Dormeasan Sleep Valerian-Hops oral drops

THR 13668/0017

UKPAR

TABLE OF CONTENTS

Lay summary Page 2
Scientific discussion Page 3
Steps taken for assessment Page 14
Summary of product characteristics Page 15
Product information leaflet Page 19
Labelling Page 23
Steps taken after THR grant Page 27
It should be noted that a variation to change the name of the product from Dormeasan Valerian-Hops oral drops to Dormeasan Sleep Valerian-Hops oral drops was granted on 22 December 2011. The following report was first published on 23 April 2009 and, therefore, refers to the original Marketing Authorisation details, however, Annex 1 (page 28) contains the updated Marketing Authorisation information.

DORMEASAN VALERIAN-HOPS ORAL DROPS

THR 13668/0017

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Bioforce (UK) Ltd a Traditional Herbal Registration certificate for the traditional herbal medicinal product Dormeasan Valerian-Hops oral drops (Traditional Herbal Registration number: THR 13668/0017). This product is available without prescription and can be bought from pharmacies and other outlets.

The active ingredients of Dormeasan Valerian-Hops oral drops come from the roots of the valerian plant, which is also known as *Valeriana officinalis* L, and the female flower of the hops plant, which is also known as *Humulus lupulus* L. Valerian root and hops flowers are traditional herbal medicines used for the temporary relief of sleep disturbances caused by the symptoms of mild anxiety. This registration is based exclusively upon the longstanding use of valerian root and hops flowers as traditional herbal medicines 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.
DORMEASAN VALERIAN-HOPS ORAL DROPS

THR 13668/0017

SCIENTIFIC DISCUSSION

TABLE OF CONTENTS

Introduction Page 4
Pharmaceutical assessment Page 5
Preclinical assessment Page 10
Clinical assessment Page 11
Overall conclusions and risk assessment Page 13
INTRODUCTION

The MHRA granted a Traditional Herbal Registration Certificate for the traditional herbal remedy Dormeasan Valerian-Hops oral drops (Traditional Herbal Registration number: THR 13668/0017) to Bioforce (UK) Ltd on 19 February 2009. This product is on the general sales list (GSL).

This application was submitted according to Article 16.c of Directive 2001/83 EC, as amended, as part of the Traditional Herbal Medicines Registration Scheme.

The data supplied by the applicant demonstrate 30 years of traditional use of Valerian (*Valeriana officinalis* L.) root and hops (*Humulus lupulus* L.) flowers in the European Community. A satisfactory review of the available safety data on valerian root and hops flowers has also been provided, together with an expert report supporting the proposed product.
HERBAL SUBSTANCE: HOP FLOWER

Scientific name of plant: *Humulus lupus* L. (Ph Eur monograph, hop strobile)
Family: Urticaceae
Synonyms: *Lupuli flos*
English name: Hop
Part of the plant: Strobiles

**General properties**
The herbal substance consists of the fresh, generally whole, female inflorescence of *Humulus lupulus* L. The hop strobiles are generally isolated and 2 cm to 5 cm long, petiolate, ovoid, made up of many oval, greenish-yellow, sessile, membranous, overlapping bracts. The external bracts are flattened and symmetrical. The internal bracts are longer and asymmetrical at the base because of a fold generally circling an induviate fruit (achene). The ovary or, rarely, the fruit, the base of the bracts and, especially, the indivial fold are covered with small orange-yellow glands.

**Manufacture**
The plant material is cultivated in central Europe (Switzerland and Germany) under organic conditions (according to EC Directive 2092/91) and in accordance with Good Agricultural and Collection Practice (GACP) guidelines.

Hops are very sensitive to diseases and pests, therefore, fungal diseases are prevented by mycosin, which is based on clay and enriched with plant extracts as well as copper. Red spider mites are controlled with soft soap and sulphur, aphids with pyrethrum. If copper and sulphur are used, the special low dosage regulations for organic crops are applied. Weeds are controlled mechanically and manually and fertilisation is performed with compost and brewer’s grains.

The seedless strobiles of female hop plants are harvested in September. After harvesting, the whole plants are cleaned.

Confirmation is given that neither fumigant treatments nor irradiation is used during storage of the herbal substance.

**Control of Herbal Substance**
An appropriate specification based on the Ph Eur monograph is applied and is acceptable. The specification is supported by the batch data provided.

**Container Closure System**
Satisfactory details of the container closure system are provided.

**Stability**
The fresh and clean strobiles are packed and sent for further processing within 24 hours after harvest. No stability data have been provided and none are needed due to the short time between harvest and processing.

HERBAL PREPARATION: HOPS TINCTURE

**General Information**
Scientific name of the plant: *Humulus lupulus* L.
Drug: extraction solvent ratio (DER): 1:12 (referring to the dry mass)
Extraction solvent: Ethanol 57.3 % (m/m)

The preparation is a clear liquid with green to brown colour, characteristic odour and bitter taste.

Manufacture
A satisfactory description of the manufacturing process of the herbal preparation has been provided.

The in-process controls are satisfactorily detailed. There are no critical steps identified as the manufacture of the herbal preparation is considered a standard procedure.

Certificates of analysis for all materials used in the manufacture of the herbal preparation have been provided.

Control of herbal preparation
A satisfactory specification with appropriate tests and limits has been provided for the herbal preparation.

Satisfactory analytical procedures are used to control the quality of the herbal preparation. Analytical procedures have been validated, as appropriate.

Certificates of analysis have been provided for production batches of the herbal preparation, demonstrating satisfactory compliance with the proposed specification.

The proposed specification has been justified satisfactorily.

Reference Standards or Materials
A suitable certificate of analysis for the working standard has been provided.

Container Closure System
The tincture is stored in an appropriate container until further processing. Due to the manufacturer’s extensive experience in the production of tincture it can be accepted that the containers are of suitable quality for use.

