

MENOHERB[®] FILM-COATED TABLETS

THR 23056/0003

UKPAR

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MENOHERB[®] FILM-COATED TABLETS

THR 23056/0003

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted M H Pharma (UK) Ltd a Traditional Herbal Registration Certificate for the traditional herbal medicinal product Menoherb[®] Film-coated Tablets (Traditional Herbal Registration number: THR 23056/0003). This product is available without prescription and can be bought from pharmacies and other outlets.

The active ingredient of Menoherb[®] Film-coated Tablets comes from the root of the plant *Cimicifuga racemosa*, also known as black cohosh. Menoherb[®] Film-coated Tablets is a traditional herbal medicinal product used for the relief of symptoms of the menopause, such as hot flushes, night sweats or temporary changes of mood. This registration is based exclusively upon evidence of traditional use of black cohosh as a herbal medicine and not upon data generated from clinical trials. There is no requirement under the Traditional Herbal Registration scheme to prove scientifically that the product works.

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

MENOHERB[®] FILM-COATED TABLETS

THR 23056/0003

SCIENTIFIC DISCUSSION

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INTRODUCTION

The MHRA granted a Traditional Herbal Registration Certificate for the traditional herbal remedy Menoherb[®] Film-coated Tablets to M H Pharma (UK) Ltd on 25 June 2007. 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 coated tablets containing 6.5 mg of a dry 60% ethanolic extract of dry *Cimicifuga racemosa* (L.) Nutt rhizomes and root, that is equivalent to 29.25mg to 55.25mg of dried root. The product is indicated as a traditional herbal medicinal product for the relief of symptoms of the menopause, such as hot flushes, night sweats, nervous irritability and restlessness based exclusively on evidence of traditional use of black cohosh. The recommended dose is one tablet daily.

The data supplied by the Applicant demonstrate 30 years of traditional use of black cohosh in the European Community. 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 REPORT

HERBAL SUBSTANCE

General information

- ***Parent plant***

Latin name: *Cimicifuga racemosa* (L.) NUTT.

Common name: Black cohosh

Other names: Cimicifuga, Black snakeroot, *Actaea racemosae radix*

Family: Ranunculaceae

- ***Parts of plant used***

Rhizome with the attached roots

- ***Constituents***

From literature the following constituents have been reported:

Triterpene glycosides – actein, cimifugoside, cimiracemoside A

Isoflavones – formononetin

Aromatic acids – isoferulic acid, salicylic acid

Resinous fraction – cimifugin

Other constituents – tannins, fatty acids, starch, sugars, alkaloids (cytisin)

- ***Laboratory code***

CIMI-01-FT

- ***Monographs***

Several monographs are available for *Cimicifuga racemosa* (L.) NUTT. (black cohosh):

Pharmeuropa Vol 14. No 2 April 2002

USP 29 (2006)

British Herbal Pharmacopoeia (1996)

British Herbal Compendium Vol. 1 (1992)

American Herbal Pharmacopoeia

Manufacture

Manufacturers

The plant is indigenous to northern USA and Canada and is collected from the wild, mainly in the USA. The herbal substance supplier has many years' experience supplying herbal substances and has been selling this herbal substance for 25 years.

A signed declaration has been provided from the supplier of the herb confirming that it is grown according to Good Agricultural and Collection Practice (GACP).

Description of Manufacturing Process and Process Controls

From May to August (before flowering to ripening) the rhizome and the attached roots are collected. These are dried under natural conditions in covered and well ventilated places.

Characterisation

Elucidation of Structure and other Characteristics

The plant is examined according to the monograph for black cohosh in the British Herbal Pharmacopoeia.

Impurities

The scope of the purity tests of the herbal substance are in line with those in the British Herbal Pharmacopoeia. The applicant has confirmed that the herbal substance will comply with the Ph. Eur once the monograph has been adopted.

Control of Herbal Substance

Specification

The herbal substance is controlled in line with a specification that complies with the British Herbal Pharmacopoeia. These tests and limits are suitable to ensure the consistent good quality of the starting material.

A signed declaration is provided to confirm that the herbal substance will comply with the Ph. Eur. monograph once it is adopted.

