Holland & Barrett Valerian Capsules
GNC Live Well Valerian Capsules
Lifecycle Valerian Capsules
Nature’s Garden Valerian Capsules

THR 21710/0001

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Medicines and Healthcare products Regulatory Agency
HOLLAND & BARRET VALERIAN CAPSULES
GNC LIVE WELL VALERIAN CAPSULES
LIFECYCLE VALERIAN CAPSULES
NATURE’S GARDEN VALERIAN CAPSULES

THR 21710/0001

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted NBTY Europe Limited a Traditional Herbal Registration Certificate for the traditional herbal medicinal product Holland & Barrett Valerian Capsules, GNC Live Well Valerian Capsules, Lifecycle Valerian Capsules and Nature’s Garden Valerian Capsules (Herbal Registration number: THR 21710/0001). This product is available without prescription and can be bought from pharmacies and other outlets.

The active ingredient of Holland & Barrett Valerian Capsules, GNC Live Well Valerian Capsules, Lifecycle Capsules and Nature’s Garden Valerian Capsules comes from the roots of the plant Valeriana officinalis L., also known as valerian. Valerian root is a traditional herbal medicine used for the temporary relief of symptoms of mild anxiety and to aid sleep. This registration is based exclusively upon the longstanding use of valerian root as a traditional herbal medicine and not upon data generated from clinical trials. There is no requirement under the Traditional Herbal Registration scheme to prove scientifically that a 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.
HOLLAND & BARRETT VALERIAN CAPSULES
GNC LIVE WELL VALERIAN CAPSULES
LIFECYCLE VALERIAN CAPSULES
NATURE’S GARDEN VALERIAN CAPSULES

THR 21710/0001

SCIENTIFIC DISCUSSION

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INTRODUCTION

The MHRA granted a Traditional Herbal Registration Certificate for the traditional herbal remedy Holland & Barrett Valerian Capsules, GNC Live Well Valerian Capsules, Lifecycle Capsules and Nature’s Garden Valerian Capsules on 23 February 2010. This product will be referred to as ‘Holland & Barrett Valerian Capsules’ throughout the rest of this report. 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.

This product consists of hard capsules containing 337 mg of extract (as dry extract) from valerian root (*Valeriana officinalis* L.), equivalent to 1683 mg–2020 mg of valerian root. The extraction solvent used is ethanol 70%v/v. This product is indicated as a traditional herbal medicinal product for temporary relief of symptoms of mild anxiety and to aid sleep based exclusively on evidence of the traditional use of valerian root. The recommended dose for temporary relief of symptoms of mild anxiety is one capsule three times daily. The recommended dose to aid sleep is one capsule 30 minutes to one hour before bedtime.

The data supplied by the Applicant demonstrate 30 years of traditional use of valerian root in the European Community. A satisfactory review of the available safety data on valerian root has also been provided, together with an Expert Safety Report supporting the proposed product.
PHARMACEUTICAL ASSESSMENT

HERBAL SUBSTANCE: VALERIAN ROOT

Scientific name of the plant: *Valeriana officinalis* L.
Family: Valerianaceae

Manufacture
The plant source of the herbal substance valerian root is *Valeriana officinalis* L., which belongs to the Valerianaceae family. The plant is cultivated in Ukraine, Bulgaria, Poland, France, the Netherlands, Germany and Hungary.

The roots are collected from autumn to winter. The roots are harvested manually and mechanically, cut, washed and oven-dried before being stored. The supplier of the valerian root has provided confirmation that the herbal substance is produced in accordance with the principles of Good Agricultural and Collection Practice (GACP) (EMEA/HMPC/246816/20050).

Control of Herbal Substance
The specifications of the herbal substance are in line with the European Pharmacopoeia monograph and are satisfactory.

Analytical methods have been appropriately validated and are satisfactory for ensuring the herbal substance’s compliance with the relevant specifications.

Container Closure System
A suitable container closure system that complies with Directive 2002/72/EC is used to store the herbal substance.

Stability
Confirmation is given that the herbal substance will be tested prior to being used to make the herbal preparation. A shelf-life for the herbal substance is not necessary because it is only a precursor of the active substance, the herbal preparation. The actual guideline requires stability testing data for the herbal preparation and the herbal product in the application documents and not for the herbal substance.

HERBAL PREPARATION: VALERIAN ROOT DRY EXTRACT

Parts of the plant used: Dried roots (rhizome, root and stolon)
Extract solvent: Ethanol 70%v/v

The dry extract preparation is a brown hygroscopic powder.

Manufacture
A satisfactory description and a flow diagram of the manufacturing process of the herbal preparation have been provided and are satisfactory.

