English Herbal Medicines Valerian Relaxisleep

Herbs Hands Healing ValRelax

Brooke Green Valerian Elixir

Swiss Herbal Remedies Valerian Elixir

THR 28255/0017

UKPAR

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The Medicines and Healthcare products Regulatory Agency (MHRA) granted Rutland Biodynamics Ltd a Traditional Herbal Registration Certificate for the traditional herbal medicinal products English Herbal Medicines Valerian Relaxisleep, Herbs Hands Healing ValRelax, Brooke Green Valerian Elixir and Swiss Herbal Remedies Valerian Elixir. These products are identical to each other apart from the difference in product name and will be collectively referred to as Valerian Oral Liquid for the remainder of this report. Valerian Oral Liquid (Traditional Herbal Registration number: THR 28255/0017) is available without prescription and can be bought from pharmacies and other outlets.

Valerian Oral Liquid is used for the temporary relief of symptoms of mild anxiety and to aid sleep, based on traditional use only. The active ingredient of this product comes from the roots of the Valerian plant, which is also known as *Valeriana officinalis* L.

This registration is based exclusively upon evidence of traditional use of Valerian as a herbal medicine and not upon data generated from clinical trials. There is no requirement under the Traditional Herbal Registration scheme to prove scientifically that the product works.

No new or unexpected safety concerns arose from this application and it was, therefore, decided that a Traditional Herbal Registration Certificate could be granted.
SCIENTIFIC DISCUSSION

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INTRODUCTION

The MHRA granted a Traditional Herbal Registration Certificate for the traditional herbal medicinal product Valerian Oral Liquid on 29 June 2010. This product is on the general sales list (GSL).

A product licence of right was granted to Potters Ltd for this product in 1972. The PLR was reviewed and a product licence granted on 30 November 1990 (PL 00250/5264R). Following a change of ownership on 3 February 2009, this product was licensed to Rutland Biodynamics Ltd (PL 28255/0005). This licence will be cancelled as the product will now been registered under the Traditional Herbal Registration scheme under Traditional Herbal Registration number: THR 28255/0017.

This THR application was made under Article 16.c of Directive 2001/83 EC in accordance with arrangements to transfer certain herbal products with a marketing authorisation (product licence) to a THR (according to MHRA Guidance dated January 2009). The application falls within the simplified THR application Category A as no changes have been made to the formulation of the product. No new data were submitted, nor was it necessary for this application, as the data are essentially identical to those of the existing product.
PHARMACEUTICAL ASSESSMENT

HERBAL SUBSTANCE: VALERIAN ROOT

Scientific name of the plant: Valeriana officinalis L.
Family: Valerianaceae
Synonyms of the herbal substance: Valerian
Parts of the plant used: root

The herbal substance complies with the Ph. Eur. monograph, it is, therefore, acceptable.

HERBAL PREPARATION: VALERIAN TINCTURE

Herbal preparation: Valerian tincture (1:8)
Parts of the plant used: dried root
Extraction solvent: ethanol 57 % v/v

The herbal preparation specification is in line with that applied to the herbal preparation used in the already licensed product. It is, therefore, acceptable.

HERBAL PRODUCT: VALERIAN ORAL LIQUID

Description and Composition of the Herbal Product
Valerian Oral Liquid contains liquorice liquid extract, orange oil, lemon oil, coriander oil, anise oil, ethanol (90%), sucrose and water. All excipients used comply with their respective European Pharmacopoeial monographs. This is satisfactory.

The formulation is essentially identical to that of the already licensed product. It is, therefore, acceptable.

Manufacture
The manufacturing process is in line with that of the already licensed product and is satisfactory.

Finished Product Specification
The finished product specification is in line with that of the already licensed product and is satisfactory.

Container Closure System
The oral liquid is stored in glass bottles containing 100ml, 150ml, 200ml or 300ml oral liquid. The bottles are stoppered with a polypropylene screwcap. This type of packaging has been used to store the already licensed product and is satisfactory.
Stability
The product shelf-life of 3 years was applied to the already licensed product and is appropriate.

