### TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lay summary</td>
<td>2</td>
</tr>
<tr>
<td>Scientific discussion</td>
<td>3</td>
</tr>
<tr>
<td>Steps taken for assessment</td>
<td>12</td>
</tr>
<tr>
<td>Summary of Product Characteristics</td>
<td>13</td>
</tr>
<tr>
<td>Product Information Leaflet</td>
<td>18</td>
</tr>
<tr>
<td>Labelling</td>
<td>28</td>
</tr>
</tbody>
</table>
The Medicines and Healthcare products Regulatory Agency (MHRA) granted NBTY Europe Limited a Traditional Herbal Registration Certificate for the traditional herbal medicinal products Holland & Barrett Black Cohosh Capsules, GNC Live Well Black Cohosh Capsules, Lifecycle Black Cohosh Capsules, Nature’s Garden Black Cohosh Capsules and Nature’s Bounty Black Cohosh Capsules (Traditional Herbal Registration number: THR 21710/0007) on 22 March 2013. These products are identical to each other apart from the difference in product name and will be collectively referred to as Black Cohosh Capsules in the remainder of this report. Black Cohosh Capsules are available without prescription and can be bought from pharmacies and other outlets.

Black Cohosh Capsules is a traditional herbal medicinal product used for the symptomatic relief of backache and muscular and rheumatic aches and pains, based on traditional use only. The active ingredient in Black Cohosh Capsules comes from the rhizome and root of the Black Cohosh plant, which is also known as *Cimicifuga racemosa* (L) Nutt.

This registration is based exclusively upon evidence of the use of Black Cohosh 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 the product works.

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

TABLE OF CONTENTS

Introduction Page 4
Pharmaceutical assessment Page 5
Non-clinical assessment Page 8
Clinical assessment Page 9
Overall conclusions and risk assessment Page 11
INTRODUCTION

The MHRA granted a Traditional Herbal Registration Certificate for the traditional herbal medicinal product Black Cohosh Capsules (THR 21710/0007) to NBTY Europe Limited on 22 March 2013. 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 product is used for symptomatic relief of backache and muscular and rheumatic aches and pains. This is based on traditional use only.

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

HERBAL SUBSTANCE: BLACK COHOSH RHIZOME AND ROOT

Scientific name of the plant: Cimicifuga racemosa (L) Nutt.
Plant family: Ranunculaceae

Manufacture
The plants are collected manually from the wild in the USA in July. The roots are washed with fresh water after collection.

The herbal substance is produced in line with the Guideline on Good Agricultural and Collection Practice (GACP) EMEA/HMPC/246816/2005 and is not treated with chemicals or irradiation.

Control
An appropriate specification based on the Ph Eur monograph for Black Cohosh root 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 and confirmation has been given that all components of the container closure system comply with current legislation relating to plastic materials and articles intended to come into contact with foodstuffs.

Stability
A shelf-life for the herbal substance is not appropriate 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: BLACK COHOSH RHIZOME AND ROOT DRY EXTRACT

Drug extract ratio (DER): 5-8:1
Extraction solvent: Ethanol 75%v/v

Manufacture
A satisfactory description of the manufacturing process of the herbal preparation and flow diagram have been provided. The in-process controls are satisfactorily detailed. 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
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.

Container Closure System
Confirmation is provided that all components of the container closure system used to store the herbal preparation comply with current legislation relating to plastic materials and articles intended to come into contact with foodstuffs.

Stability
Stability studies have been performed in accordance with current guidelines. The proposed re-test period for the herbal preparation is acceptable.

HERBAL PRODUCT: BLACK COHOSH CAPSULES

Description and Composition
The herbal product is a two-piece, clear, hard capsule with a brown fill. Each capsule contains 19mg dry extract from Black Cohosh rhizome and root and the pharmaceutical excipients microcrystalline cellulose, magnesium stearate, colloidal hydrated silica, maltodextrin, colloidal anhydrous silica and hypromellose.

The compatibility of the herbal preparation with the excipients is demonstrated by the stability testing results. The excipients are controlled in line with their respective Ph Eur monograph and representative Certificates of Analysis are provided to demonstrate full compliance with the Ph Eur.

The magnesium stearate used in the product is confirmed to be of vegetable origin.

Manufacture
A flow diagram outlining the various stages of the manufacturing process and the in-process controls is provided.

In-process controls are appropriate considering the nature of the product and the method of manufacture. An acceptable process validation protocol is given for the commercial batches which will be produced following approval.

Control
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**
Black Cohosh Capsules are stored in green, polyethylene terephthalate (PET) bottles with a chiffon green hinge cap (polypropylene) and an inner seal liner designed to lift ‘n’ peel. The inner seal acts as a tamper evident seal under the cap. The inner seal liner is made up of polyester film, polymer adhesive layer, polyester tab, polyolefin foam, aluminium foil and sealable polyester film. Pack sizes of 50 and 100 capsules have been authorised.

**Stability**
The product shelf-life of 30 months is acceptable when the storage precautions ‘Do not store above 25ºC’, ‘Keep in the original packaging’ and ‘Keep the bottle tightly closed’ are applied.