Analytical Procedures

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

Batch Analyses

Satisfactory batch data have been provided to support the specifications.

Reference Standards or Materials

A suitable certificate of analysis has been provided for the reference standard. Full details are given of the tests performed; all details are acceptable.

Container Closure System

The dried herbal drug is stored protected from light, heat and moisture in a container closure system that complies with Directive 2002/72/EC.

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 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

General information

Dry extract

Yellow-brown, flowable powder with a characteristic odour and slightly bitter taste. It consists of native extract, lactose monohydrate, powdered cellulose and colloidal anhydrous silica. It does not dissolve in water and ethanol (60%) due to the presence of powdered cellulose and colloidal anhydrous silica.

Manufacture

Manufacturer

The GMP certificate issued by the regional authority states that the herbal preparation manufacturer operates in compliance with the requirements for GMP.

Description of Manufacturing Process and Process Controls

A flow diagram of the manufacturing process of the herbal preparation has been provided and is satisfactory.

Control of Materials

All excipients used in the dry extract comply with the Ph. Eur. Certificates of analysis have been provided for the excipients, showing all to meet the required specification limits.

A satisfactory declaration from the supplier of lactose monohydrate with respect to TSE status has been provided.

Controls of Critical Steps and Intermediates

Satisfactory in process-controls are performed at various steps in the manufacture of the dry extract.

Process Validation and Manufacturing Process Development

The manufacture of the dry extract is a standard procedure. Process validation results of different batches are provided to demonstrate that the method consistently produces product of suitable quality. Additionally, adequate in-process controls are included during the manufacturing process.

Characterisation

Elucidation of Structure and other Characteristics

Suitable tests are performed.

Impurities

Suitable tests for purity are included in the herbal preparation specification.

Control of Herbal Preparation

Specification

A satisfactory specification, with appropriate tests and limits has been provided for the herbal preparation

Analytical Procedures / Validation of Analytical Procedures

Details of the analytical methods used have been provided and these methods have been fully validated.

Batch Analyses

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

Reference Standards or Materials

Suitable details have been provided for the reference standards.

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 round, white, convex, curved coated tablets have a score mark on one side. The qualitative composition is outlined as follows.

The finished product is packed in PVC/PVDC aluminium blisters with 10 tablets each and inserted into a cardboard outer carton with a total of 30, 60 or 90 tablets.

Qualitative composition of Menoherb[®] Film-coated Tablets

Name of Ingredient	Function	Reference to standards
Active ingredient:		
Dry extract of <i>Cimicifuga</i> rhizome (DER 4.5 – 8.5:1) [extraction solvent: ethanol 60% v/v*]	active ingredient	In House
Other constituents		
<i>Tablet core</i>		
Cellulose, powdered	Flowability agent (extract)	Ph. Eur
Silica, colloidal anhydrous	Flowability agent	Ph. Eur
Lactose monohydrate	Carrier (extract)	Ph. Eur
Magnesium stearate	Lubricant	Ph. Eur
Maize starch	Disintegrant	Ph. Eur
Cellulose, microcrystalline	Binding agent	Ph. Eur
Sodium starch glycollate (type A)	Disintegrant	Ph. Eur
<i>Film coating</i>		
Hydroxymethylcellulose	Binding agent	Ph.Eur
Macrogol 4000	Film coating	Ph. Eur
Titanium dioxide (E171)	Colouring agent	Ph. Eur
Purified water *		

* not contained in the drug product.

Manufacture

Manufacture

A copy of the manufacturing licence is provided. The site complies with GMP standards. A flow diagram summarising the manufacturing process and in-process controls has been provided.

The tablet components are sieved and mixed and then pressed into tablet cores. The tablet cores are then film-coated and dried and packed into the blister strips that are put into cartons with the patient information leaflet.

Control of Critical Steps and Intermediates

A number of in-process control tests are performed during manufacture. All are considered adequate.

Process Validation and/or Evaluation

The manufacturing procedure is a standard procedure for direct tableting, film coating and blister packing. Process validation results for production scale batches of tablets are provided. All results are satisfactory.

Control of Excipients

All excipients comply with the Ph. Eur. and suitable certificates of analysis are provided.