Stability
Stability studies have been carried out on the herbal preparation under ICH conditions. The results support the proposed retest period of 3 months when stored between 15-25°C.

HERBAL SUBSTANCE: VALERIAN

General Information
Scientific name of plant: Valeriana officinalis L. (Ph Eur monograph, Valerian Root)
Family: Valerianaceae
Synonyms: Radix Valerianae off.; Baldrian, St. George’s herb, Valériane, Valeriana.

English name: Valerian
Parts of the plant used: Underground parts, including rhizome, roots and stolons

General properties
The rhizome is yellowish-grey to pale brownish-grey, obconical to cylindrical, up to about 50 mm long and 30 mm in diameter; the base is elongated or compressed, usually entirely covered by numerous roots. The apex usually exhibits a cup-shaped scar from the aerial parts; stem bases are rarely present. When cut longitudinally, the pith exhibits a central cavity transversed by septa. The
roots are numerous, almost cylindrical, of the same colour as the rhizome, 1 mm to 3 mm in diameter and sometimes more than 100 mm long. A few filiform, fragile, secondary roots are present. The fracture is short. The stolons show prominent nodes separated by longitudinally striated internodes, each 20 mm to 50 mm long, with a fibrous fracture.

**Manufacture**
The plant material is cultivated in central Europe (Switzerland and Germany) under organic conditions (according to EC Directive 2092/91) and in accordance with Good Agricultural and Collection Practice (GACP) guidelines.

The plants are planted on embankments between April and May. The roots are harvested at the end of the first growth period between the end of September and October. The roots are stored in the cold after harvest and washed. The washed roots are dried for one day before further processing.

No pesticides are used during cultivation and weeds are controlled manually and mechanically. Fertilisation is performed with compost.

Confirmation is given that neither fumigant treatments nor irradiation is used during storage of the herbal substances.

**Control of Herbal Substance**
The specifications of the herbal substance are in line with the European Pharmacopoeia monograph and are satisfactory. Certificates of analysis are presented for batches of the herbal drug giving full results for test parameters to support the proposed specification.

**Reference Standards or Materials**
Appropriate reference solutions are used.

**Container Closure System**
The fresh valerian roots are stored in containers of the type commonly used in agriculture. Detailed specifications on the material are not available, however taking into consideration the very short storage time of a maximum 3 days and the fact that the containers are commonly used for vegetables intended for human consumption, the risk of possible negative interactions between the primary packaging and the herbal substance is considered negligible.

**Stability**
Confirmation is given that the herbal substance is tested prior to making the herbal preparation. A shelf-life for the herbal drug based on real time stability data is not necessary because it is a precursor of the active substance, the herbal preparation.

**HERBAL PREPARATION: VALERIAN TINCTURE**

**General Information**

**Name of the herbal substance:** Valerian root (*Radix Valerianae off.*)

**Drug: extraction solvent ratio (DER):** 1:10 (referred to the dry mass of the fresh herbal drug)

**Extraction solvent:** Ethanol 50 % (m/m)

The tincture is described in the Ph Eur monograph on valerian tincture. The preparation is a clear liquid with a coffee brown colour, a strong odour of valerian and a bitter taste.

**Manufacture**
Manufacture of the tincture is a standard procedure. A satisfactory description of the manufacturing process of the herbal substance and flow diagram has been provided.

The in-process controls are satisfactorily detailed. There are no critical steps identified as the manufacture of the herbal preparation is considered a standard procedure.

Certificates of analysis for all materials used in the manufacture of the herbal preparation have been provided.

**Control of Herbal Preparation**
A satisfactory specification with appropriate tests and limits has been provided for the herbal preparation

Satisfactory analytical procedures are used to control the quality of the herbal preparation. Analytical procedures have been validated, as appropriate.

Certificates of analysis have been provided for production batches of the herbal preparation, demonstrating satisfactory compliance with the proposed specification.

The proposed specification has been justified satisfactorily.

**Reference Standards or Materials**
A suitable certificate of analysis for the working standard has been provided.

**Container Closure System**
The tincture is stored in an appropriate container until further processing. Due to the manufacturer’s extensive experience in the production of tincture it can be accepted that the containers are of suitable quality for use.

**Stability**
Stability studies have been carried out on the herbal preparation under ICH conditions. The results support the proposed retest period of 24 months.

**HERBAL PRODUCT**

**Description and Composition of the Herbal Product**
The herbal product is a green to brown clear liquid with the odour of hop and valerian and a strongly bitter taste of hop. The herbal product is a 1:1 mixture (by weight) of hops tincture and valerian tincture. The herbal product contains the two herbal preparations as active ingredients. There are no additional excipients in the herbal product other than the excipients used in the manufacture of the herbal preparations. These comply with the Ph Eur.

**Manufacture**
A description and flow-chart of the manufacturing method has been provided. The manufacturing method is a standard procedure and the manufacturer has longstanding experience in the manufacture of ethanolic tinctures.

In-process controls are appropriate considering the nature of the product and the method of manufacture. Process validation has been carried out on product batches and the results are satisfactory.
Control of Herbal Product
The finished product specification is satisfactory. Acceptance limits have been justified with respect to conventional pharmaceutical requirements and, where appropriate, safety. Test methods have been described and have been adequately validated, as appropriate. Batch data have been provided and comply with the release specification.

Reference Standards or Materials
Certificates of analysis have been provided for any working standards used.

Container Closure System
The herbal product is packaged in type III, hydrolytic, brown glass dropper bottles (50ml and 100ml) with a twist off PE cap. Suitable specifications have been provided for the container closure system. The components of the primary packaging system also comply with Directive 2002/72 relating to contact with foodstuffs.

Stability
Finished product stability studies have been conducted in accordance with current guidelines. Based on the results, a product shelf-life of 3 years with no special storage conditions is appropriate.