**Summary of Product Characteristics, product labels 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.

**CONCLUSION**
There are no objections to granting of a Traditional Herbal Registration from a quality point of view.
NON-CLINICAL ASSESSMENT

NON-CLINICAL 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 suitably qualified professional.

The overview submitted in support of this application is satisfactory.

Due to a shortage of published data on Black Cohosh root, it is not possible to assess if the safety package for the phytochemical constituents of this active ingredient 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 (SmPC)
The SmPC for this product is satisfactory from a non-clinical 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
There are no objections to granting of a Traditional Herbal Registration from a non-clinical point of view.
CLINICAL ASSESSMENT

LEGAL STATUS
Black Cohosh root is on the general sales list for internal use.

INDICATION
The applicant has submitted the following therapeutic indications:

“A traditional herbal medicinal product used for symptomatic relief of backache, muscular and rheumatic aches and pains. This is based on traditional use only.”

These indications are acceptable.

POSOLOGY AND METHOD OF ADMINISTRATION
The applicant has submitted the following:

“For oral use only.

Adults and the elderly
Take 1 capsule 3 times daily. Swallow the whole capsule with water.

Do not exceed the stated dose.

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

Hepatic and renal impairment
The safety of Black cohosh extract has not been studied in patients with hepatic and/or renal impairment. This product should not be taken by patients who have hepatic or renal impairment.

Not recommended for use in children under 18 years (see Section 4.4, Special Warnings and Precautions for Use.)

This is acceptable.

Efficacy
No clinical efficacy data is required for registration of Traditional Herbal Medicinal Products.

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 EU.
The applicant has provided a bibliographic review as evidence for the use of Black Cohosh root within the EU for a period exceeding 30 years. In addition, the extract used in Black Cohosh Capsules is similar to the extracts listed in the Committee on Herbal Medicinal Products (HMPC) monograph for Black Cohosh root. The requirements of the Directive are considered to be met.

SAFETY REVIEW
Article 16 c 1 (d) requires the applicant to provide a bibliography of the safety data together with an Expert Safety Report.

A safety review has been provided as well as an Expert Safety Report written by a suitably qualified professional. The HMPC monograph also covers the relevant safety issues.

The Safety Review and Expert Safety Report are satisfactory.

PRODUCT LITERATURE
The SmPC, PIL and labelling for this product are medically satisfactory.

CONCLUSION
There are no objections to granting of a Traditional Herbal Registration from a clinical point of view.
OVERALL CONCLUSION AND RISK ASSESSMENT

QUALITY
The quality data submitted with this application are satisfactory.

NON-CLINICAL
No new non-clinical data were submitted with this application. However, assurance was provided that the results of genotoxicity testing will be provided before renewal of this registration. This is satisfactory.

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

The applicant has provided a bibliographic review which shows ample evidence for the use of Black Cohosh root within the EU for a period exceeding 30 years and a satisfactory review of the safety data has been provided.

Furthermore, the HMPC monograph for Black Cohosh root adequately covers the evidence for traditional use of the extract in the product under assessment for at least 30 years and the safety issues associated with Black Cohosh root.

The SmPC, PIL and labelling are satisfactory.

RISK ASSESSMENT
The quality of the product is acceptable and no new non-clinical or clinical safety concerns have been identified. The risk: benefit balance is acceptable and a Traditional Herbal Registration may be granted.
HOLLAND & BARRETT BLACK COHOSH CAPSULES  
GNC LIVE WELL BLACK COHOSH CAPSULES  
LIFECYCLE BLACK COHOSH CAPSULES  
NATURE’S GARDEN BLACK COHOSH CAPSULES  
NATURE’S BOUNTY BLACK COHOSH CAPSULES

THR 21710/0007

**STEPS TAKEN FOR ASSESSMENT**

1. The MHRA received the Traditional Herbal Registration application on 5 October 2010
2. Following standard checks and communication with the applicant the MHRA considered the application valid on 25 October 2010
3. Following assessment of the application the MHRA requested further information relating to the clinical dossier on 1 December 2010
4. The applicant responded to the MHRA’s request, providing further information on the clinical dossier on 16 January 2011
5. Following assessment of the application the MHRA requested further information relating to the quality dossier on 1 November 2012
6. The applicant responded to the MHRA’s request, providing further information on the quality dossier on 10 December 2012
7. Following assessment of the applicant’s response the MHRA requested further information relating to the clinical dossier on 17 December 2012
8. The applicant responded to the MHRA’s request, providing further information on the clinical dossier on 21 January 2013
9. Following assessment of the applicant’s response the MHRA requested further information relating to the quality dossier on 12 February 2013
10. The applicant responded to the MHRA’s request, providing further information on the quality dossier on 19 February 2013
11. A THR was granted on 22 March 2013
1 NAME OF THE MEDICINAL PRODUCT
Holland & Barrett Black Cohosh Capsules
GNC Live Well Black Cohosh Capsules
Lifecycle Black Cohosh Capsules
Nature’s Garden Black Cohosh Capsules
Nature’s Bounty Black Cohosh Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each hard capsule contains 19mg extract (as dry extract) from Black Cohosh rhizome and root (*Cimicifuga racemosa* (L) Nutt.) (equivalent to 97mg – 155mg of Black Cohosh rhizome and root). Extraction solvent: Ethanol 75%v/v.