The in-process controls (IPC) and specifications are satisfactorily detailed.
Control of herbal preparation
The specification for valerian root dry extract is satisfactory.

Satisfactory details of the analytical methods are provided.

Batch analysis data are provided and comply with the proposed specification.

Container Closure System
The container closure system used to store the dry extract complies with Directive 2002/72/EC.

Stability
Batches were packed in the final container closure system and stored under ICH real time, intermediate and accelerated conditions. The data support the storage conditions used.

HERBAL PRODUCT
Description and Composition of the Herbal Product
The product consists of two piece, hard, vegetarian, capsules with grey/brown powder fill. Holland & Barrett Valerian Capsules contain magnesium stearate (vegetable grade), maltodextrin, silica colloidal anhydrous and hypromellose.

All excipients are standard pharmaceutical excipients used in capsules formulations of this type and comply with the Ph. Eur.

Manufacture
A description and flow-chart of the manufacturing method has been provided. The manufacturing procedure is a standard procedure and is satisfactory for the product.

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.

Container Closure System
The hard capsules are presented in dark amber polyethylene terephthalate (PET) bottles with a chiffon black hinge cap, with a tamper evident under the cap or green polyethylene terephthalate (PET) bottles with an angled flip top cap with the neck of the bottle sealed with a “lift n peel” seal.

The capsules are stored in packs of 30 capsules or 60 capsules.

Suitable specifications have been provided by the packaging suppliers and it has been
confirmed that all primary packaging materials comply with Directive 2002/72/EC.

**Stability**
Finished product stability studies have been conducted in accordance with current guidelines. Based on the results, a product shelf-life of 20 months is appropriate.

**Pharmaceutical Expert**
The Quality Overall Summary has been written by a chemist employed as by Holland & Barrett and is satisfactory

**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 and quality**
The grant of a Traditional Herbal Registration is acceptable.
PRE-CLINICAL ASSESSMENT

PRE-CLINICAL SAFETY DATA
The Safety Expert Report submitted by the applicant lists relevant references to published work studying the toxicology of valerian root.

PRE-CLINICAL OVERVIEW
The applicant has submitted an adequate literature review with this application. An Expert Safety Report was also provided, which included reviews of some non-clinical data. The Expert Safety Report was written by a pharmacologist with expertise in herbal medicines, and is dated 5 January 2009.

The overview contains a short review of some pre-clinical data for valerian. Some of the studies in the literature review were conducted and published before GLP was a regulatory requirement. Moreover, it is not possible to ascertain if the data assessed in the review would comply with today’s regulatory safety testing requirements with regards to design, conduct and analysis.

Due to a shortage of published data on valerian root it is not possible to assess if the safety package for the phytochemical constituents of valerian root meets current standards of 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
The Summary of Product Characteristics for this product is satisfactory.

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 demonstrating traditional use of valerian root is acceptable. An adequate literature review for valerian root has been carried out by the applicant and no new non-clinical data were submitted for assessment with this application. Granting of a THR is acceptable.
CLINICAL ASSESSMENT

LEGAL STATUS
General Sales List status is requested for this product. Valerian is currently on the GSL order.

PROPOSED INDICATION
The applicant has proposed the following indication, which is acceptable:

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

EVIDENCE OF TRADITIONAL USE
Article 16 c 1 (c) requires the Applicant to provide bibliographic or expert evidence showing 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 European Community.

The Applicant has provided a bibliographic review as evidence of the use of *Valeriana officinalis* L./valerian root within the EU for a period exceeding 30 years.

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

The applicant has provided satisfactory information supporting the safety of valerian.

The information provided is acceptable and reference has been made to the adopted HMPC Community Monograph and the HMPC Assessment Report for valerian root which covers the bibliographic data available.

SUMMARY OF PRODUCT CHARACTERISTICS
The SmPC for this product is satisfactory.

PATIENT INFORMATION LEAFLET
The PILs for this product are satisfactory.

LABELLING
All labelling is satisfactory.

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 of corresponding products and satisfactory safety data have been provided supporting the proposed product.

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

QUALITY
The quality data submitted with this application are satisfactory.

PRECLINICAL
No new 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 within the EU for a period exceeding 30 years.

A satisfactory review of the safety data has been provided.

The SmPC, PILs and labelling are satisfactory.