Assessor’s comments on the Summary of Product Characteristics, label and Patient Information Leaflet
All product literature is satisfactory.

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 Traditional Herbal Registrations is acceptable.
NONCLINICAL ASSESSMENT

NONCLINICAL ASPECTS
The Expert Safety Report submitted by the applicant lists relevant references to published work studying the toxicology of valerian and hops.

NONCLINICAL OVERVIEW
The applicant has submitted a literature review with this application. An Expert Safety Report was provided, which included reviews of some non-clinical data. The Expert Safety Report was written by a medically qualified expert.

The overview submitted in support of this application is satisfactory.

Due to a shortage of published data on valerian and hops, it is not possible to assess if the safety package for the phytochemical constituents of valerian and hops is acceptable to the standards of today’s GLP and safety testing requirements. However, the information supplied demonstrating traditional use is acceptable and thus the lack of provision of a complete standard safety package is acceptable and in compliance with guideline EMEA/HMPC/32116/05.

In view of the absence of results of genotoxicity testing the applicant has provided assurance that results will be provided before the renewal of the registration.

SUMMARY OF PRODUCT CHARACTERISTICS (SPC)
The SPC for this product is satisfactory from a preclinical point of view.

ENVIRONMENTAL RISK ASSESSMENT
An environmental risk assessment is not required for herbal medicinal products according to guidance CPMP/SWP/4447/00.

CONCLUSION
The information supplied demonstrates the traditional use of valerian root and hops strobile. An adequate literature review of valerian and hops has been carried out by the applicant and no new non-clinical data was submitted for assessment with this application. Granting of a THR is acceptable.
CLINICAL ASSESSMENT

BACKGROUND INFORMATION
Valerian products are currently widely available in the UK as herbal remedies exempt from licensing, under Section 12(2) of the Medicines Act 1968. Valerian is currently used as an ingredient in a number of licensed products.

Hops products are currently widely available in the UK as herbal remedies exempt from licensing, under Section 12(2) of the Medicines Act 1968. Hops is currently used as an ingredient in a number of licensed products.

LEGAL STATUS
General Sales List (GSL) status is requested for the product. Valerian and hops are both currently on the GSL order.

PROPOSED INDICATION
The applicant has proposed the following:

“A traditional herbal medicinal product used for the temporary relief of sleep disturbances caused by the symptoms of mild anxiety based on traditional use only.”

The indication is acceptable.

EVIDENCE OF TRADITIONAL USE
Article 16 c 1 (c) requires the applicant to provide bibliographic or expert evidence to show that the medicinal product in question, or a corresponding product, has been in medicinal use throughout a period of at least 30 years, including at least 15 years within the Community.

The applicant has provided a bibliographic review which shows evidence for the use of *Valeriana officinalis* and *Humulus lupulus* within the EU for a period exceeding 30 years.

Assessor’s comment:
The information provided is sufficient to demonstrate that the proposed product has been in use for at least 30 years of which at least 15 years have been in an EU Member State. The product has in fact been on the EU market since 1964 and has been on the UK market since 1987.

SAFETY REVIEW
Article 16 c 1 (D) requires the Applicant to provide bibliographic review of the safety data together with an expert report.

Assessor’s comment
A safety review has been presented, along with an Expert Report.

The clinical Review of Safety submitted in the dossier outlined adverse events from controlled and uncontrolled studies relevant to the safety of valerian and hops.

Assessor’s comment
A good review of the literature has been provided. Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed. However, the applicant has provided assurance that appropriate genotoxicity testing will be performed prior to renewal of the registration.
Product literature
The product literature (Summary of Product Characteristics, Patient Information Leaflet and labelling) for this product are medically satisfactory.

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.

DISCUSSION
This is an application for registration under the Traditional Herbal Medicinal Products Directive.

The data supplied by the Applicant are sufficient to demonstrate 30 years of traditional use within the European Community as required for registration under the Traditional Herbal Medicines Product Directive. A satisfactory review of the available safety data relating to valerian and hops has been provided together with an expert report supporting the registration of the product.

RECOMMENDATIONS
A Traditional Registration may be granted.
OVERALL CONCLUSION AND RISK ASSESSMENT

QUALITY
Bioforce (UK) Ltd has over 30 years of experience in manufacturing herbal medicinal products. The quality data submitted with this application are satisfactory.

PRECLINICAL
No preclinical data were submitted and none are required for an application of this type.

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

The Applicant has provided a bibliographic review which shows ample evidence for the use of valerian root and hops strobile within the EU for a period exceeding 30 years.

The SPC, PIL and labelling are satisfactory.

RISK ASSESSMENT
The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The risk: benefit ratio is, therefore, acceptable.
DORMEASAN VALERIAN-HOPS ORAL DROPS

THR 13668/0017

STEPS TAKEN FOR ASSESSMENT

1. The MHRA received the Traditional Herbal Registration application on 14 December 2007

2. Following standard checks and communication with the applicant the MHRA considered the application valid on 3 April 2008

3. Following assessment of the application the MHRA requested further information relating to the quality dossier on 4 April 2008 and the clinical dossier on 28 April 2008

4. The applicant responded to the MHRA’s requests, providing further information on the dossiers on 27 October 2008

5. Following assessment of the response the MHRA requested further information relating to the quality dossier on 20 November 2008

6. The applicant responded to the MHRA’s requests, providing further information on the quality dossier on 11 December 2008

7. Following assessment of the response the MHRA requested further information relating to the quality dossier on 19 December 2008

8. The applicant responded to the MHRA’s requests, providing further information on the quality dossier on 19 February 2009

9. A THR was granted on 19 February 2009
SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Dormeasan Valerian-Hops oral drops

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
1 ml of oral liquid contains:

0.5 ml of tincture from Valerian root (*Valeriana officinalis* L.) (1:10-11). Extraction solvent: Ethanol 58% V/V.

and

0.5 ml of tincture from Hop strobile (*Humulus lupulus* L.) (1:12-13). Extraction solvent: Ethanol 65% V/V.