Confirmation is provided that the stearic acid and magnesium stearate used in product manufacture are of vegetable origin and, therefore, do not require TSE certification. Satisfactory certification regarding the TSE status of lactose monohydrate has been provided from the supplier.

Control of Herbal Product

Specification

The finished product specifications for release and end of shelf life are detailed and the tests and limits used were found to be satisfactory for a product of this nature.

Analytical Procedures / Validation of Analytical Procedures

Satisfactory details have been provided on all analytical procedures and these analytical procedures are valid.

Batch Analyses

Satisfactory batch data have been provided to support the specifications.

Characterisation of Impurities

Whilst it is stated that, characterisation of impurities is not applicable for herbal medicinal products and that *Cimicifuga* rhizome does not contain any known toxic degradation products, satisfactory tests are used to ensure that there is good comparison between the raw material and the finished product. This is acceptable.

Justification of Specification

The specification includes standard tests for tablets and is considered to be acceptable for a product of this type.

Reference Standards or Materials

Identity and purity of the employed reference substance is sufficiently established by the combination of several tests.

Container Closure System

The film-coated tablets are sealed into mono blisters made of polypropylene (sealing foil: white; thermofoil: transparent) with 10 tablets each. This is inserted into an outer cardboard carton with a total of 30 or 60 tablets.

Specifications and certificates are provided from the manufacturers and the applicant has confirmed that all components of the final container closure system comply with Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs.

Stability

Data are provided for production scale batches. Batches were packed in the final packaging and tested under ICH conditions of real, intermediate and accelerated time.

Based on the data provided, a shelf life of 48 months with the storage warning 'Do not store above 30°C' is acceptable.

ASSESSOR'S COMMENTS ON THE SUMMARY OF PRODUCT CHARACTERISTICS, LABEL AND PATIENT INFORMATION LEAFLET

Summary of Product Characteristics (SPC)

The SPC for this product is satisfactory.

Patient Information Leaflet (PIL)

The PIL for this product is satisfactory.

Labelling

All labelling is satisfactory.

ADMINISTRATIVE

Comment on the Quality Overall Summary

The Quality Overall Summary has been written by a pharmacist with suitable pharmaceutical and pharmacognosy experience and is satisfactory.

ASSESSOR'S OVERALL CONCLUSIONS ON QUALITY

This product is satisfactory and a Traditional Herbal Registration can be granted.

NON-CLINICAL ASSESSMENT

Non-clinical aspects

The Safety Expert Report submitted by the applicant lists relevant references to published work studying the toxicology of black cohosh.

Non-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 pharmacist with expertise in herbal medicines, and is dated 28 December 2005.

The overview contains a short review of some non-clinical data for black cohosh. 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 black cohosh it is not possible to assess if the safety package for the phytochemical constituents of black cohosh 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 may be 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 black cohosh is acceptable. An adequate literature review for black cohosh has been carried out by the applicant and no new nonclinical data were submitted for assessment with this application. Granting of a THR is acceptable.

CLINICAL ASSESSMENT

BACKGROUND

Black cohosh (*Cimicifuga racemosa* (L.) Nutt) is a member of the Ranunculaceae (buttercup) family. The traditional uses of black cohosh are for rheumatism, rheumatoid arthritis, intercostal myalgia, sciatica, whooping cough, chorea, tinnitus, dysmenorrhoea and uterine colic. The modern use of black cohosh is focused on its use in treating peri- and post-menopausal symptoms.

Published literature indicates that the following adverse reactions may be associated with the use of black cohosh; gastrointestinal irritation, headache, dizziness and vomiting when large doses are taken. The long term safety of black cohosh has not been established.

PROPOSED INDICATION

The applicant has proposed the following:

“A traditional herbal medicinal product used for the relief of symptoms of the menopause, such as hot flushes, night sweats, and temporary changes in mood (such as nervous irritability and restlessness) 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.”

Medical Assessor’s Comment

This indication is appropriate.

POSOLOGY AND METHOD OF ADMINISTRATION

The applicant has submitted the following:

“For oral use only.

For women experiencing menopausal symptoms, take 1 tablet daily. Tablets should be taken at the same time of day if possible (morning or evening) and swallowed whole with plenty of liquid. Do not chew the tablets.