RISK ASSESSMENT
The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified.
HOLLAND & BARRETT VALERIAN CAPSULES
GNC LIVE WELL VALERIAN CAPSULES
LIFECYCLE VALERIAN CAPSULES
NATURE’S GARDEN VALERIAN CAPSULES

THR 21710/0001

STEPS TAKEN FOR ASSESSMENT

1. The MHRA received the Traditional Herbal Registration application on 29 January 2009

2. Following standard checks and communication with the applicant the MHRA considered the application valid on 4 February 2009

3. Following assessment of the application the MHRA requested further information relating to the clinical dossier on 12 April 2009 and the quality dossier on 29 May 2009

4. The applicant responded to the MHRA’s requests, providing further information on the clinical dossier on 9 June 2009 and the quality dossier on 2 July 2009

5. A THR was granted on 23 February 2010
SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
- Holland & Barrett Valerian Capsules
- GNC Live Well Valerian Capsules
- Lifecycle Valerian Capsules
- Nature’s Garden Valerian Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each capsule contains 337mg of extract (as dry extract) from Valerian root 
(*Valeriana officinalis* L) (equivalent to 1683mg – 2020mg of Valerian root). 
Extraction solvent: ethanol 70%v/v.

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM
Capsule, hard

Two piece clear hard capsules with grey/brown powder fill.

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 use only

*Adults and elderly:*
For the temporary relief of symptoms of mild anxiety: take 1 capsule 3 
times daily.

*To aid sleep:* take one capsule 30 minutes to one hour before bedtime with an 
earlier dose during the evening if necessary.

Swallow capsule with water.

As the effects of this product may not occur immediately, the capsules should 
be taken continuously for 2 – 4 weeks. Do not exceed the stated dose.

Maximum dose: 4 capsules per day.

Duration of use:
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 (see Section 4.4. Special warnings and precautions for use)

4.3 Contraindications
Hypersensitivity to Valerian or any of the excipients

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

The use of this product is not recommended in children and adolescents below the age of 18 years because data are not sufficient 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, CYP1A2 or CYP 2E1 pathway has not been observed. Additive effects with hypnotics and other sedative drugs cannot be excluded and therefore co-medication is not recommended as a general precaution.

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

4.6 Pregnancy and lactation
Safety 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
May impair the ability to drive and use machines. If affected, patients should not drive or operate machinery.

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 qualified health care practitioner should be consulted.

4.9 Overdose
Valerian root at a dose of approximately 20g (equivalent to approximately 10-12 capsules of Valerian root 337mg) 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
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
Magnesium stearate

Excipients in the extract:
Maltodextrin
Silica colloidal anhydrous

Capsule shell:
Hypermellose

6.2 Incompatibilities
Not applicable

6.3 Shelf life
20 months

6.4 Special precautions for storage
Store below 25ºC. Keep the bottle tightly closed.

6.5 Nature and contents of container
Container:
Dark amber Polyethylene terephthalate (PET) bottles with a chiffon black hinge cap, with a tamper evident seal under the cap.
Or,
Green Polyethylene terephthalate (PET) bottles with an angled flip top cap. The neck of the bottle sealed with a “lift n peal” seal.

Pack size: 30 capsules and 60 capsules

6.6 Special precautions for disposal
No special requirements

7 MARKETING AUTHORISATION HOLDER
NBTY Europe Limited
8 MARKETING AUTHORISATION NUMBER(S)
THR 21710/0001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
23/02/2010

10 DATE OF REVISION OF THE TEXT
01/02/2011
PATIENT INFORMATION LEAFLET

HOLLAND & BARRETT
VALERIAN CAPSULES
Valerian Root Extract

Important Notes
◆ Please read this leaflet carefully before you use this product as it contains important information
◆ Keep this leaflet; you may need to read it again
◆ Seek professional advice if you need more information
◆ Please tell a Doctor or a qualified Healthcare Practitioner if your symptoms worsen or do not improve after 4 weeks of taking this product
◆ Please tell a Doctor or a qualified Healthcare Practitioner if you suffer from side effects not listed in this leaflet or if any of the side effects become serious

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
Holland & Barrett Valerian Capsules is a traditional herbal medicinal product used for the temporary relief of symptoms of mild anxiety and to aid sleep. This is based on traditional use only.

2 - Before you take this product
Do not take this product if you are:
◆ Under 18 years of age
◆ Pregnant or breastfeeding
◆ Allergic to Valerian or any of the excipients in this product
◆ Already taking a medicine for sleep or anxiety

The effects of this product may be increased by alcohol. Excessive use of alcohol should therefore be avoided.

3 - How to take this product
For the temporary relief of symptoms of mild anxiety - Take 1 capsule 3 times daily.
To aid sleep - Take 1 capsule 30 minutes to 1 hour before bedtime with an earlier dose during the evening if necessary.
Swallow the capsule with water.

As the effects of this product may not occur immediately, the capsule should be taken continuously for 2 - 4 weeks. Do not exceed the stated dose.

The maximum dose is 4 capsules per day.

If you take too much of the product (overdose); speak to a Doctor or a qualified Healthcare Practitioner immediately and take this leaflet and bottle with you.