1 ml is equivalent to 35 drops.

For full list of excipients see Section 6.1

3 PHARMACEUTICAL FORM
Oral liquid.
Green to brown, clear liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
A traditional herbal medicinal product used for the temporary relief of sleep disturbances caused by the symptoms of mild anxiety based on traditional use only.

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

Adults and the elderly:
To aid sleep:
Take 30 drops half an hour before bedtime.

For relief of symptoms of mild anxiety:
During daytime: Take 10-20 drops once or twice a day.

As treatment effects may not be apparent immediately, the product should be taken for 2-4 weeks continuously.

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

Not for children or adolescents under 18 years.
4.3 Contraindications
Hypersensitivity to Valerian, Hops or any of the excipients in the product.

This product should not be used in children or adolescents under 18 years.

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

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

This product contains 62 vol% ethanol (alcohol).

This corresponds to:
- 420 mg alcohol equivalent to 10.6 ml beer or 4.4 ml wine (30 drops)
- 140 mg alcohol equivalent to 3.5 ml beer or 1.5 ml wine (10 drops)

Harmful for those suffering from alcoholism. To be taken into account in pregnant, or breast-feeding women, children and high-risk groups such as patients with liver disease or epilepsy.

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 metabolized by the CYP 2D6, CYP 3A4/5, CYP 1A2 or CYP 2E1 pathway has not been observed.

Combination with synthetic sedatives is not recommended.

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

4.6 Pregnancy and lactation
The safety of this product during pregnancy and lactation has not been established, therefore the use of this product during pregnancy and lactation is not recommended.

4.7 Effects on ability to drive and use machines
May impair ability to drive and use machines. If affected do not drive or operate machinery. This product contains alcohol (See Section 4.4 for details of alcohol content).

4.8 Undesirable effects
Gastrointestinal symptoms such as nausea, abdominal cramps may occur. The frequency is not known.

If other adverse reactions not mentioned above occur, a doctor or a qualified healthcare practitioner should be consulted.

4.9 Overdose
Valerian root at a dose of approximately 20 g (equivalent to 93 doses) caused benign symptoms (fatigue, abdominal cramp, chest tightness, lightheadedness, 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 30 g of the drug) withdrawal symptoms (delirium) have been reported.

No cases of overdose have been reported for Hops.

Overdose of this product may result in alcohol intoxication: the amount of alcohol in a full bottle (24.8 g in 50 ml; 49.6 g in 100 ml: equivalent to 1 or 2 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
Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended, unless necessary for the safe use of the product.

The preclinical toxicology data available are limited. Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
From tincture:
Ethanol
Water

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
3 years

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

6.5 Nature and contents of container
Brown glass dropper bottles (Type III glass) with a twist-off cap.

Pack sizes: 50 ml
100 ml

Not all pack sizes may be marketed.
6.6 Special precautions for disposal
No special requirements.

7 MARKETING AUTHORISATION HOLDER
Bioforce (UK) Ltd
2 Brewster Place
Irvine, Ayrshire
KA11 5DD, United Kingdom
Tel: 01294 277 344
enquiries@avogel.co.uk

8 MARKETING AUTHORISATION NUMBER(S)
THR 13668/0017

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
19/02/2009

10 DATE OF REVISION OF THE TEXT
19/02/2009
1. What this product is for

Dormeasan is a traditional herbal medicinal product used for the temporary relief of:
- Sleep disturbances resulting from mild anxiety
This is based on traditional use only.

Important things you need to know

- This product is used for the temporary relief of sleep disturbances resulting from mild anxiety.
- This product is suitable for adults over 18 years. It is not known to be habit forming.
- Don't take this product if you are allergic to any of the ingredients: see section 6.
- Don't take this product if you are already taking medication for your symptoms.
- Before you take this product, read section 2.
- Dosage instructions: see section 3.
- Talk to your doctor if your symptoms worsen or you do not feel any benefit from this product within 4 weeks.
- Side effects are minor: see section 4.

Now read the rest of this leaflet carefully. Keep this leaflet. You may need to read it again.
Do not take this product:
- If you are under 18 years of age.
- If you are already taking another medicine for your symptoms.
- If you are taking another medicine which is affected by alcohol.
- If you are allergic to any of the ingredients in this product (see section 6 Further information).
- If you are pregnant or breastfeeding.

You should also know
- This medicinal product contains 62 vol % ethanol (alcohol), i.e. up to 420 mg per 30 drop dose, equivalent to 11 ml beer (less than a tablespoon) or 4 ml wine (less than a teaspoon) per dose.
- If you suffer from alcoholism the alcohol content of this product may be harmful.
- If you are in a high-risk group (patients with liver disease or epilepsy) you should consider the alcohol content before taking this product.

Using

3. How to use this product

Adults and the elderly:
To aid sleep: Take 30 drops in a little water half an hour before bedtime.
This product may also be used to relieve the symptoms of mild anxiety: Take 10–20 drops in a little water once or twice daily.

The effects of this product may not be felt immediately. You may need to take it for up to 4 weeks for best results.
Don’t take more than the recommended dose.
This product is not known to be habit forming.

Please turn over...
Using

If you take too much
- If you feel ill, talk to your doctor. Taking too much is unlikely to be harmful.
- 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
- Don’t worry about the missed dose. Take the next dose as usual.

If you feel this product isn’t working
- See your doctor if your symptoms worsen or do not improve within 4 weeks.

Side effects

4. Possible side effects

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

Minor side effects
The following minor side effects can occur when using this product.
- Feeling sick
- Stomach discomfort

These are often short-lived and should go away by themselves. However if they are troubling you, talk to your doctor or pharmacist.