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM
Capsule, hard
Two piece clear hard capsules with brown fill.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
A traditional herbal medicinal product used for symptomatic relief of backache, muscular and rheumatic aches and pains. This is based on traditional use only.

As there is evidence that Black cohosh may have hormone-like actions, it should only be used by women of childbearing potential if contraception is used.

4.2 Posology and method of administration
For oral use only.

*Adults and the elderly*
Take 1 capsule 3 times daily. Swallow the whole capsule with water.

Do not exceed the stated dose.

**Duration of use:**
If symptoms worsen or do not improve after 4 weeks, a Doctor or a qualified Healthcare Practitioner should be consulted.
**Hepatic and renal impairment**
The safety of Black cohosh extract has not been studied in patients with hepatic and/or renal impairment. This product should not be taken by patients who have hepatic or renal impairment.

Not recommended for use in children under 18 years (see Section 4.4, Special Warnings and Precautions for Use.)

**4.3 Contraindications**
Hypersensitivity to Black Cohosh or any of the excipients

Women who are pregnant or breastfeeding or women of child bearing potential and not using contraception

Patients who have or who have ever had liver disease

Patients currently receiving treatment for or who have ever had an oestrogen dependent tumour

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

There have been rare reports of hepatic reactions associated with the use of Black Cohosh. Patients should stop taking this product immediately and consult their doctor if they develop signs and symptoms that suggest liver dysfunction (fatigue, anorexia, yellowing of the skin and eyes or severe stomach pain with nausea and vomiting or dark urine.)

Advice should be sought from a doctor if the patient has a family history of an oestrogen dependent tumour.

Oestrogens may only be taken simultaneously with this product under medical supervision, as their effects may be intensified by Black Cohosh.

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

If joint pain is experienced accompanied by swelling of the joints, redness or fever, a Doctor or qualified Healthcare Practitioner should be consulted.

The use in children or adolescents under 18 years of age is not recommended because data are not sufficient and medical advice should be sought.

**4.5 Interaction with other medicinal products and other forms of interaction**
No studies have been carried out to determine if drug interactions occur with this product.
4.6 **Fertility, 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.

Due to the potential for Black Cohosh to have hormone-like actions, the product should not be used by women who could become pregnant unless contraception is used.

Studies on the effects on fertility have not been carried out.

4.7 **Effects on ability to drive and use machines**
No studies on the effect on the ability to drive and use machines have been performed.

4.8 **Undesirable effects**
Possible side effects are:
- Allergic skin reactions (such as nettle rash, itching of the skin and skin rash)
- Digestive upsets (such as indigestion and/or diarrhoea)
- Facial oedema and peripheral oedema
- Weight gain

The frequency is not known.

In rare cases, Black cohosh may cause liver reactions (including hepatitis, jaundice and disturbances in liver function tests).

The frequency is not known.

If other adverse reactions not mentioned above occur, a Doctor or qualified Healthcare Practitioner should be consulted.

4.9 **Overdose**
No case of overdose has been reported.

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.
In a six-month study in rats the no-observed-effect-level (NOEL) for the isopropanolic extract (Granulate) was defined with 21.06 mg native extract/kg bodyweight. Evidence from in-vitro and in-vivo pharmacological studies suggests that Cimicifuga extracts do not influence the latency or development of breast cancer. However, contradictory results have been obtained in other in-vitro experiments.

In Cimicifuga-treated (isopropanolic black cohosh extract equivalent to 40 mg of root and rhizome), tumour-bearing, female transgenic mice, the percentage of mice with detectable metastatic lung tumours at necropsy was increased compared to those on the control diet. However, in the same experimental model, no increase in primary breast tumour was seen. Influence on breast cancer or other hormone-depending tumours cannot be completely excluded.

A genotoxicity study (AMES-test) of the ethanolic extract (4.5-8.5:1, ethanol 60% (V/V)) was performed to a concentration of 1 mg/plate. The test does not fulfil the recent criteria of such testing and therefore the relevance of these results for safety assessment is doubtful.

There are no conclusive studies on carcinogenicity and reproductive toxicity.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Microcrystalline cellulose
Magnesium stearate
Colloidal hydrated silica

Excipients in the extract:
Maltodextrin
Colloidal anhydrous silica

Capsule Shell:
Hyromellose

6.2 Incompatibilities
Not applicable

6.3 Shelf life
30 months

6.4 Special precautions for storage
Do not store above 25ºC
Keep in the original packaging
Keep the bottle tightly closed

6.5 Nature and contents of container
Green Polyethylene terephthalate (PET) bottles with a chiffon green hinge cap (Polypropylene), with an inner seal liner designed to lift ‘n’ peel. The inner seal acts as a tamper evident seal under the cap. The inner seal liner is made up
of polyester film, polymer adhesive layer, polyester tab, polyolefin foam, aluminium foil and sealable polyester film.