Summary of Product Characteristics, label and Patient Information Leaflet
All product literature is in line with that of the already licensed product, with some details amended in line other valerian-containing products registered under the THR scheme.

A package leaflet has been submitted to the MHRA along with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the package leaflet is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

Assessor’s Overall Conclusions on Quality
The grant of a Traditional Herbal Registration is acceptable.
NON-CLINICAL ASSESSMENT

INTRODUCTION
No new preclinical data have been supplied with this application and none is required for an application of this type.

Assurance has been given that the results of genotoxicity testing will be provided by the renewal date of the THR.

PRODUCT LITERATURE
All product literature is satisfactory from a preclinical point of view.

ASSESSOR’S OVERALL CONCLUSIONS
It is recommended that a Traditional Herbal Registration can be granted.
CLINICAL ASSESSMENT

INTRODUCTION
The clinical particulars for Valerian Oral Liquid are identical to those for the already licensed product. This is satisfactory.

PRODUCT LITERATURE
All product literature is medically satisfactory.

ASSESSOR’S OVERALL CONCLUSIONS
It is recommended that a Traditional Herbal Registration can be granted.
OVERALL CONCLUSION AND RISK ASSESSMENT

QUALITY
Valerian Oral Liquid is identical to an already licensed product. It is, therefore, pharmaceutically satisfactory.

PRECLINICAL
No new preclinical data were submitted and none are required for an application of this type. The results of genotoxicity testing will be provided before the THR is renewed.

EFFICACY
No clinical efficacy data are required for registration of Traditional Herbal Medicinal Products (THMP).

SAFETY
No new or unexpected safety concerns arose from this application.

RISK ASSESSMENT
The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified.
THE MHRA received the Traditional Herbal Registration application on 28 July 2009

2 Following standard checks and communication with the applicant the MHRA considered the application valid on 5 August 2009

3 Following assessment of the application the MHRA requested further information relating to the dossier on 3 December 2009. The applicant responded to the MHRA’s requests, providing further information on the dossier on 3 March 2010

4 Following assessment of the response the MHRA requested further information relating to the dossier on 20 April 2010. The applicant responded to the MHRA's requests, providing further information on the dossier on 7 May 2010

5 Following assessment of the response the MHRA requested further information relating to the dossier on 11 June 2010. The applicant responded to the MHRA’s requests, providing further information on the dossier on 17 June 2010

6 A THR was granted on 29 June 2010
SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
English Herbal Medicines Valerian Relaxisleep
Herbs Hands Healing ValRelax
Brooke Green Valerian Elixir
Swiss Herbal Remedies Valerian Elixir

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
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.

5 ml of oral liquid contains approximately 1.25g Ethanol (alcohol), equivalent to 32 ml of beer or 13 ml of wine and 734 mg sucrose.

For list of excipients see Section 6.1.

3 PHARMACEUTICAL FORM

4 CLINICAL PARTICULARS
4.1 Therapeutic indications
A traditional herbal medicinal product used for the temporary relief of symptoms of mild anxiety and to aid sleep, based on traditional use only.

4.2 Posology and method of administration
For oral short term use only.

Adults and Elderly
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.

As treatment effects may not be apparent immediately, this product should be taken 2-4 weeks continuously.
Maximum daily dose:- 4 single doses
Duration of use:- If symptoms persist, worsen or do not improve after 4 weeks during the use of this product, a doctor or qualified healthcare practitioner should be consulted. The use of this product is not recommended in children and adolescents below the age of 18 years (see also 4.4 Special warnings and precautions for use).
4.3 **Contraindications**
Patients with known hypersensitivity to Valerian root or any of the excipients.

4.4 **Special warnings and precautions for use**
Do not exceed the stated dose.

Contains alcohol – up to 2.5g ethanol per dose (equivalent to 64 ml of beer or 26 ml of wine).
Harmful for those suffering from alcoholism. To be taken into account in high-risk groups such as patients with liver-disease or epilepsy.