If you forget to take this product: Do not take a double dose to make up for the missed dose(s). Continue to take your usual dose at the usual time. It does not matter if you have missed a dose.

Duration of use: If symptoms worsen or do not improve after 4 weeks, a Doctor or a qualified Healthcare Practitioner should be consulted.

4 - Possible side effects
Like all medicines, Valerian can have side effects. Possible side effects are:
◆ Abdominal cramps
◆ Nausea

If these symptoms persist for more than a few days or become troublesome, stop taking this product.

Other side effects: This product may cause drowsiness. If you are affected, do not drive or operate machinery.

Tell a Doctor or a qualified Healthcare Practitioner if you notice any other side effects.

More information on back panel
5 - How to store this product

- Keep the capsules in the bottle until it is time to take them.
- Do not take the capsules after the expiry date (see outer label).
- Store the capsules below 25°C.
- Keep the bottle tightly closed.
- Keep the capsules out of sight and reach of children.

6 - Further Information

About this product: This product is a traditional herbal medicinal product containing Valerian. Each capsule contains 337mg of extract (as dry extract) from Valerian root (Valeriana officinalis L) (equivalent to 1683mg-2020mg of Valerian root). Extraction solvent: Ethanol 70% v/v. This product also contains the following inactive (excipient) ingredients: Magnesium stearate. Excipients in the extract: Maltodextrin, Silica colloidal anhydrous.

Capsule shell: Hypromellose. Each bottle contains 30 or 60 clear, two piece capsules.

After taking this product: You must speak to a Doctor or a qualified Healthcare Practitioner:

- If your symptoms get worse
- If your symptoms do not improve after 4 weeks
- If side effects not listed in this leaflet occur

Traditional Registration Holder:
THR 21710/0001

NBTY Europe Ltd
Samuel Ryder House
Barling Way
Nuneaton
Warwickshire, CV10 7RH
United Kingdom

Manufacturer of this product:
Vita Health Products Inc
150 Beigin Avenue
Winnipeg
Manitoba, R2J 3W2
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For: NBTY Europe Ltd
Samuel Ryder House
Barling Way
Nuneaton
Warwickshire, CV10 7RH
United Kingdom

If you would like further information about this product, please contact:

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Regulatory Services
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United Kingdom

Is this leaflet hard to see or read?
Contact us on:
Telephone: +44 (0) 2476 215 400
Fax: +44 (0) 2476 215 452
Email: customerservices@NBTYeurope.com

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
PATIENT INFORMATION LEAFLET

GNC Live Well

VALERIAN CAPSULES
Valerian Root Extract

Important Notes
◆ Please read this leaflet carefully before you use this product as it contains important information
◆ Keep this leaflet; you may need to read it again
◆ Seek professional advice if you need more information
◆ Please tell a Doctor or a qualified Healthcare Practitioner if your symptoms worsen or do not improve after 4 weeks of taking this product
◆ Please tell a Doctor or a qualified Healthcare Practitioner if you suffer from side effects not listed in this leaflet or if any of the side effects become serious

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

GNC Live Well Valerian Capsules is a traditional herbal medicinal product used for the temporary relief of symptoms of mild anxiety and to aid sleep. This is based on traditional use only.

2 - Before you take this product

Do not take this product if you are:
◆ Under 18 years of age
◆ Pregnant or breastfeeding
◆ Allergic to Valerian or any of the excipients in this product
◆ Already taking a medicine for sleep or anxiety

The effects of this product may be increased by alcohol. Excessive use of alcohol should therefore be avoided.

3 - How to take this product

For the temporary relief of symptoms of mild anxiety - Take 1 capsule 3 times daily.
To aid sleep - Take 1 capsule 30 minutes to 1 hour before bedtime with an earlier dose during the evening if necessary. Swallow the whole capsule with water.

As the effects of this product may not occur immediately, the capsule should be taken continuously for 2 - 4 weeks. Do not exceed the stated dose.

The maximum dose is 4 capsules per day.

If you take too much of the product (overdose); speak to a Doctor or a qualified Healthcare Practitioner immediately and take this leaflet and bottle with you.

If you forget to take this product; Do not take a double dose to make up for the missed dose(s). Continue to take your usual dose at the usual time. It does not matter if you have missed a dose.

Duration of use: If symptoms worsen or do not improve after 4 weeks, a Doctor or a qualified Healthcare Practitioner should be consulted.

4 - Possible side effects

Like all medicines, Valerian can have side effects. Possible side effects are:
◆ Abdominal cramps
◆ Nausea

If these symptoms persist for more than a few days or become troublesome, stop taking this product.

Other side effects: This product may cause drowsiness. If you are affected, do not drive or operate machinery.