Pack size: 50 and 100 capsules

6.6 Special precautions for disposal
No special requirements

7 MARKETING AUTHORISATION HOLDER
NBTY Europe Limited
Samuel Ryder House
Barling Way
Nuneaton
Warwickshire
CV10 7RH
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)
THR 21710/0007

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
22/03/2013

10 DATE OF REVISION OF THE TEXT
22/03/2013
PRODUCT INFORMATION LEAFLET

HOLLAND & BARRETT
BLACK COHOSH CAPSULES
Black Cohosh Root Extract 19mg

Important notes
◆ Please read this leaflet carefully before you use this product because 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 you 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 and/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

I - What this product is and what it is used for
This product contains Black Cohosh rhizome and root extract. It is a traditional herbal medicinal product used for symptomatic relief of backache, muscular and rheumatic aches and pains. 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
◆ Of childbearing age and not using contraception
◆ Allergic to Black Cohosh or any of the ingredients in this product (see section 6 of this leaflet)
◆ Suffering from or have had liver or kidney disease (e.g. hepatitis, jaundice or cirrhosis)
◆ Suffering from or have had an oestrogen dependent tumour

3 - How to take this product
For oral use only.
Adults and elderly: Take 1 capsule 3 times daily. Swallow the whole capsule with water.
Do not exceed the stated dose.

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 of taking this product or if joint pain is experienced, accompanied by swelling of the joints, redness or fever, or if any of the side effects listed in the leaflet become serious or if side effects not listed occur, a Doctor or a qualified Healthcare Practitioner should be consulted.

4 - Possible side effects
Like all medicines, this product can have side effects, although not everybody gets them. Possible side effects are:
◆ Allergic skin reactions (such as nettle rash and/or itching of the skin)
◆ Digestive upsets (such as indigestion and/or diarrhoea)
◆ Swelling of the face or extremities
◆ Weight gain

If these symptoms persist or become troublesome stop taking this product or if you experience any other side effects not listed above consult a Doctor, Pharmacist or a qualified Healthcare Practitioner.

As there is evidence that Black Cohosh may have hormone-like actions, it should only be used by women of child-bearing potential if contraception is used.
Consult a Doctor or a qualified Healthcare Practitioner if you:
◆ are currently taking medicine containing oestrogen
◆ have a family history of estrogen dependant tumours

More information on back panel
If you experience any allergic reactions, stop taking this product and consult a Doctor.

Black Cohosh may rarely cause liver problems. If you notice symptoms such as yellowing of the skin/eyes, nausea, vomiting, dark urine, abdominal pain or unusual tiredness, stop taking the product immediately and consult a Doctor, Pharmacist or a qualified Healthcare Practitioner.

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 GP’s surgery or pharmacy, or call freephone 0808 100 3352.

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). The expiry date refers to the last day of the month
- Do not store above 25°C
- Store in the original packaging
- Keep the bottle tightly closed
- Keep the capsules out of sight and reach of children

6 - Further information

About this product: Each hard capsule contains 19mg of extract (as dry extract) from Black Cohosh rhizome and root (Cimicifuga racemosa (L) Nutt.) (equivalent to 97mg-155mg of Black Cohosh rhizome and root). Extraction solvent: Ethanol 75% v/v.

This product also contains the following inactive (excipient) ingredients: Microcrystalline cellulose, Magnesium stearate, Silica colloidal hydrated.

Excipients in the extract: Maltodextrin, Silica colloidal anhydrous.

Capsule shell: Hypromellose. Each bottle contains 50 or 100 clear, hard two pieces capsules with brown fill.

THR 21710/0007

Traditional Herbal Registration Holder
NBTY Europe Limited
Samuel Ryder House
Barling Way
Nuneaton
Warwickshire, CV10 7RH
United Kingdom

Manufacturer
NBTY Europe Limited
Vitality House
Sixth Avenue
Centrum 100
Burton-on-Trent
Staffordshire, DE14 2WP
United Kingdom

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

NBTY Europe Limited
Regulatory Services Department
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

This leaflet was prepared on: 26/02/2013

BM521 000 00A 137848 000 CERIFICATION MARK
PATIENT INFORMATION LEAFLET

GNC Live Well
BLACK COHOSH CAPSULES
Black Cohosh Root Extract 19mg

Important notes
- Please read this leaflet carefully before you use this product because 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 you are taking medication or have a family history of estrogen dependent conditions.
- Please tell a Doctor or a qualified Healthcare Practitioner if you are currently taking medicine containing oestrogen.
- Consult a Doctor or a qualified Healthcare Practitioner if you:
- have a family history of estrogen dependent conditions.

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
This product contains Black Cohosh rhizome and root extract. It is a traditional herbal medicinal product used for symptomatic relief of backache, muscular and rheumatic aches and pains. 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
- Of childbearing age and not using contraception
- Allergic to Black Cohosh or any of the ingredients in this product (see section 6 of this leaflet)
- Suffering from or have had liver or kidney disease (e.g. hepatitis, jaundice or cirrhosis)
- Suffering from or have had an oestrogen dependent tumour

3 - How to take this product
For oral use only.
Adults and elderly: Take 1 capsule 3 times daily. Swallow the whole capsule with water. Do not exceed the stated dose.