Contains sucrose – if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. May be harmful to the teeth.

The use of this product is not recommended in children and adolescents below the age of 18 years because data are insufficient and medical advice should be sought.

4.5 **Interaction with other medicinal products and other forms of interaction**
Only limited data on pharmacological interactions with other medicinal products are available.
Clinically relevant interactions with drugs metabolised by the CYP 2D6, CYP 3A4/5, CYP 1A2 or CYP 2E1 pathway has not been observed. Additive effects with hypnotics and other sedatives cannot be excluded and therefore co-medication is not recommended.

Contains alcohol, and should therefore be avoided in patients taking other medication known to interact with alcohol (e.g. metronidazole).

The effect of Valerian may be potentiated by alcohol. Excessive concomitant consumption of alcohol should therefore be avoided.

4.6 **Pregnancy and lactation**
The safety of this product during pregnancy and lactation has not been established. Due to the lack of data, use during pregnancy and lactation is not recommended.

4.7 **Effects on ability to drive and use machines**
This product may impair ability to drive or use machinery. Affected patients should not drive or operate machinery. This product contains alcohol (see Section 2).
4.8 Undesirable effects
Gastrointestinal symptoms (eg nausea, abdominal cramps) may occur after ingesting Valerian root. The frequency is not known. If other adverse reactions not mentioned above occur, a doctor or qualified healthcare practitioner should be consulted.

4.9 Overdose
No case of overdose has been reported.

Valerian root at a dose of approximately 20g (equivalent to 533 ml of this product) caused benign symptoms (fatigue, abdominal cramp, chest tightness, light headedness, hand tremor and mydriasis), which disappeared within 24 hours. If symptoms arise, treatment should be supportive.

After intake of very high doses of Valerian root over several years (daily consumption corresponding to approximately 30g of the drug) withdrawal symptoms (delirium) have been reported.

Overdose of this product may result in alcohol intoxication: the amount in a full bottle: (25.2g in 100ml, 37.9g in 150ml, 50.5g in 200ml and 75.6g in 300ml: equivalent to 1.5, 2.3, 3 and 4.5 large glasses of wine respectively) may result in intoxication and should be treated accordingly.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.2 Pharmacokinetic properties
Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.3 Preclinical safety data
Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Liquorice Liquid Extract
Orange Oil
Lemon Oil
Coriander Oil
Anise Oil
Ethanol (90%)
Sucrose
Water
6.2 Incompatibilities
Not applicable.

6.3 Shelf life
Three years.

6.4 Special precautions for storage
This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container
Glass bottle with polypropylene screwcap: 100ml, 150ml, 200ml and 300ml. Not all pack sizes may be marketed.

6.6 Special precautions for disposal
No special requirements.

7 MARKETING AUTHORISATION HOLDER
Rutland Biodynamics Ltd, Town Park Farm, Brooke, Rutland, LE15 8DG.

8 MARKETING AUTHORISATION NUMBER(S)
THR 28255/0017

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
29/06/2010

10 DATE OF REVISION OF THE TEXT
29/06/2010
Patient Information Leaflet
Herbs Hands Healing ValRelax
Valerian Root Extract

Please read this leaflet carefully before using Herbs Hands Healing ValRelax. 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
5. How to store this product
6. Further information

1. What this product is and what it is used for

Herbs Hands Healing ValRelax 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.

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.

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

If you would like further information about this product
Contact: Herbs Hands Healing, Station Road, Fulham Market, Norfolk, IP21 4XF.
Leaflet prepared June 2010

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 0808 100 3352 (available 10.00 am - 2.00 pm Monday – Friday).

Certification Mark

MHRA PAR; ENGLISH HERBAL MEDICINES VALERIAN RELAXISLEEP, HERBS HANDS HEALING VALRELAX, BROOKE GREEN VALERIAN ELIXIR AND SWISS HERBAL REMEDIES VALERIAN ELIXIR, THR 28255/0017

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Patient Information Leaflet
Brooke Green Valerian Elixir
Valerian Root Extract

Please read this leaflet carefully before using Brooke Green Valerian 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
5. How to store this product
6. Further information

1. What this product is and what it is used for

Brooke Green Valerian 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.
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.