Tell a Doctor or a qualified Healthcare Practitioner if you notice any other side effects.

More information on back panel
5 - How to store this product

- Keep the capsules in the bottle until it is time to take them
- Do not take the capsules after the expiry date (see outer label)
- Store the capsules below 25°C
- Keep the bottle tightly closed
- Keep the capsules out of sight and reach of children

6 - Further Information

About this product: This product is a traditional herbal medicinal product containing Valerian. Each capsule contains 337mg of extract (as dry extract) from Valerian root (Valeriana officinalis L) (equivalent to 1683mg-2020mg of Valerian root). Extraction solvent: Ethanol 70% v/v. This product also contains the following inactive (excipient) ingredients: Magnesium stearate. Excipients in the extract: Maltodextrin, Silica colloidal anhydrous.

Capsule shell: Hypromellose. Each bottle contains 30 or 60 clear, two piece capsules.

After taking this product: You must speak to a Doctor or a qualified Healthcare Practitioner:
- If your symptoms get worse
- If your symptoms do not improve after 4 weeks
- If side effects not listed in this leaflet occur

Traditional Registration Holder:
THR 21710/0001

NBTY Europe Ltd
Samuel Ryder House
Barling Way
Nuneaton
Warwickshire, CV10 7RH
United Kingdom

Manufacturer of this product:
Vita Health Products Inc
150 Beegh Avenue
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For: NBTY Europe Ltd
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United Kingdom

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Fax: +44 (0) 2476 215 452
Email: customerservices@NBTeurope.com

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
# Patient Information Leaflet

**LIFECYCLE VALERIAN CAPSULES**
Valerian Root Extract

## Important Notes
- Please read this leaflet carefully before you use this product as it contains important information.
- Keep this leaflet; you may need to read it again.
- Seek professional advice if you need more information.
- Please tell a Doctor or a qualified Healthcare Practitioner if your symptoms worsen or do not improve after 4 weeks of taking this product.
- Please tell a Doctor or a qualified Healthcare Practitioner if you suffer from side effects not listed in this leaflet or if any of the side effects become serious.

## 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

Lifecycle Valerian Capsules is a traditional herbal medicinal product used for the temporary relief of symptoms of mild anxiety and to aid sleep. This is based on traditional use only.

## 2 - Before you take this product

Do not take this product if you are:
- Under 18 years of age
- Pregnant or breastfeeding
- Allergic to Valerian or any of the excipients in this product
- Already taking a medicine for sleep or anxiety

The effects of this product may be increased by alcohol. Excessive use of alcohol should therefore be avoided.

## 3 - How to take this product

For the temporary relief of symptoms of mild anxiety:
- Take 1 capsule 3 times daily.

To aid sleep:
- Take 1 capsule 30 minutes to 1 hour before bedtime with an earlier dose during the evening if necessary.

Swallow the capsule with water.

As the effects of this product may not occur immediately, the capsule should be taken continuously for 2 - 4 weeks. Do not exceed the stated dose.

The maximum dose is 4 capsules per day.

If you take too much of the product (overdose): speak to a Doctor or a qualified Healthcare Practitioner immediately and take this leaflet and bottle with you.

If you forget to take this product: Do not take a double dose to make up for the missed dose(s). Continue to take your usual dose at the usual time. It does not matter if you have missed a dose.

**Duration of use:** If symptoms worsen or do not improve after 4 weeks, a Doctor or a qualified Healthcare Practitioner should be consulted.

## 4 - Possible side effects

Like all medicines, Valerian can have side effects. Possible side effects are:
- Abdominal cramps
- Nausea

If these symptoms persist for more than a few days or become troublesome, stop taking this product.

Other side effects: This product may cause drowsiness. If you are affected, do not drive or operate machinery.

Tell a Doctor or a qualified Healthcare Practitioner if you notice any other side effects.

More information on back panel.
5 - How to store this product

- Keep the capsules in the bottle until it is time to take them
- Do not take the capsules after the expiry date (see outer label)
- Store the capsules below 25°C
- Keep the bottle tightly closed
- Keep the capsules out of sight and reach of children

6 - Further Information

About this product: This product is a traditional herbal medicinal product containing Valerian. Each capsule contains 337mg of extract (as dry extract) from Valerian root (Valeriana officinalis L) (equivalent to 1683mg-2020mg of Valerian root). Extraction solvent: Ethanol 70% v/v. This product also contains the following inactive (excipient) ingredients: Magnesium stearate. Excipients in the extract: Maltodextrin, Silica colloidal anhydrous.

Capsule shell: Hypromellose. Each bottle contains 30 or 60 clear, two piece capsules.

After taking this product: You must speak to a Doctor or a qualified Healthcare Practitioner:
- If your symptoms get worse
- If your symptoms do not improve after 4 weeks
- If side effects not listed in this leaflet occur

Traditional Registration Holder:
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Manufacturer of this product:
Vita Health Products Inc
150 Beghin Avenue
Winnipeg
Manitoba, R2J 3W2
Canada

For: NBTY Europe Ltd
Samuel Ryder House
Barling Way
Nuneaton
Warwickshire, CV10 7RH
United Kingdom

If you would like further information about this product, please contact:

NBTY Europe Limited
Regulatory Services
Samuel Ryder House
Barling Way
Nuneaton
Warwickshire, CV10 7RH
United Kingdom

Is this leaflet hard to see or read?
Contact us on:
Telephone: +44 (0) 2476 215 400
Fax: +44 (0) 2476 215 452
Email: customerservices@NBTYEurope.com

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
3 - How to take this product

For the temporary relief of symptoms of mild anxiety - Take 1 capsule 3 times daily.

To aid sleep - Take 1 capsule 30 minutes to 1 hour before bedtime with an earlier dose during the evening if necessary. Swallow the capsule with water.

As the effects of this product may not occur immediately, the capsule should be taken continuously for 2 - 4 weeks. Do not exceed the stated dose.

The maximum dose is 4 capsules per day.

If you take too much of the product (overdose): speak to a Doctor or a qualified Healthcare Practitioner immediately and take this leaflet and bottle with you.

If you forget to take this product: Do not take a double dose to make up for the missed dose(s). Continue to take your usual dose at the usual time. It does not matter if you have missed a dose.

Duration of use: If symptoms worsen or do not improve after 4 weeks, a Doctor or a qualified Healthcare Practitioner should be consulted.

4 - Possible side effects

Like all medicines, Valerian can have side effects. Possible side effects are:

◆ Abdominal cramps
◆ Nausea

If these symptoms persist for more than a few days or become troublesome, stop taking this product.

Other side effects: This product may cause drowsiness. If you are affected, do not drive or operate machinery.

Tell a Doctor or a qualified Healthcare Practitioner if you notice any other side effects.

More information on back panel
5 - How to store this product

- Keep the capsules in the bottle until it is time to take them
- Do not take the capsules after the expiry date (see outer label)
- Store the capsules below 25°C
- Keep the bottle tightly closed
- Keep the capsules out of sight and reach of children

6 - Further Information

About this product: This product is a traditional herbal medicinal product containing Valerian. Each capsule contains 337mg of extract (as dry extract) from Valerian root (Valeriana officinalis L) (equivalent to 1683mg-2020mg of Valerian root). Extraction solvent: Ethanol 70% v/v. This product also contains the following inactive (excipient) ingredients: Magnesium stearate. Excipients in the extract: Maltodextrin, Silica colloidal anhydrous.

Capsule shell: Hypromellose. Each bottle contains 30 or 60 clear, two piece capsules.

After taking this product: You must speak to a Doctor or a qualified Healthcare Practitioner:

- If your symptoms get worse
- If your symptoms do not improve after 4 weeks
- If side effects not listed in this leaflet occur

Traditional Registration Holder:
THR 21710/0001

NBTY Europe Ltd
Samuel Ryder House
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LABELLING

Holland & Barrett Valerian Capsules:

Labels
Holland & Barrett Valerian Capsules:

Cartons
Storage: Store the capsules below 25°C. Keep the bottle tightly closed. Keep out of sight and reach of children.

Expiry Date: see below.

Warnings:
DO NOT EXCEED THE STATED DOSE
Do not take this product if you are:
- Under 16 years of age
- Pregnant or breastfeeding
- Allergic to Valerian or any of the excipients in this product
- Already taking a medicine for sleep or anxiety

The effects of the capsules may be increased if alcohol is also taken. Excessive use of alcohol should be avoided.

You must read the Product Information carefully before using this product.

Active Ingredients: Each capsule contains 257 mg of extract (as dry extract) of Valeriana officinalis L. (equivalent to 193.4 mg/200mg of Valerian root). Extraction solvent Ethanol 70% v/v.

Dosage: For oral use only.
For adults and seniors:
- Mild anxiety - take 1 capsule 3 times daily.
- To aid sleep - take 1 capsule 30 minutes to 1 hour before bedtime with an earlier dose during the evening if necessary.

Swallow the capsules with water.

As the effects of this product may not occur immediately the capsule should be taken continuously for 3-4 weeks.
The maximum dose is 6 capsules per day.