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 of taking this product or if joint pain is experienced, accompanied by swelling of the joints, redness or fever, or if any of the side effects listed in the leaflet become serious or if side effects not listed occur, a Doctor or a qualified Healthcare Practitioner should be consulted.

4 - Possible side effects
Like all medicines, this product can have side effects, although not everybody gets them. Possible side effects are:
- Allergic skin reactions (such as nettle rash and/or itching of the skin)
- Digestive upsets (such as indigestion and/or diarrhoea)
- Swelling of the face or extremities
- Weight gain

If these symptoms persist or become troublesome stop taking this product or if you experience any other side effects not listed above consult a Doctor, Pharmacist or a qualified Healthcare Practitioner.

More information on back panel
If you experience any allergic reactions, stop taking this product and consult a Doctor.
Black Cohosh may rarely cause liver problems. If you notice symptoms such as yellowing of the skin/eyes, nausea, vomiting, dark urine, abdominal pain or unusual tiredness, stop taking the product immediately and consult a Doctor, Pharmacist or a qualified Healthcare Practitioner.
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 GP’s surgery or pharmacy, or call freephone 0808 100 3352

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). The expiry date refers to the last day of the month
◆ Do not store above 25°C
◆ Store in the original packaging
◆ Keep the bottle tightly closed
◆ Keep the capsules out of sight and reach of children

6 - Further Information

About this product: Each hard capsule contains 19mg of extract (as dry extract) from Black Cohosh rhizome and root (Cimicifuga racemosa (L) Nutt.) (equivalent to 97mg-155mg of Black Cohosh rhizome and root).
Extraction solvent: Ethanol 75% v/v.
This product also contains the following inactive (excipient) ingredients: Microcrystalline cellulose, Magnesium stearate, Silica colloidal hydrated.
Excipients in the extract: Maltodextrin, Silica colloidal anhydrous.
Capsule shell: Hypromellose. Each bottle contains 50 or 100 clear, hard two pieces capsules with brown fill.
**PATIENT INFORMATION LEAFLET**

**LIFECYCLE BLACK COHOSH CAPSULES**
Black Cohosh Root Extract 19mg

---

**Important notes**
- Please read this leaflet carefully before you use this product because 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 and/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**

This product contains Black Cohosh rhizome and root extract. It is a traditional herbal medicinal product used for symptomatic relief of backache, muscular and rheumatic aches and pains. 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
- Of childbearing age and not using contraception
- Allergic to Black Cohosh or any of the ingredients in this product (see section 6 of this leaflet)
- Suffering from or have had liver or kidney disease (e.g. hepatitis, jaundice or cirrhosis)
- Suffering from or have had an oestrogen dependent tumour

---

**3 - How to take this product**

For oral use only.

**Adults and elderly:** Take 1 capsule 3 times daily. Swallow the whole capsule with water. Do not exceed the stated dose.

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 of taking this product or if joint pain is experienced, accompanied by swelling of the joints, redness or fever, or if any of the side effects listed in the leaflet become serious or if side effects not listed occur, a Doctor or a qualified Healthcare Practitioner should be consulted.

---

**4 - Possible side effects**

Like all medicines, this product can have side effects, although not everybody gets them. Possible side effects are:
- Allergic skin reactions (such as nettle rash and/or itching of the skin)
- Digestive upsets (such as indigestion and/or diarrhoea)
- Swelling of the face or extremities
- Weight gain

If these symptoms persist or become troublesome stop taking this product or if you experience any other side effects not listed above consult a Doctor, Pharmacist or a qualified Healthcare Practitioner.

More information on back panel.
If you experience any allergic reactions, stop taking this product and consult a Doctor.

Black Cohosh may rarely cause liver problems. If you notice symptoms such as yellowing of the skin/eyes, nausea, vomiting, dark urine, abdominal pain or unusual tiredness, stop taking the product immediately and consult a Doctor, Pharmacist or a qualified Healthcare Practitioner.

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 GP's surgery or pharmacy, or call freephone 0808 100 3352

---

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). The expiry date refers to the last day of the month
- Do not store above 25°C
- Store in the original packaging
- Keep the bottle tightly closed
- Keep the capsules out of sight and reach of children

---

6 - Further information

About this product: Each hard capsule contains 19mg of extract (as dry extract) from Black Cohosh rhizome and root (Cimicifuga racemosa (L) Nutt.) (equivalent to 97mg-155mg of Black Cohosh rhizome and root).
Extraction solvent: Ethanol 75% v/v.
This product also contains the following inactive (excipient) ingredients: Microcrystalline cellulose, Magnesium stearate. Silica colloidal hydrated.
Excipients in the extract: Maltodextrin, Silica colloidal anhydrous.
Capsule shell: Hypromellose. Each bottle contains 50 or 100 clear, hard two pieces capsules with brown fill.

---

THR 21710/0007

Traditional Herbal Registration Holder
NBTY Europe Limited
Samuel Ryder House
Barling Way
Nuneaton
Warwickshire, CV10 7RH
United Kingdom

Manufacturer
NBTY Europe Limited
Vitality House
Sixth Avenue
Centrum 100
Burton-on-Trent
Staffordshire, DE1 42WP
United Kingdom

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

NBTY Europe Limited
Regulatory Services Department
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

This leaflet was prepared on: 26/02/2013
Important notes
- Please read this leaflet carefully before you use this product because 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 and/or if any of the side effects become serious

3 - How to take this product
For oral use only.
Adults and elderly: Take 1 capsule 3 times daily. Swallow the whole capsule with water. Do not exceed the stated dose.

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 of taking this product or if joint pain is experienced, accompanied by swelling of the joints, redness or fever; or if any of the side effects listed in the leaflet become serious or if side effects not listed occur; a Doctor or a qualified Healthcare Practitioner should be consulted.

4 - Possible side effects
Like all medicines, this product can have side effects, although not everybody gets them. Possible side effects are:
- Allergic skin reactions (such as nettle rash and/or itching of the skin)
- Digestive upsets (such as indigestion and/or diarrhoea)
- Swelling of the face or extremities
- Weight gain

If these symptoms persist or become troublesome stop taking this product or if you experience any other side effects not listed above consult a Doctor, Pharmacist or a qualified Healthcare Practitioner.

More information on back panel
If you experience any allergic reactions, stop taking this product and consult a Doctor.

Black Cohosh may rarely cause liver problems. If you notice symptoms such as yellowing of the skin/eyes, nausea, vomiting, dark urine, abdominal pain or unusual tiredness, stop taking the product immediately and consult a Doctor, Pharmacist or a qualified Healthcare Practitioner.

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 GP's surgery or pharmacy, or call freephone 0808 100 3352

---

**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). The expiry date refers to the last day of the month.
- Do not store above 25°C.
- Store in the original packaging.
- Keep the bottle tightly closed.
- Keep the capsules out of sight and reach of children.

---

**6 - Further Information**

**About this product:** Each hard capsule contains 19mg of extract (as dry extract) from Black Cohosh rhizome and root (Cimicifuga racemosa (L) Nutt.) (equivalent to 97mg-155mg of Black Cohosh rhizome and root).

*Extraction solvent: Ethanol 75% v/v.*

**This product also contains the following inactive (excipient) ingredients:** Microcrystalline cellulose, Magnesium stearate, Silica colloidal hydrated.

**Excipients in the extract:** Maltodextrin, Silica colloidal anhydrous.

**Capsule shell:** Hypromellose. Each bottle contains 50 or 100 clear, hard two pieces capsules with brown fill.
PATIENT INFORMATION LEAFLET

BLACK COHOSH CAPSULES
Black Cohosh Root Extract 19mg

Important notes
- Please read this leaflet carefully before you use this product because 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 and/or if any of the side effects become serious.

Suffering from or have had an oestrogen dependent tumour
As there is evidence that Black Cohosh may have hormone-like actions, it should only be used by women of child-bearing potential if contraception is used.
Consult a Doctor or a qualified Healthcare Practitioner if you:
- are currently taking medicine containing oestrogen
- have a family history of estrogen dependant tumours

3 - How to take this product
For oral use only.
Adults and elderly: Take 1 capsule 3 times daily. Swallow the whole capsule with water. Do not exceed the stated dose.

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 of taking this product or if joint pain is experienced, accompanied by swelling of the joints, redness or fever, or if any of the side effects listed in the leaflet become serious or if side effects not listed occur, a Doctor or a qualified Healthcare Practitioner should be consulted.

4 - Possible side effects
Like all medicines, this product can have side effects, although not everybody gets them. Possible side effects are:
- Allergic skin reactions (such as nettle rash and/or itching of the skin)

More information on back panel
• Digestive upsets (such as indigestion and/or diarrhoea)
• Swelling of the face or extremities
• Weight gain

If these symptoms persist or become troublesome stop taking this product or if you experience any other side effects not listed above consult a Doctor, Pharmacist or a qualified Healthcare Practitioner.

If you experience any allergic reactions, stop taking this product and consult a Doctor.

Black Cohosh may rarely cause liver problems. If you notice symptoms such as yellowing of the skin/eyes, nausea, vomiting, dark urine, abdominal pain or unusual tiredness, stop taking the product immediately and consult a Doctor, Pharmacist or a qualified Healthcare Practitioner.

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 GP's surgery or pharmacy, or call freephone 0808 100 3352

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). The expiry date refers to the last day of the month
• Do not store above 25°C
• Store in the original packaging
• Keep the bottle tightly closed
• Keep the capsules out of sight and reach of children

6 - Further information
About this product: Each hard capsule contains 19mg of extract (as dry extract) from Black Cohosh rhizome and root (Cimicifuga racemosa (L) Nutt.) (equivalent to 97mg-155mg of Black Cohosh rhizome and root).
Extraction solvent: Ethanol 75% v/v.
This product also contains the following inactive (excipient) ingredients: Microcrystalline cellulose, Magnesium stearate, Silica colloidal hydrated.
Excipients in the extract: Maltodextrin, Silica colloidal anhydrous.
Capsule shell: Hypromellose. Each bottle contains 50 or 100 clear, hard two piece capsules with brown fill.
LABELLING

Holland & Barrett Black Cohosh Capsules

Labels:

Holland & Barrett Black Cohosh Capsules

Active Ingredients: Each hard capsule contains 130mg of extract (as dry extract) from Black Cohosh rhizome and root (Cimicifuga racemosa L., Nutt.) (equivalent to 10mg-15mg of Black Cohosh rhizome and root). Extraction solvent: Ethanol 75% v/v.

Dosage: For oral use only.
- Adults and elderly: Take 1 capsule 3 times daily. Swallow the whole capsule with water.
- Duration of use: If symptoms worsen or do not improve after 4 weeks of taking this product or if any of the side effects listed in the leaflet become severe or if side effects not listed occur, 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.
  - Of childbearing age and not using contraception.
  - Allergic to Black Cohosh or any of the ingredients in this product.
  - Suffering from or have had liver or kidney problems.
  - Suffering from or have had an oestrogen dependent tumour.

Black Cohosh may rarely cause liver problems. If you notice symptoms such as yellowing of the skin/eyes, nausea, vomiting, dark urine, abdominal pain or unusual tiredness, stop taking this product and consult a Doctor, Pharmacist or a qualified Healthcare Practitioner.

Please read the enclosed leaflet carefully before using this product.

GNC Live Well Black Cohosh Capsules

Labels:

Active Ingredients: Each hard capsule contains 15mg of extract (as dry extract) from Black Cohosh rhizome and root (Cimicifuga racemosa (L.) Nutt.) (equivalent to 9mg of Black Cohosh rhizome and root).

Warnings:
- Do not exceed the stated dose.
- Do not take this product if you are:
  - Under 18 years of age
  - Pregnant or breastfeeding
  - Of childbearing age and not using contraception
  - Allergic to Black Cohosh or any of the ingredients in this product
  - Suffering from or have had liver or kidney problems
  - Suffering from or have had an oestrogen dependent tumour
  -黑 cohosh may rarely cause liver problems. If you notice symptoms such as yellowing of the skin/eyes, nausea, vomiting, dark urine, abdominal pain or unusual tiredness, stop taking this product and consult a Doctor, Pharmacist or a qualified Healthcare Practitioner.


Active Ingredients: Each hard capsule contains 160mg of extract (as dry extract) from Black Cohosh rhizome and root (Cimicifuga racemosa (L.) Nutt.) (equivalent to 9mg of Black Cohosh rhizome and root).

Warnings:
- Do not exceed the stated dose.
- Do not take this product if you are:
  - Under 18 years of age
  - Pregnant or breastfeeding
  - Of childbearing age and not using contraception
  - Allergic to Black Cohosh or any of the ingredients in this product
  - Suffering from or have had liver or kidney problems
  - Suffering from or have had an oestrogen dependent tumour

Lifecycle Black Cohosh Capsules

Labels:

Active Ingredients: Each hard capsule contains 19mg of extract (as dry extract) from Black Cohosh rhizome and root (Cimicifuga racemosa (L) Nutt.) equivalent to 279mg of Black Cohosh rhizome and root. Extraction solvent: Ethanol 75% v/v.

Dosage: For oral use only.
Adults and elderly: Take 1 capsule 3 times daily. Swallow the whole capsule with water.

Duration of use: If symptoms worsen or do not improve after 4 weeks of taking this product or if any of the side effects listed in the leaflet become serious or if side effects not listed occur, 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 16 years of age
  - Pregnant or breastfeeding
  - Of childbearing age and not using contraception
  - Allergic to Black Cohosh or any of the ingredients in this product
  - Having from or have had liver or kidney problems
  - Having from or have had an oestrogen dependent tumour

Black Cohosh may rarely cause liver problems. If you notice symptoms such as yellowing of the skin or eyes, nausea, vomiting, dark urine, abdominal pain or unusual tiredness, stop taking this product and consult a Doctor, Pharmacist or a qualified Healthcare Practitioner.

Please read the enclosed leaflet carefully before using this product.

**Warnings:**

**Do not exceed the stated dose.** Do not take this product if you are:
- Under 18 years of age.
- Pregnant or breastfeeding.
- Of childbearing age and not using contraception.
- Allergic to Black Cohosh or any of the ingredients of this product.
- Suffering from or having had liver or kidney problems.
- Suffering from or having had an oesophageal or peptic ulcer.

Black Cohosh may very rarely cause liver problems. If you notice any changes in the appearance of the skin, unusual tiredness, dark urine, abdominal pain, or unusual bleeding, stop taking this product and consult a healthcare professional.

Please read the enclosed leaflet carefully before using this product.

**Active Ingredients:** Each hard capsule contains 50 mg of extract (as dry extract) from Black Cohosh (roots) and root Cimicifuga racemosa (L) Nutt (equal to 35 mg of Black Cohosh (roots) and root).

**Dosage:** For oral use only. Adults and elderly: Take 1 capsule 3 times daily. Swallow the whole capsule with water.

**Duration of use:** If symptoms improve but do not improve after 4 weeks of taking this product or if any of the side effects listed in the leaflet become serious or if side effects not listed occur, a doctor or a qualified healthcare professional should be consulted.