Children and adolescents less than 18 years old

This product is not indicated in patients less than 18 years.

Hepatic and renal impairment

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

Medical Assessor’s Comment

This is acceptable.

TOXICOLOGY

See preceding preclinical assessment report.

EFFICACY

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

EVIDENCE OF TRADITIONAL USE

Black cohosh is generally accepted to have a tradition of use as a herbal medicine.

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 *Cimicifuga racemosa* (L.) Nutt / black cohosh within the EU for a period exceeding 30 years.

Assessor's Comments

There is ample evidence of traditional use of *black cohosh* for a period exceeding 30 years, including evidence of its use in the treatment of climacteric symptoms. Therefore, a herbal license can be granted for these indications.

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.

A safety review has been provided as well as an expert report written by a pharmacist with expertise in herbal medicines. His CV has also been provided.

The Clinical Review of Safety submitted in the dossier outlined adverse events from controlled and uncontrolled studies relevant to the safety of black cohosh. These included the data available on the possible oestrogen-like effects of black cohosh extracts and reported liver adverse events which have caused concern about a potential risk of hepatic reactions associated with the black cohosh.

It has been agreed that these issues will be addressed by information to be included in the product literature and labelling.

Assessor's Comments

The Safety Review is comprehensive and reveals the main safety issues associated with treatment with black cohosh; the herb's possible hormonal effects and the number of reports of hepatic adverse reactions. The SPC includes information taking account of the known safety profile of black cohosh.

SUMMARY OF PRODUCT CHARACTERISTICS

The SPC for this product is satisfactory.

PATIENT INFORMATION LEAFLET

The PIL for this product is 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 black cohosh within the EU for a period exceeding 30 years.

A satisfactory review of the safety data has been provided.

The SPC, PIL and labelling are satisfactory.

RISK ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified.

MENOHERB[®] FILM-COATED TABLETS

THR 23056/0003

STEPS TAKEN FOR ASSESSMENT

- 1 The MHRA received the Traditional Herbal Registration application on 9 January 2006
- 2 Following standard checks and communication with the applicant the MHRA considered the application valid on 10 April 2006
- 3 Following assessment of the application the MHRA requested further information relating to the quality dossier on 6 July 2006 and 3 August 2006, the non-clinical dossier in December 2006 and the clinical dossier on 23 January 2007. In addition, the Herbal Medicines Advisory Committee requested further information on 6 Feb 2007
- 4 The applicant responded to the MHRA's requests, providing further information on the dossier on 30 August 2006 and 5 March 2007
- 5 Following assessment of the response the MHRA requested further information relating to the quality dossier on 16 April 2007
- 6 The applicant responded to the MHRA's requests, providing further information on the quality dossier 4 May 2007
- 7 Following assessment of the response the MHRA requested further information relating to the quality dossier on 6 June 2007
- 8 The applicant responded to the MHRA's requests, providing further information on the quality dossier on 15 June 2007
- 9 Following assessment of the response the MHRA requested further information relating to the quality dossier on 22 June 2007
- 10 A THR was granted on 25 June 2007

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Menoherb[®] Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains:

6.5 mg of extract (as dry extract) from Black Cohosh rhizome and root (*Cimicifuga racemosa* (L.) Nutt.) (4.5-8.5:1) (equivalent to 29.25-55.25 mg of Black Cohosh).

Extraction solvent: Ethanol 60% v/v.

One film-coated tablet contains 142mg lactose monohydrate.

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet.

White, round, convex curved and with a score mark on one side.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A traditional herbal medicinal product used for the relief of symptoms of the menopause, such as hot flushes, night sweats, and temporary changes in mood (such as nervous irritability and restlessness) 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.

For women experiencing menopausal symptoms, take 1 tablet daily. Tablets should be taken at the same time of day if possible (morning or evening) and swallowed whole with plenty of liquid. Do not chew the tablets.

Children and adolescents less than 18 years old

This product is not indicated in patients less than 18 years.