Duration of use: if symptoms worsen or do not improve after 4 weeks, a Doctor or a qualified Healthcare Practitioner should be consulted.
GNC Live Well Valerian Capsules:

**Labels**

**Active Ingredients:** Each capsule contains 337mg of extract (as dry extract) from Valerian root (Valeriana officinalis L) (equivalent to 1600mg-2000mg of Valerian root). Extraction solvent: Ethanol 70% v/v.

**Dosage:** For oral use only.
- For adults and elderly:
  - Mild anxiety: Take 1 capsule 3 times daily.
  - To aid sleep: Take 1 capsule 30 minutes to 1 hour before bedtime with an earlier dose during the evening if necessary.
- Swallow the capsule with water.
- As the effects of this product may not occur immediately, the capsule should be taken continuously for 2-4 weeks.
- The maximum dose is 4 capsules per day.

**Duration of use:** If symptoms worsen or do not improve after 4 weeks, a Doctor or a qualified Healthcare Practitioner should be consulted.

**Warnings:**
- DO NOT EXCEED THE STATED DOSE
- Do not take this product if you are:
  - Under 18 years of age
  - Pregnant or breastfeeding
  - Allergic to Valerian or any of the excipients in this product
  - Already taking a medicine for sleep or anxiety
- The effects of this product may be increased by alcohol. Excessive use of alcohol should therefore be avoided.

**Storage:** Store the capsules below 25°C. Keep the bottle tightly closed. Keep out of sight and reach of children.

THI 21710/0001
Registration Holder: BNTY Europe Limited, Samuel Ryder House, Basing Way, Nuneaton, Warwickshire, CV10 7RH, United Kingdom

Batch Numbers: 0297/451000, 00000000451000, 0297/451000, 00000000451000

Best Before Date: 05/2020

MHRA PAR; HOLLAND & BARRETT VALERIAN CAPSULES, THR 21710/0001
GNC Live Well Valerian Capsules:

Carton
Lifecycle Valerian Capsules:

Labels

**Inactive Ingredients:** Each capsule contains 322mg of extract (as dry extract) from Valerian root (Valeriana officinalis L.) (equivalent to 168mg-250mg of Valerian root). Extraction solvent: Ethanol 70% v/v.

**Dosage:** For oral use only.

For adults and elderly:
- Mild anxiety - Take 1 capsule 3 times daily.
- To aid sleep - Take 1 capsule 30 minutes to 1 hour before bedtime with an earlier dose during the evening if necessary. Swallow the capsule with water.

As the effects of this product may not occur immediately, the capsule should be taken continuously for 2-4 weeks.

The maximum dose is 4 capsules per day.

**Duration of use:** If symptoms worsen or do not improve after 4 weeks, a doctor or a qualified Healthcare Practitioner should be consulted.

**Warnings:**
- DO NOT EXCEED THE STATED DOSE
- Do not take this product if you are:
  - Under 18 years of age
  - Pregnant or breastfeeding
  - Allergic to Valerian or any of the excipients in this product
  - Already taking a medicine for sleep or anxiety

The effects of this product may be increased by alcohol. Excessive use of alcohol should therefore be avoided.

**Storage:** Store the capsules below 25°C. Keep the bottle tightly closed. Keep out of sight and reach of children.

**Regulation:**
THR 21715/0001
Regulation holder: NB4 Europe Limited, Samuel Ryder House, Bunting Way, Nunton, Ware, Hertfordshire, CB10 7JH, United Kingdom
Lifecycle Valerian Capsules:

Carton

Storage: Store the capsules below 25°C. Keep the bottle tightly closed. Keep out of sight and reach of children.

Expiry Date - see below.

Warnings:
- DO NOT EXCEED THE STATED DOSE
- Do not use this product if you are allergic to:
  - Plants in the Valerian family
  - Expiry Date:

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

Active Ingredients: Each capsule contains: 50mg of extract (400mg of Valerian root) from Valeriana officinalis. The extract contains 0.8% total valerenic acids, 10% total valerenol.

Directions: For oral use only.
- For adults and adolescents:
  - Mild anxiety: Take 1 capsule daily.
  - To aid sleep: Take 1 capsule 30 minutes to 1 hour before bedtime with an empty stomach during the evening if necessary.

Swallow the capsule with water.

As the effects of this product may not occur immediately, the capsule should be taken continuously for 4 weeks. The maximum daily dose is 4 capsules per day.

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

MHRA PAR; HOLLAND & BARRET VALERIAN CAPSULES, THR 21710/0001
Nature’s Garden Valerian Capsules:

Labels

**Active Ingredients:** Each capsule contains 337mg of extract (as dry extract) from Valerian root (Valeriana officinalis L) (equivalent to 1983mg-2520mg of Valerian root). Extraction solvent: Ethanol 70% v/v.