If you are concerned about any side effect or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Driving and using machines
- This product is intended to help you fall asleep. If you feel drowsy do not drive or operate machinery.
- The effects of the product may be increased by alcohol. Excessive use of alcohol should therefore be avoided.
5. How to store this product

- Keep out of the reach and sight of children.
- Do not use this product after the expiry date on the packaging. The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage conditions.
- Do not use this product if you notice a change in colour. It should be a clear liquid that is greenish brown in colour.

6. Further Information

What this product contains

1 ml of oral liquid contains:

Valerian root tincture 0.5 ml
(Valeriana officinalis L. (1:10-11))
Extraction solvent: ethanol 58% V/V

Hops strobile tincture 0.5 ml
(Humulus lupulus L. (1:12-13))
Extraction solvent: ethanol 65% V/V

1 ml of Dormeasan is equivalent to 35 drops.

The other ingredients used for the liquid are ethanol and water.

What this product looks like and the contents of the pack

Dormeasan is a clear liquid that is greenish brown in colour. Dormeasan is available in 50 ml and 100 ml bottles. Not all pack sizes may be marketed.

Traditional Herbal Registration Holder and Manufacturer

Traditional Herbal Registration Holders and Batch Release:

Bioforce (UK) Ltd,
2 Brewster Place,
Irvine, Ayrshire, UK
KA11 5DS

Manufacturer:
Bioforce AG, CH-9325, Roggwil,
Switzerland

THR No. 13668/0017

This leaflet was approved on 02/2009

What is Valerian?

Valerian is a flowering plant which is native to Europe and parts of Asia. It is the extract of Valerian roots which is used to make Dormeasan.

What are Hops?

Hops are flowering plants native to the Northern Hemisphere. Each plant produces either male or female flowers. The extract of the female flowers (commonly called Hops) is used to make Dormeasan.

You should also know

Bioforce runs a helpline by phone and email which can provide you with further information.

Email: enquiries@avogel.co.uk
Phone: 0845 608 5858

You can get a larger print or audio version of this leaflet. Call this number:

0845 608 5858.
50 ml label:

Dormeasan is a traditional herbal medicinal product used for the temporary relief of sleep disturbances resulting from mild anxiety, this is based on traditional use only.

Directions for use: Adults and the elderly:
To aid sleep: Take 30 drops in a little water half an hour before bedtime.
This product may also be used to relieve the symptoms of mild anxiety: Take 10-20 drops in a little water once or twice daily.
Not for use in children or those under 18.
For oral use only. Read leaflet before use.
Keep out of the reach and sight of children. This medicinal product does not require any special storage conditions.

Traditional Herbal Registration Holder: Biocare (UK) Ltd. Irvine, UK. K4112-000
THR No. 13668/0017

Ingredients:
1 ml of oral liquid contains:
Valerian root tincture 0.5 ml
(Valeriana officinalis L.) (1:10–11)
Extraction solvent: ethanol 50% V/V
Hops strobile tincture 0.5 ml
(Humulus lupulus L.) (1:12–13)
Extraction solvent: ethanol 65% V/V
1 ml of Dormeasan is equivalent to 35 drops.
This product contains ethanol. Harmful for people suffering from alcoholism. See leaflet for further information.
Safety Sealed Bottle. If ring at bottom of cap is missing or separated, do not use!
Dormeasan® Valerian-Hops oral drops

Dormeasan is a traditional herbal medicinal product used for the temporary relief of:

- Sleep disturbances resulting from mild anxiety

This is based on traditional use only.

Ingredients:
1 ml of oral liquid contains
Valerian root tincture 0.5 ml
(Valeriana officinalis L.) 1:10 (w/v)
Extraction solvent, ethanol 95% V/V
Hops strobile tincture 0.5 ml
(Humulus lupulus) L 1:10
Extraction solvent, ethanol 95% V/V
1 ml of Dormeasan is equivalent to 35 drops.

This product contains ethanol. Harmful for people suffering from alcoholism. See leaflet for further information.

Traditional Herbal Registration Holder:
Bioforce (UK) Ltd.
Irving, UK, KA11 5DD
Telephone: 01294 227244
enquiries@avogel.co.uk
THR No. 13668/0017

Directions for use:
Adults and the elderly:
To aid sleep: Take 30 drops in a little water half an hour before bedtime.
This product may also be used to relieve the symptoms of mild anxiety:
Take 10-20 drops in a little water once or twice daily.
Not for use in children or those under 18.
For oral use only. Read leaflet before use.
Do not use if you are allergic to any of the ingredients.
Keep out of the reach and sight of children.
This medicinal product does not require any special storage conditions.

Product of Switzerland
Oral drops

Traditional herbal medicinal product for temporary relief of SLEEP DISTURBANCES

50 ml
Dormesan is a traditional herbal medicinal product used for the temporary relief of sleep disturbances resulting from mild anxiety. This is based on traditional use only.

Directions for use: Adults and the elderly:
To aid sleep: Take 30 drops in a little water half an hour before bedtime.

This product may also be used to relieve the symptoms of mild anxiety: Take 10-20 drops in a little water once or twice daily.

Not for use in children or those under 18.
For oral use only. Read leaflet before use.
Keep out of the reach and sight of children.
This medicinal product does not require any special storage conditions.

Traditional Herbal Registration Holder: Bioforce (UK) Ltd, Irvine, UK, KA11 5DF
THR No. 13668/0017

Ingredients:
1 ml of oral liquid contains:
Valerian root tincture (Valeriana officinalis L.) (1:10–11)
Extraction solvent: ethanol 58% V/V
Hops strobile tincture (Humulus lupulus L.) (1:12–13)
Extraction solvent: ethanol 65% V/V

1 ml of Dormesan is equivalent to 35 drops.
This product contains ethanol. Harmful for people suffering from alcoholism. See leaflet for further information.

Safely Sealed Bottle. If ring at bottom of cap is missing or separated, do not use.
100 ml carton:

Dormeasan®
Valerian-Hops oral drops

Dormeasan is a traditional herbal medicinal product used for the temporary relief of:
- Sleep disturbances resulting from mild anxiety

This is based on traditional use only.

Ingredients:
- 1 ml of oral liquid contains:
  - Valerian root tincture 0.5 ml (Valeriana officinalis L. (Valerianaceae))
  - Hops strobile tincture 0.5 ml (Humulus lupulus L. (Cannabaceae))

This product contains ethanol. Harmful for people suffering from alcoholism. See leaflet for further information.

Traditional Herbal Registration Holder:
Bioloce (UK) Ltd
Ircone, UK, KA11 5SD
Telephone: 01294 227344
enquiry@avogel.com/uk
THOR No. 13668/0017

Directions for use:
Adults and the elderly:
To aid sleep: Take 30 drops in a little water half an hour before bedtime.

This product may also be used to relieve the symptoms of mild anxiety: take 10-20 drops in a little water once or twice daily.

Not for use in children or those under 18.

For oral use only. Read leaflet before use.
Do not use if you are allergic to any of the ingredients.
Keep out of the reach and sight of children.

This medicinal product does not require any special storage conditions.

Product of Switzerland
Oral drops

100 ml
Module 6

Steps taken after THR grant

The following table lists the updates made to the Traditional Herbal Registration for this product that have been approved by the MHRA since the product was first granted a THR.

<table>
<thead>
<tr>
<th>Date submitted</th>
<th>Application type</th>
<th>Scope</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>23/08/2011</td>
<td>Type IB variation</td>
<td>To register additional pack sizes of 15 ml and 30 ml to the already approved pack sizes with consequential changes to section 6.5 (Container) of the SmPC, the PIL and labelling.</td>
<td>Approved 17/10/2011</td>
</tr>
<tr>
<td>29/11/2011</td>
<td>Type IB variation</td>
<td>To change the invented name of the medicinal product from Dormeasan Valerian-Hops oral drops to Dormeasan Sleep Valerian-Hops oral drops.</td>
<td>Approved 22/12/2011</td>
</tr>
<tr>
<td>29/11/2011</td>
<td>Type IB variation</td>
<td>To amend section 4.2 of the SmPC to include the advice to take the product in a little water or fruit juice. The labels and leaflet have been updated accordingly.</td>
<td>Approved 10/02/2012</td>
</tr>
</tbody>
</table>
Annex 1 - Assessment report for variation to amend section 4.2 of the SmPC to include the advice to take the product in a little water or fruit juice.

As this variation was classified as a Type IB variation, no assessment report was needed during the assessment process. However, in this case, the assessor has provided one:

VARIATION ASSESSMENT REPORT

Reason for variation:
To amend section 4.2 of the SmPC to include the advice to take the product in a little water or fruit juice.

The applicant was also asked to include a maximum daily dose on the SmPC, labels and leaflet in line with other similar THRs.

The applicant stated that the maximum recommended daily dose is 70 drops, which is equivalent to 2 mls of the product. This maximum daily dose is in line with the Clinical Overview submitted with the initial application.

Also a report of a clinical trial using 2 mls of Dormesan was included in the initial application and the adverse effects reported were considered not to be due to Dormesan.

It is considered that the maximum daily dose is acceptable.

The SmPC, labels and leaflet have been updated satisfactorily. The MAH has confirmed that the 30 ml pack size is not currently marketed and, therefore, mock ups for the 15 ml and 50 ml pack sizes have been submitted.
Following approval of this variation on 10 February 2012 the following updated SmPC, PIL and labelling have been incorporated into the THR for Dormeasan Sleep Valerian-Hops oral drops:

**SUMMARY OF PRODUCT CHARACTERISTICS**

### 1 NAME OF THE MEDICINAL PRODUCT
Dormeasan Sleep Valerian-Hops oral drops

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION
1 ml of oral liquid contains:

- 0.5 ml of tincture from Valerian root (*Valeriana officinalis* L.) (1:10-11). Extraction solvent: Ethanol 58% V/V.
- and
- 0.5 ml of tincture from Hop strobile (*Humulus lupulus* L.) (1:12-13). Extraction solvent: Ethanol 65% V/V.

1 ml is equivalent to 35 drops.

For full list of excipients see Section 6.1

### 3 PHARMACEUTICAL FORM
Oral liquid.
Green to brown, clear liquid.

### 4 CLINICAL PARTICULARS

#### 4.1 Therapeutic indications
A traditional herbal medicinal product used for the temporary relief of sleep disturbances caused by the symptoms of mild anxiety based on traditional use only.

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

**Adults and the elderly:**
To aid sleep:
Take 30 drops in a little water or fruit juice half an hour before bedtime.

For relief of symptoms of mild anxiety:
During daytime: Take 10-20 drops in a little water or fruit juice once or twice a day.

Maximum daily recommended dose is 70 drops.

As treatment effects may not be apparent immediately, the product should be taken for 2-4 weeks continuously.
If symptoms worsen or do not improve after 4 weeks a doctor or qualified healthcare practitioner should be consulted.

Not for children or adolescents under 18 years.

4.3 **Contraindications**
Hypersensitivity to Valerian, Hops or any of the excipients in the product.

This product should not be used in children or adolescents under 18 years.

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

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

This product contains 62 vol% ethanol (alcohol).

This corresponds to:
- 420 mg alcohol equivalent to 10.6 ml beer or 4.4 ml wine (30 drops)
- 140 mg alcohol equivalent to 3.5 ml beer or 1.5 ml wine (10 drops)

Harmful for those suffering from alcoholism. To be taken into account in pregnant, or breast-feeding women, children and high-risk groups such as patients with liver disease or epilepsy.

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 metabolized by the CYP 2D6, CYP 3A4/5, CYP 1A2 or CYP 2E1 pathway has not been observed.