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

**If you would like further information about this product**
Contact: Brooke Green Limited, Woodfield House, Moreton Valence, Glos.GL2 7NB
Leaflet prepared June 2010

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 0808 100 3352 (available 10.00am - 2.00 pm Monday - Friday).
Patient Information Leaflet
Swiss Herbal Remedies Valerian Elixir
Valerian Root Extract

Please read this leaflet carefully before using Swiss Herbal Remedies Valerian 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
5. How to store this product
6. Further information

1. What this product is and what it is used for

Swiss Herbal Remedies Valerian 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 is 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.

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.

### 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

Swiss Herbal Remedies Valerian 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:**

Rutland Biodynamics Ltd.,

Town Park Farm, Brooke, Rutland LE15 8DG

THR No: 28255/0017

**If you would like further information about this product**

Contact: Swiss Herbal Remedies Ltd, 3 St Mary Street, CARDIFF, CF10 1AT.

Leaflet prepared June 2010

You can help to make medicines safer by reporting any side-effects to the Yellow Card Scheme at [www.yellowcard.gov.uk](http://www.yellowcard.gov.uk). Alternatively you can get a paper Yellow Card form from your GP's surgery or pharmacy, or call freephone 0808 100 3352 (available 10.00am – 2.00 pm Monday – Friday).
English Herbal Medicines Valerian Relaxsleep:

**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. Consult your healthcare provider for further precautions.

**Product Description:**
- Valerian Relaxsleep 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 (1:1). Extraction solvent: ethyl alcohol 57% v/v.
- This product also contains the following ingredients:
  - Liquorice Liquid Extract, Orange Oil, Lemon Oil, Citronellol Oil, Anis Oil, Ethanol (99%), Sucrose, Water.

**Manufacturer and Traditional Herbal Registration Holder:**
- Rutland Biodynamics Ltd.,
- Town Park Farm, Brooke, Rutland LE15 6EQ
- THR No: 28255/0017
- Leaflet prepared: June 2010

**Before You Take This Product:**
- Do not take this product if you:
  - have an allergy 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 machinery. Alcohol may increase the effects of this product. Excessive use of alcohol should therefore be avoided.

You should also know:
- This product contains approx. 35% (v/v) ethanol (alcohol). Each 5ml of oral liquid contains approx. 1.3% of alcohol, equivalent to 22ml 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 professional.

**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.
- Keep out of reach of children.
- 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 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 telephone: 0800 100 3362 (available 16:00am - 2:00pm Monday – Friday).

If you forgot 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 6EQ

200ml
Herbs Hands Healing ValRelax:

Ingredients:
Each 10ml oral liquid contains:
- 95% Valerian root extract 0.5g
- 95% Passionflower extract 0.5g
- 95% Chamomile extract 0.5g

Also contains: Aniseed; Lemon Oil; NaturalVanilla; Sucrose and Citric Acid.

Directions for use:
For the temporary relief of mild anxiety and sleeplessness, take three 10ml spoonfuls 30 minutes before bedtime and any further dose during the evening if necessary.

For oral use only.

Manufacturer and Traditional Herbal Registration holder:
Herbs Hands Healing Ltd, Station Road, Pulham Market, Norfolk PE3 6XF

For further information about this product:
Herbs Hands Healing Ltd, Station Road, Pulham Market, Norfolk PE3 6XF

200ml
Brooke Green Valerian Elixir:

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 0.5g of root of valerian (Valeriana officinalis L.) root (1:1). Extraction solvent: ethanol 57% v/v. Extraction solvent: ethanol 57% v/v. Also contains: propylene glycol, liquid extract, orange oil, lemon oil, coriander oil, anise oil, ethanol and ascorbic acid.

Directions for use: For symptomatic relief of mild anxiety: take two 5ml spoonfuls three times a day with water or fruit juice as desired.

To aid sleep: take two 5ml spoonfuls 30 mins before bed with an earlier dose during the evening if necessary.

Minimum daily dose: four single doses.

For oral use only. Read leaflet before use.

Caution: Not for use in children or those under 18.
Do not use if you are allergic to any of the ingredients, pregnant or breastfeeding already.

This product does not require special storage.

Manufacturer & Traditional Herbal Medicine Registration Holder:
Rutland Biodynamics Ltd, Brooks, Rutland LE14 0DS.

Traditional Herbal Reg. No.: THR 23056/0017

Use by: 100ml

Batch Number
Swiss Herbal Remedies Valerian Elixir:

**Swiss Herbal Remedies**

VALERIAN ELIXIR

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

200 ml

**Ingredients:**

- Each 5ml of oral liquid contains Valerian root tincture 1.5ml
- Valeriana officinalis L. (Valerian)
- Extraction solvent: ethanol 57% v/v
- Also contains Liquorice Liquid Extract, Orange Oil, Lemon Oil, Coriander Oil, Anise Oil, Fennel and Star Anise.

**DIRECTIONS FOR USE:**

- 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. Maximum daily dose: Four single doses.
- Do not exceed the stated dose. Not for use in children or those under 18.

**Caution:**

- Do not use if you are allergic to any of the ingredients. This product contains ethanol. Harmful for people suffering from alcoholism. See leaflet for further information. This product contains aromatics. If symptoms persist or women, or adverse reactions not mentioned in the leaflet occur, consult a doctor or qualified healthcare practitioner.

**FOR ORAL USE ONLY**

Please read the enclosed patient information leaflet before taking this product. Keep out of reach and sight of children.

Store in original packaging.

Do not use if security seal is broken.
A traditional herbal medicinal product for temporary relief of symptoms of mild anxiety and to aid sleep, based on traditional use only.

200ml

Recipe:

For further information about this product, contact:
Swiss Herbal Remedies Ltd.
Gardiff CF11 3AT
Telephone: 039-2547703
info@swissherbalremedes.com

Ingredients:

- Each fluid ounce contains:
- 12g of the flowering head of Valerian (Valeriana officinalis L.) and 1% Extractive equivalent of 12% Valerian.
- Also contains Liquorice Liquid Extract, Orange Oil, Lemon Oil, Geranium Oil, Anise Oil, Ethanol and water.

Directions for Use:

- For the temporary relief of mild anxiety:
  Take 15ml of the liquid in a glass of water or ambrosia if desired.
- To aid sleep:
  Take 15ml approximately 30 minutes before bed, with or without food, during the evening or morning.
- Maximum daily dose: Four single doses.
- Do not exceed the stated dose.

Caution:

- Not for use in children or those under 16.
- Avoid use if you are allergic to any of the ingredients, pregnant or breastfeeding.
- This product contains alcohol.
- Harmful for people suffering from alcoholism.
- This product contains=s alcohol.
- If you have been told you have an intolerance to some ingredients, consult your doctor before taking this medicinal product.
- May be harmful to the teeth.

For further information, contact:
Swiss Herbal Remedies Ltd.
Gardiff CF11 3AT
Telephone: 039-2547703
info@swissherbalremedes.com

Manufactured and Traditional Herbal Registration holder: Robert Bradly, Roland Ltd's 65, DGG

Traditional Herbal Registration Number: THR 28255/0017

Par Oral Use Only

Please read the enclosed patient information booklet before taking this product.

Keep out of reach and sight of children.

Store in original packaging.

Do not take if sealed seal is broken.

Expiry Date and Batch No. printed on bottle.

MHRA PAR; ENGLISH HERBAL MEDICINES VALERIAN RELAXISLEEP, HERBS HANDS HEALING VALREAX, BROOKE GREEN VALERIAN ELIXIR AND SWISS HERBAL REMEDIES VALERIAN ELIXIR, THR 28255/0017