**Dosage:** For oral use only.
For adults and elderly:
- Mild anxiety: 1 capsule 3 times daily.
- To aid sleep: Take 1 capsule 30 minutes to 1 hour before bedtime with an earlier dose during the evening if necessary.
Swallow the capsule with water.

As the effects of this product may not occur immediately, the capsule should be taken continuously for 2-4 weeks.

The maximum dose is 4 capsules per day.

**Duration of use:** If symptoms worsen or do not improve after 4 weeks, a Doctor or a qualified Healthcare Practitioner should be consulted.

**Warnings:** DO NOT EXCEED THE STATED DOSE
Do not take this product if you are:
- Under 18 years of age
- Pregnant or breastfeeding
- Allergic to Valerian or any of the excipients in this product
- Already taking a medicine for sleep or anxiety

The effects of this product may be increased by alcohol. Excessive use of alcohol should therefore be avoided.

**Storage:** Store the capsules below 25°C. Keep the bottle tightly closed. Keep out of sight and reach of children.

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**Active Ingredients:** Each capsule contains 937mg of extract (as dry extract) from Valerian root (Valeriana officinalis L) (equivalent to 1983mg-2520mg of Valerian root). Extraction solvent: Ethanol 70% v/v.

**Dosage:** For oral use only.
For adults and elderly:
- Mild anxiety: 1 capsule 3 times daily.
- To aid sleep: Take 1 capsule 30 minutes to 1 hour before bedtime with an earlier dose during the evening if necessary.
Swallow the capsule with water.

As the effects of this product may not occur immediately, the capsule should be taken continuously for 2-4 weeks.

The maximum dose is 4 capsules per day.

**Duration of use:** If symptoms worsen or do not improve after 4 weeks, a Doctor or a qualified Healthcare Practitioner should be consulted.

**Warnings:** DO NOT EXCEED THE STATED DOSE
Do not take this product if you are:
- Under 18 years of age
- Pregnant or breastfeeding
- Allergic to Valerian or any of the excipients in this product
- Already taking a medicine for sleep or anxiety

The effects of this product may be increased by alcohol. Excessive use of alcohol should therefore be avoided.

**Storage:** Store the capsules below 25°C. Keep the bottle tightly closed. Keep out of sight and reach of children.

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MHRA PAR; HOLLAND & BARRETT VALERIAN CAPSULES, THR 21710/0001
Nature’s Garden Valerian Capsules:

Carton

Storage: Store the capsules below 25°C. Keep the bottle tightly closed. Keep out of sight and reach of children.

Expiry Date – see below.

Warnings:
- DO NOT EXCEED THE STATED DOSE
- Do not use this product if you are:
  - Under 12 years of age
  - Pregnant or breastfeeding
  - Allergic to Valerian or any of the excipients in this product
  - Allergic to milk or milk products

The effects of this product may be increased by alcohol. Exercise use of alcohol before bedtime is advised.

You must read the enclosed Leaflet carefully before using this product.

Dosage: For oral use only.
- For adults and elderly:
  - Take 1 capsule a few hours before bedtime with or without food.
- For children 12 years and above:
  - Take 1 capsule 30 minutes before bedtime.

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

Active ingredients: Each capsule contains 330mg of extract (as dry extract from Valeriana officinalis L. and Valeriana walensis Hager) equivalent to 168mg of Valerian root. Ethanol solvent: Ethanol 70% v/v.

The product contains: Valerian root, Ethanol 70% v/v.

NATURAL PRODUCT, NATURE'S GARDEN

Manufactured by: NAGA Consumer Healthcare Ltd., Unit 21, Scawby Business Park, Scawby, Louth, LN11 7RT, United Kingdom
Storage: Store the capsules below 25°C. Keep the bottle tightly closed. Keep out of sight and reach of children.

Expiration Date - see below.

Warning:
DO NOT USE THE SHOTDOSE.
Do not use this product if you are:
- Under 18 years of age
- Pregnant or breastfeeding
- Allergic to Valerian or any of the excipients in this product
- Already taking a medicine for sleep or anxiety

The effects of this product may be increased or altered if the use of alcohol or other medicine is avoided.

You may need to adjust your dose carefully when adding this product.

Active Ingredients: Each capsule contains: 175mg of extract (as dry extract) of Valerian root (Valeriana officinalis L.) (equivalent to 175mg of 200mg of Valerian root

Extraction solvent: Ethanol 70% v/v.

Dosage: For oral use only.
For adults and elderly.
Mild anxiety - Take 1 capsule 3 times daily.
To aid sleep - take 1 capsule 30 minutes to 1 hour before bedtime with an evening drink during the evening

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

60 Capsules

Duration of use: If symptoms worsen or do not improve after 4 weeks, a Doctor or a qualified Healthcare Practitioner should be consulted.