**Cartons:**

MHRA PAR; HOLLAND & BARRETT BLACK COHOSH CAPSULES, GNC LIVE WELL BLACK COHOSH CAPSULES, LIFECYCLE BLACK COHOSH CAPSULES, NATURE’S GARDEN BLACK COHOSH CAPSULES AND NATURE’S BOUNTY BLACK COHOSH CAPSULES, THR 21710/0007
Nature’s Garden Black Cohosh Capsules

Labels:

Active Ingredients: Each hard capsule contains 15mg of extract (as dry extract) from Black Cohosh rhizome and root (Cimicifuga racemosa (L.) Nutt.) (equivalent to 50mg of Black Cohosh rhizome and root). Extraction solvent: Ethanol 75% v/v.

Dosage: For oral use only. Adults and elderly: Take 1 capsule 3 times daily. Swallow the whole capsule with water.

Duration of use: If symptoms worsen or do not improve after 4 weeks of taking this product or if any of the side effects listed occur, 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
  - Of childbearing age and not using contraception
  - Allergic to Black Cohosh or any of the ingredients in this product
  - Suffering from or have had liver or kidney problems
  - Suffering from or have had an oestrogen dependent tumour
Black Cohosh may rarely cause liver problems. If you notice symptoms such as yellowing of the skin/eyes, nausea, vomiting, dark urine, abdominal pain or unusual tiredness, stop taking this product and consult a Doctor, Pharmacist or a qualified Healthcare Practitioner.

Please read the enclosed leaflet carefully before using this product.


Active Ingredients: Each hard capsule contains 15mg of extract (as dry extract) from Black Cohosh rhizome and root (Cimicifuga racemosa (L.) Nutt.) (equivalent to 50mg of Black Cohosh rhizome and root). Extraction solvent: Ethanol 75% v/v.

Dosage: For oral use only. Adults and elderly: Take 1 capsule 3 times daily. Swallow the whole capsule with water.

Duration of use: If symptoms worsen or do not improve after 4 weeks of taking this product or if any of the side effects listed occur, 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
  - Of childbearing age and not using contraception
  - Allergic to Black Cohosh or any of the ingredients in this product
  - Suffering from or have had liver or kidney problems
  - Suffering from or have had an oestrogen dependent tumour
Black Cohosh may rarely cause liver problems. If you notice symptoms such as yellowing of the skin/eyes, nausea, vomiting, dark urine, abdominal pain or unusual tiredness, stop taking this product and consult a Doctor, Pharmacist or a qualified Healthcare Practitioner.

Please read the enclosed leaflet carefully before using this product.

Warnings:
DO NOT EXCEED THE STATED DOSE.
Do not take this product if you are:
- Under 16 years of age
- Pregnant or breastfeeding
- On any medication or not using contraception
- Allergic to Black Cohosh or any of the ingredients in this product
- Suffering from or prone to liver or kidney problems
- Suffering from a severe haemolytic anemia (previously documented haemolysis)

Black Cohosh may rarely cause liver problems. If you notice symptoms such as yellowing of the eyes or skin, nausea, vomiting, dark urine, abdominal pain or unusual tiredness, stop taking this product immediately and consult a doctor, pharmacist or a qualified healthcare practitioner.

Please read the enclosed leaflet carefully before using this product.

Active ingredients: Each hard capsule contains 18mg of extract (as dry extract) from Black Cohosh rhizome and root (Cimicifuga racemosa L. Nut.) equivalent to 97mg-153mg of Black Cohosh rhizome and root.
Extraction solvent: Ethanol 75% v/v.

Dosage: For oral use only.
Adults and elderly: Take 1 capsule 3 times daily. Swallow the whole capsule with water.

Duration of use: If symptoms worsen or do not improve after 4 weeks of taking this product or if any of the side effects listed in the package become severe or if side effects not listed occur, a doctor or a qualified healthcare practitioner should be consulted.
Nature’s Bounty Black Cohosh Capsules

Labels:

**Nature’s Bounty Black Cohosh Capsules**

**Active Ingredients:** Each hard capsule contains 10mg of extract (as dry extract) from Black Cohosh rhizome and root (Cimicifuga racemosa (L.) Nutt.) (equivalent to 75mg-155mg of Black Cohosh rhizome and root).

**Extraction solvent:** Ethanol 35% v/v.

**Dosage for use only:** Adults and elderly: Take 1 capsule 3 times daily. Swallow the whole capsule with water.

**Duration of use:** If symptoms worsen or do not improve after 4 weeks of taking this product or if any of the side effects listed in this leaflet become severe or if side effects not listed occur, 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.
  - Of childbearing age and not using contraception.
  - Allergic to Black Cohosh or any of the ingredients in this product.
  - Suffering from or have had liver or kidney problems.
  - Suffering from or have had an oestrogen dependent tumour.

Black Cohosh may rarely cause liver problems. If you notice symptoms such as yellowing of the skin/eyes, nausea, vomiting, dark urine, abdominal pain or unusual tiredness, stop taking this product and consult a Doctor, Pharmacist or a qualified Healthcare Practitioner.

Please read the enclosed leaflet carefully before using this product.

**Storage:** Do not store above 25°C. Keep in the original packaging. Keep the bottle tightly closed. Keep out of sight and reach of children.