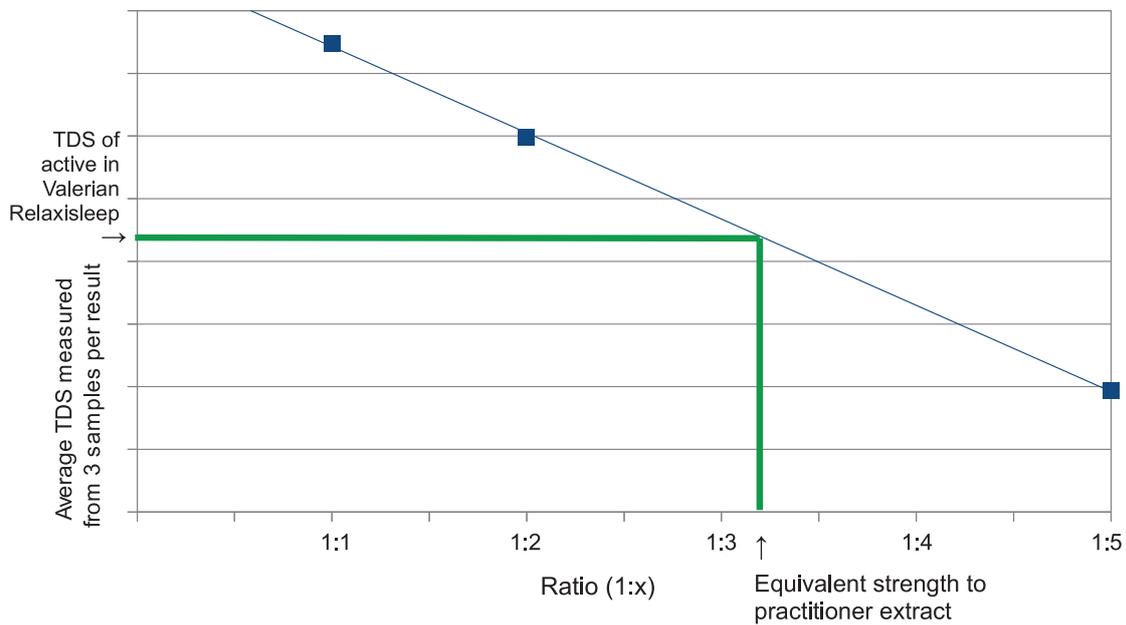


Valeriana officinalis L.

References:

1. Biodynamic agricultural association UK6/334
2. MHRA (Dept. of Health) MIA /MANA 28255
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4. Culpeper, N., *The Complete Herbal* c. 1640 Reprinted London: Foulsham (1967)
5. Woodville, W. 1790. *Medical Botany*, 3 vols. London: James Phillips (for the author).
6. Dweck AC, Houghton (Ed) , 1996 *Medicinal and Aromatic Plants, Industrial Profile*. London: King's College.
7. Weiss, R.F.: 1986, *Herbal Medicine* (transl. of *Der Lehrbuch der Phytotherapie* 6th Edn.), Gothenburg: Arcanum.
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9. Dweck AC, Houghton (Ed) , 1996 *Medicinal and Aromatic Plants, Industrial Profile*. King's Coll., London
10. European Medicines Agency *Committee on Herbal Medicinal Products (HMPC), Valeriana officinalis* L.,radix, Valerian root, EMA/HMPC/575871/2007 HMPC Assessment Report Summary for the Public
11. British Pharmacopoeia, British Pharmacopoeia Codices, European Pharmacopoeia 1885 – 2010 and British Herbal Pharmacopoeia 1983

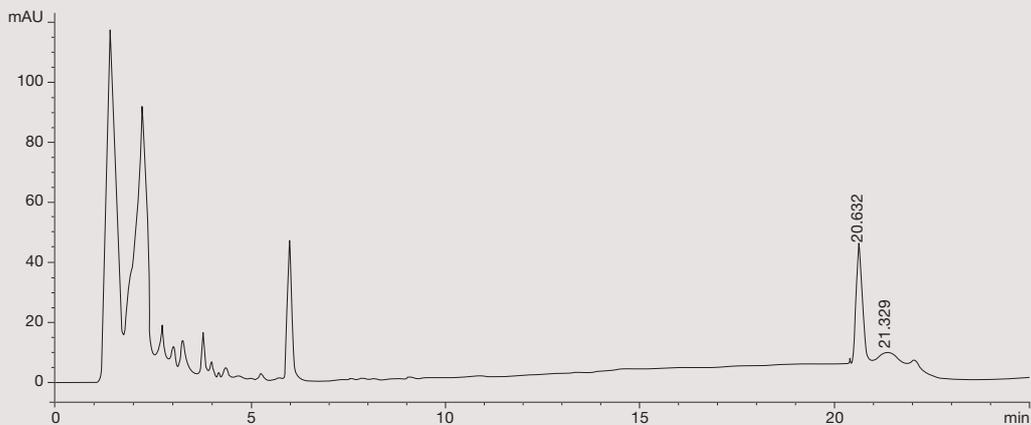
Active ingredient strength in Valerian Relaxisleep compared to commonly used Practitioner Grade formulations



Although nominally a 1:8, the license provision of this product requires the manufacturing method to provide a result for a total dissolved solids (a good way of measuring strength) which is approximately equivalent to a cold macerated practitioner grade product of 1:3, 25% alcohol (see green line).

Although the alcohol strength of the original extract is high, by the time this is reduced by dilution with flavouring etc., the result is an extremely effective medicine without the unpleasant taste associated by many people with strong Valerian products, or with alcohol.

Our English grown Valerian Relaxisleep shows high levels of Valerenic acid under High Performance Liquid Chromatography



Column: Phenomenex Luna C18(2) 250 x 4.6mm x 5.0µm, Flow rate: 1.5ml/min, Wavelength: 220nm, Injection volume: 20µl, Mobile phase: 5g/l phosphoric acid / acetonitrile.

HOW TO TAKE THIS PRODUCT:

Adults and the elderly:

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.

DO NOT EXCEED THE STATED DOSE

This formulation is not suitable for children or those under 18, pregnant or breastfeeding women, or patients already taking medicines for sleep or anxiety. Keep all medicines out of the reach and sight of children.

Peel where shown for further precautions.



Certification
Mark



0 16 1 0074 1 693307

Batch No:

Expiry:

ENGLISH HERBAL
MEDICINES

Valerian Relaxisleep

A traditional herbal medicinal
product used for the temporary
relief of symptoms of mild
anxiety and to aid sleep,
based on traditional use only

200ml

PRODUCT DESCRIPTION:

English Herbal Medicines Valerian Relaxisleep 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.

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.

Manufacturer and Traditional Herbal Registration Holder:

Rutland Biodynamics Ltd.,
Town Park Farm, Brooke, Rutland
LE15 8DG
THR No: 28255/0017

Leaflet prepared June 2010

PEEL HERE BUT DO NOT REMOVE

BEFORE YOU TAKE THIS PRODUCT

Do not take this product if you:

- are allergic to any of the ingredients
- 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.

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

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.

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

STORING 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.

FURTHER INFORMATION

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.

You can help to make medicines safer by reporting any side-effects to the Yellow Card Scheme at www.yellowcard.gov.uk.

Alternatively you can get a paper Yellow Card form from your GP's surgery or pharmacy, or call freephone 0800 100 3352 (available 10.00am - 2.00pm Monday – Friday).

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.

This product is available in packs of 100ml, 150ml, 200ml and 300ml. Not all pack sizes may be marketed.

If you would like further information about this product

Contact: English Herbal Medicines Ltd,
Town Park Farm, Brooke, Rutland LE15 8DG

ENGLISH HERBAL
MEDICINES

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Mixed Sources

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