Hepatic and renal impairment

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

4.3 Contraindications

Menoherb should not be used:

- In patients under 18 years old.
- Women who are pregnant or breast feeding or in women who could become pregnant (unless contraception is used).
- In patients who have active liver disease or a history of liver damage.
- In patients currently receiving treatment for or has had a history of an estrogen dependent tumour.

4.4 Special warnings and precautions for use

There have been rare cases of hepatic reactions associated with the use of black cohosh. Patients taking Menoherb should be informed to immediately stop the use of the product and consult their doctor if they develop signs and symptoms suggestive of liver dysfunction. (Fatigue, anorexia, yellowing of the skin and eyes or severe upper stomach pain with nausea and vomiting or dark urine).

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

Oestrogens may only be taken simultaneously with Menoherb[®] under medical supervision, as their effect may be intensified by Black cohosh.

If menstrual disorders occur or menstruation re-appears and if the symptoms are persistent, of unknown origin, or have recently occurred, a doctor should be consulted as this may indicate the presence of other conditions which need to be medically diagnosed.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine

4.5 Interaction with other medicinal products and other forms of interaction

No studies have been conducted to determine if drug interactions occur with Menoherb.

4.6 Pregnancy and lactation

The safety of the product during pregnancy and lactation has not been established. Therefore it should be avoided during pregnancy or lactation. Additionally, because of the potential for the product to have hormone-like actions the product should also be avoided by women who could become pregnant unless contraception is used.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Very rarely (less than 1 in 1000, but more than 1 in 10000 treated patients), there may be gastrointestinal symptoms (dyspeptic symptoms, diarrhoea), allergic skin reactions (nettle rash, itching of the skin, skin rash), facial oedema and peripheral oedema, and weight gain.

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

4.9 Overdose

In the event of an overdose, patients are advised to contact a doctor, pharmacist or qualified healthcare professional. A small overdose (up to 4 tablets) is unlikely to cause any symptoms. In the event of a larger overdose (more than 4 tablets), advice should be sought from a doctor. Management of a large overdose should be symptomatic and supportive in nature.

Older herbal texts state that doses of over 5 g unprocessed drug daily may produce symptoms of nausea, vomiting, dizziness, visual and nervous disturbances, reduced pulse rate and increased perspiration.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code:G02CP03

ATC Group: G02CP

It is not possible to make conclusive statements about the oestrogen-like stimulating or inhibiting effect of Black cohosh, because the literature data are contradictory.

5.2 Pharmacokinetic properties

No data available

5.3 Preclinical safety data

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Excipients of the herbal preparation:

Lactose monohydrate

Cellulose powdered

Silica, colloidal anhydrous

Excipients of the tablet:

Silica, colloidal anhydrous
Magnesium stearate
Maize starch
Cellulose, microcrystalline
Sodium starch glycolate (type A)

Excipients of the film-coating:

Hypromellose
Macrogol 4000
Titanium dioxide E 171

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf life is 4 years

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Original packages containing 30, 60 or 90 film-coated tablets

Menoherb[®] film-coated tablets are packed in PVC/ PVDC aluminium blisters and inserted into a carton.

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

M H Pharma (UK) Ltd

T/a Medic Herb

PO Box 2835

Brewery Courtyard

Draymans Lane

Marlow

Buckinghamshire

SL7 2XG

8 MARKETING AUTHORISATION NUMBER(S)

THR 23056/0003

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

25/06/2007

10 DATE OF REVISION OF THE TEXT

25/06/2007

PATIENT INFORMATION LEAFLET

MenoHerb[®] film-coated tablets



MedicHerb

Black Cohosh root extract 6.5mg

Please read this leaflet carefully before you start taking these tablets.

It contains some important information about MenoHerb.

Keep this leaflet with the tablets.

You may want to read it again or show it to your doctor, pharmacist or healthcare practitioner.

What is in this leaflet

1: What this product is and what it is used for.....	page 1
2: Before you take this product	page 2
3: How to take this product	page 2
4: Side-effects	page 3
5: After taking this product	page 3
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1: What this product is and what it is used for

This product is a traditional herbal medicinal product containing Black Cohosh root. Each film-coated tablet of this product contains 6.5mg of extract (as dry extract) from Black Cohosh rhizome and root (*Cimicifuga racemosa* (L.) Nutt.) (4.5-8.5:1) (equivalent to 29.25-55.25mg of Black Cohosh). Extraction solvent: Ethanol 60% v/v.