Combination with synthetic sedatives is not recommended.

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

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

4.7 **Effects on ability to drive and use machines**
May impair ability to drive and use machines. If affected do not drive or operate machinery. This product contains alcohol (See Section 4.4 for details of alcohol content).

4.8 **Undesirable effects**
Gastrointestinal symptoms such as nausea, abdominal cramps may occur. The frequency is not known.

If other adverse reactions not mentioned above occur, a doctor or a qualified healthcare practitioner should be consulted.
4.9 **Overdose**
Valerian root at a dose of approximately 20 g (equivalent to 93 doses) caused benign symptoms (fatigue, abdominal cramp, chest tightness, lightheadedness, 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 30 g of the drug) withdrawal symptoms (delirium) have been reported.

No cases of overdose have been reported for Hops.

Overdose of this product may result in alcohol intoxication: the amount of alcohol in a full bottle (24.8 g in 50 ml: 49.6 g in 100 ml: equivalent to 1 or 2 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**
Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended, unless necessary for the safe use of the product.

The preclinical toxicology data available are limited. Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6 **PHARMACEUTICAL PARTICULARS**

6.1 **List of excipients**
*From tincture:*
- Ethanol
- Water

6.2 **Incompatibilities**
Not applicable.

6.3 **Shelf life**
3 years

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

6.5 **Nature and contents of container**
Brown glass dropper bottles (Type III glass) with a twist-off cap.
Pack sizes: 15 ml  
            30 ml  
            50 ml  
            100 ml  

Not all pack sizes may be marketed.

6.6 Special precautions for disposal
No special requirements.

7 MARKETING AUTHORISATION HOLDER
Bioforce (UK) Ltd
2 Brewster Place
Irvine, Ayrshire
KA11 5DD, United Kingdom
Tel: 01294 277 344
enquiries@avogel.co.uk

8 MARKETING AUTHORISATION NUMBER(S)
THR 13668/0017

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORIZATION
19/02/2009

10 DATE OF REVISION OF THE TEXT
10/02/2012
Information

Important things you need to know:

- This product is used for the temporary relief of sleep disturbances resulting from mild anxiety.
- This product is suitable for adults over 18 years. It is not known to be habit forming.
- Don’t take this product if you are allergic to any of the ingredients; see section 6.
- Don’t take this product if you are already taking another medicine to help you sleep or for anxiety.
- Before you take this product: read section 2.
- Dosage instructions: see section 3.

Do not use this product:

- If you are under 18 years of age.
- If you are already taking another medicine to help you sleep or for anxiety.
- If you are taking another medicine which is affected by alcohol.
- If you are allergic to any of the ingredients in this product (see section 6 Further Information).
- If you are pregnant or breastfeeding.
- You should also know:

   - This medicinal product contains 62 vol.% ethanol (alcohol), i.e. up to 420 mg per 30 drop dose: equivalent to 11 ml beer (less than a tablespoon) or 4 ml wine (less than a teaspoon) per dose.
   - If you suffer from alcoholism the alcohol content of this product may be harmful.
   - If you are in a high-risk group (patients with liver disease or epilepsy) you should consider the alcohol content before taking this product.

1. What this product is for:
Dormeasan Sleep is a traditional herbal medicinal product used for the temporary relief of:
- Sleep disturbances resulting from mild anxiety.
This is based on traditional use only.

2. Before you use this product:

Do not take this product:
- If you are under 18 years of age.
- If you are already taking another medicine to help you sleep or for anxiety.
- If you are taking another medicine which is affected by alcohol.
- If you are allergic to any of the ingredients in this product (see section 6 Further Information).
- If you are pregnant or breastfeeding.

You should also know:
- This medicinal product contains 62 vol.% ethanol (alcohol), i.e. up to 420 mg per 30 drop dose: equivalent to 11 ml beer (less than a tablespoon) or 4 ml wine (less than a teaspoon) per dose.
- If you suffer from alcoholism the alcohol content of this product may be harmful.
- If you are in a high-risk group (patients with liver disease or epilepsy) you should consider the alcohol content before taking this product.

3. How to use this product:

Adults and the elderly:
- To aid sleep: Take 10 drops in a little water or fruit juice half an hour before bedtime.
- This product may also be used to relieve the symptoms of mild anxiety. Take 10-20 drops in a little water or fruit juice once or twice daily.
- Do not take more than 70 drops a day.
- The effects of this product may not be felt immediately. You may need to take it for up to 4 weeks for best results.
- Don’t take more than the recommended dose.

This product is not known to be habit forming.
Using
If you take too much
- If you feel ill, talk to your doctor. Taking too much is unlikely to be harmful.
- Ovulate of this product may result in alcoholic intoxication and should be treated accordingly (see section 2 You should also know).

If you forget to take this product
- Don’t worry about the missed dose. Take the next dose as usual.

If you feel this product isn’t working
- See your doctor if your symptoms worsen or do not improve within 4 weeks.

You can get a larger print or audio version of this leaflet. Call this number: 0845 608 5858.

Side effects
4. Possible side effects
Like all medicines, this product can cause side effects, although not everybody gets them.

Minor side effects
The following minor side effects can occur when using this product:
- Feeling sick
- Stomach discomfort

These are often short-lived and should go away by themselves. However, if they are troubling you, talk to your doctor or pharmacist.

If you are concerned about any side effect or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Driving and using machines
- This product is intended to help you fall asleep. If you feel drowsy do not drive or operate machinery.
- The effects of this product may be increased by alcohol. Excessive use of alcohol should therefore be avoided.

Information
5. How to store this product
- Keep out of the reach and sight of children.
- Do not use this product after the expiry date on the packaging. The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage conditions.
- Do not use this product if you notice a change in colour. It should be a clear liquid that is greenish brown in colour.

6. Further Information
What this product contains
1 ml of oral liquid contains:
- Valerian root tincture 0.5 ml (Valeriana officinalis L) (1:10-11)
- Extraction solvent: ethanol 58% V/V
- Hops strobile tincture 0.5 ml (Humulus lupulus L) (1:12-13)
- Extraction solvent: ethanol 65% V/V

1 ml of Dormeasan Sleep is equivalent to 35 drops.

The other ingredients used for the liquid are ethanol and water.

What this product looks like and the contents of the pack
Dormeasan Sleep is a clear liquid that is greenish brown in colour.
Dormeasan Sleep is available in 15 ml, 30 ml, 50 ml and 100 ml bottles. Not all pack sizes may be marketed.

Traditional Herbal Registration Holder and Manufacturer
Traditional Herbal Registration Holder and Batch Release:
Bioforce (UK) Ltd, 2 Brewester Place, Irvine, Ayrshire, UK KA11 5DD

Manufacturer:
Bioforce AG, CH-9325, Raggwil Switzerland
THQ No. 13668/0017

Certification Mark
This leaflet was revised on 02/2012

What is Valerian?
Valerian is a flowering plant which is native to Europe and parts of Asia. It is the extract of Valerian roots which is used to make Dormeasan Sleep.

What are Hops?
Hops are flowering plants native to the Northern Hemisphere. Each plant produces either male or female flowers. The extract of the female flowers (commonly called Hops) is used to make Dormeasan Sleep.

You should also know
Bioforce runs a helpline by phone and email which can provide you with further information.
Email: enquiries@avogel.co.uk
Phone: 0845 608 5858

You can help to make medicines safer by reporting any side effects to the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. Alternatively you can get a paper Yellow Card form from your doctor’s surgery or pharmacy, or call freephone 0800 109 3352 (available 10am-2pm Monday-Friday).
Dormeousan Sleep is a traditional herbal medicinal product used for the temporary relief of sleep disturbances resulting from mild anxiety. This is based on traditional use only.

**Directions for use:** Adults and the elderly:
- **To aid sleep:** Take 30 drops in a little water or fruit juice half an hour before bedtime.
  - This product may also be used to relieve the symptoms of mild anxiety: Take 10-20 drops in a little water or fruit juice once or twice daily.
  - Do not take more than 70 drops a day.
  - Not for use in children or those under 18.
  - For oral use only. Read leaflet before use. Keep out of the reach and sight of children. This medicinal product does not require any special storage conditions.

**Traditional Herbal Registration Holder:**
Biocrest (UK) Ltd, Irvine, UK KA11 5DD
THR No. 13668/0017

**Ingredients:**
1 ml of oral liquid contains:
Valerian root tincture (Valeriana officinalis L.) (1:10-11). Extraction solvent: ethanol 58% V/V.
Hops strobile tincture (Humulus lupulus L.) (1:12-13).
Extraction solvent: ethanol 65% V/V.

1 ml of Dormeousan Sleep is equivalent to 35 drops. This product contains ethanol. Harmful for people suffering from alcoholism. See leaflet for further information.

Safety Sealed Bottle. If ring at bottom of cap is missing or separated, do not use.

**Batch:**
EXP:

---

**Ingredients:**
1 ml of oral liquid contains:
Valerian root tincture (Valeriana officinalis L.) (1:10-11). Extraction solvent: ethanol 58% V/V.
Hops strobile tincture (Humulus lupulus L.) (1:12-13).
Extraction solvent: ethanol 65% V/V.

1 ml of Dormeousan Sleep is equivalent to 35 drops. This product contains ethanol. Harmful for people suffering from alcoholism. See leaflet for further information.

Safety Sealed Bottle. If ring at bottom of cap is missing or separated, do not use.

**Batch:**
EXP:
Dormeasan® Sleep
Valerian-Hops oral drops

Dormeasan Sleep is a traditional herbal medicinal product used for the temporary relief of:
- Sleep disturbances resulting from mild anxiety

This is based on traditional use only.

Ingredients:
1 ml of oral liquid contains 0.5 ml of Valerian root tincture (Valeriana officinalis L. (1:10:1)), Extraction solvent: ethanol 58% V/V) and 0.5 ml of Hops sprout tincture (Humulus lupulus L. (1:12:13)). Extraction solvent: ethanol 65% V/V).

1 ml of Dormeasan Sleep is equivalent to 35 drops.

This product contains ethanol, harmful for people suffering from alcoholism. See leaflet for further information.

Keep out of the reach and sight of children.

This medicinal product does not require any special storage conditions.

Directions for use:
Adults and the elderly:
To aid sleep: Take 30 drops in a little water or fruit juice half an hour before bedtime.

This product may also be used to relieve the symptoms of mild anxiety:
Take 10-20 drops in a little water or fruit juice once or twice daily.
Do not take more than 70 drops a day.

Not for use in children or those under 18.
For oral use only. Read leaflet before use.
Do not use if you are allergic to any of the ingredients or if you are already taking another medicine to help you sleep or for anxiety.
Dormeasan® Sleep
Valerian-Hops oral drops

Dormeasan Sleep is a traditional herbal medicinal product used for the temporary relief of:
- Sleep disturbances resulting from mild anxiety

This is based on traditional use only.

Directions for use:
- Adults and the elderly: To aid sleep: Take 30 drops in a little water or fruit juice half an hour before bedtime. This product may also be used to relieve the symptoms of mild anxiety: take 10-20 drops in a little water or fruit juice once or twice daily.
- Do not take more than 70 drops a day.
- Not for use in children or those under 18.
- For oral use only. Read leaflet before use.
- Do not use if you are allergic to any of the ingredients or if you are already taking another medicine to help you sleep or for anxiety.
- Keep out of reach and sight of children.

This medicinal product does not require any special storage conditions.

Product of Switzerland
Oral drops
SLEEP DISTURBANCES
50 ml