MenoHerb is a traditional herbal medicinal product used for the relief of symptoms of the menopause, such as hot flushes, night sweats, and temporary changes in mood (such as nervous irritability and restlessness). This usage 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 child-bearing potential if contraception is used.

1

2: Before you take this product

DO NOT TAKE this product if you:

- have ever had or are suffering from **liver or kidney disease (e.g. hepatitis, jaundice or cirrhosis)**
- have ever had or are suffering from an **oestrogen dependent tumour**
- are **of childbearing potential and do not use contraception**
- are **lactose-intolerant** (react badly to lactose or milk)
- are **pregnant or breastfeeding**
- are **allergic to any of the ingredients** (see section 6)
- are **under 18 years of age**

Tell your doctor before taking this product if you:

- have a persistent **history of menstrual disorders**
- are currently taking a **medicine containing oestrogen**

3: How to take this product

Adults

For women experiencing menopausal symptoms, take 1 tablet daily

Tablets should be taken at the same time of day if possible (morning or evening). Swallow the tablet whole with some water or other liquid. Do not chew the tablets.

Do not exceed the stated dose.

If you take too much of this product (overdose)

If you take more than the recommended dose, speak to a doctor, pharmacist or healthcare practitioner and take this leaflet with you.

If you forget to take this product

Continue to take your usual dose at the usual time, it does not matter if you have missed a dose.

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

2

4: Side-effects

Like all medicines, this product can have side-effects. These are listed below.

Uncommon side-effects (affecting fewer than 1 in 1000 people)

- | | |
|--|--|
| <ul style="list-style-type: none">● digestive upsets such as indigestion or diarrhoea● facial swelling● weight gain● allergic skin reactions such as nettle rash, itching of the skin | If these persist for more than a few days, or become troublesome, stop taking this product. These common side-effects are often only temporary. Stop taking this product immediately if you experience any allergic skin reaction. |
|--|--|

Other side-effects

Black Cohosh may rarely cause liver problems. If you become unwell (yellowing eyes/skin, nausea, vomiting, dark urine, abdominal pain, unusual tiredness) stop taking immediately and seek medical advice. Tell your doctor or pharmacist if you notice any other side-effect.

5: After taking this product

You must speak to a healthcare practitioner if your symptoms worsen, if they do not improve after 12 weeks, or if you notice any re-appearance or changes in menstrual bleeding.

Do not use your tablets after the expiry date. Return any out-of-date tablets to your pharmacist who will dispose of them for you. The expiry date is printed on the box and the blister pack.

Store the tablets in a cool dry place. Do not store the tablets in a place where the temperature goes above 30°C.

Keep the tablets out of the reach and sight of children.

Keep your tablets in the blister pack until it is time to take them.

6: Product description

Each film-coated tablet contains 6.5mg of extract (as dry extract) from Black Cohosh rhizome and root (*Cimicifuga racemosa* (L.) Nutt.) (4.5-8.5:1) (equivalent to 29.25-55.25mg of Black Cohosh). Extraction solvent: Ethanol 60% v/v.

This product also contains the following ingredients:

Tablet core:

Cellulose powdered, lactose monohydrate, silica colloidal anhydrous, magnesium stearate, maize starch, cellulose microcrystalline, sodium starch glycolate (type A).

Film-coating:

hypromellose, macrogol 4000, titanium dioxide (E171).

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this product. Each film-coated tablet contains 142mg of lactose.

Each pack contains 30, 60 or 90 film-coated tablets.

Registration holder for this product

M H Pharma (UK) Ltd, t/a MedicHerb, PO Box 2835,
Brewery Courtyard, Draymans Lane,
Marlow, Bucks, SL7 2XG

Manufacturer of this product

Wiewelhove GmbH, Gildestrasse 39, 49477 Ibbenbüren, Germany

Traditional herbal registration number: THR 23056/0003

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

Blister foil:



Carton:

Batch No:
 Expiry date:
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Carton showing Brialle:



Batch No:
Expiry date:

