

English Herbal Medicines Black Cohosh Rumatix

THR 28255/0018

UKPAR

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ENGLISH HERBAL MEDICINES BLACK COHOSH RUMATIX

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LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Rutland Biodynamics Ltd a Traditional Herbal Registration certificate for the traditional herbal medicinal product English Herbal Medicines Black Cohosh Rumatix (Traditional Herbal Registration number: THR 28255/0018). This product is available without prescription and can be bought from pharmacies and other outlets.

English Herbal Medicines Black Cohosh Rumatix is a traditional herbal medicinal product used for the symptomatic relief of backache and muscular and rheumatic aches and pains. The active ingredient in this product comes from the rhizome and roots of the Black cohosh (*Cimicifuga racemosa* L. Nutt.) plant.

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.

ENGLISH HERBAL MEDICINES BLACK COHOSH RUMATIX

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SCIENTIFIC DISCUSSION

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INTRODUCTION

The MHRA granted a Traditional Herbal Registration certificate for the traditional herbal medicine English Herbal Medicines Black Cohosh Rumatix (THR 28255/0018) to Rutland Biodynamics Ltd on 8 February 2011. This product is on the general sales list (GSL).

A product licence of right (PLR) was granted to Potters Limited for this product (under the name Liquid Extract of Black Cohosh, PL 00250/5364R) in 1972. The PLR was reviewed and a product licence was granted on 27 February 1991. Following a change of ownership on 23 June 2009 the product licence was transferred to Rutland Biodynamics Ltd under product licence number PL 28255/0016. Confirmation is given that PL 28255/0016 will be cancelled after the THR is granted.

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

PHARMACEUTICAL ASSESSMENT

HERBAL SUBSTANCE: **BLACK COHOSH ROOT AND RHIZOME**

Scientific name of the plant: *Cimicifuga racemosa* L. Nutt.
Family: Ranunculaceae
Synonyms of the herbal substance: Cimicifuga, Black snakeroot, *Actaea racemosae*

Assurance has been provided that the herbal substance will comply with the Ph. Eur. monograph once the monograph is adopted. This is acceptable.

HERBAL PREPARATION: **BLACK COHOSH RHIZOME AND ROOT LIQUID EXTRACT**

Parts of the plant used: Rhizome with the attached roots
Ratio of the herbal substance to the herbal preparation (native): 1:1
Extraction solvent: Ethanol 82 % (v/v)

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

HERBAL PRODUCT: **ENGLISH HERBAL MEDICINES BLACK COHOSH RUMATIX**

Description and Composition of the Herbal Product

English Herbal Medicines Black Cohosh Rumatix is a medium brown liquid given as oral drops. Each 1 ml of the herbal product contains 1 ml of liquid extract from dried Black Cohosh rhizome and root (the herbal preparation). There are no excipients in this product. The ethanol in this product comes from the herbal preparation. The formulation is identical to that of the already licensed product. It is, therefore, acceptable.

Manufacture

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

Finished Product Specification

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

Container Closure System

The liquid is packed in 50 ml glass bottles with either a polyethylene dropper cap or butyl-rubber bulb and HDPE plastic cap. This type of packaging has been used to store the already licensed product and is satisfactory.

Stability

The product shelf-life of 3 years was applied to the already licensed product and is appropriate

Summary of Product Characteristics, label and Patient Information Leaflet

All product literature is in line with that of the already licensed product. The Patient Information Leaflet and labelling are combined as a foldable, peelable leaflet which is attached to the bottle.

The combined package leaflet/labelling 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/labelling is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

Assessor's Overall Conclusions on Quality

The grant of a Traditional Herbal Registration is acceptable.

PRECLINICAL ASSESSMENT

INTRODUCTION

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

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

PRODUCT LITERATURE

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

ASSESSOR'S OVERALL CONCLUSIONS

It is recommended that a Traditional Herbal Registration can be granted.

CLINICAL ASSESSMENT

INTRODUCTION

The clinical particulars for English Herbal Medicines Black Cohosh Rumatix are identical to those for the already licensed product. This is satisfactory.

PRODUCT LITERATURE

All product literature is medically satisfactory.

ASSESSOR'S OVERALL CONCLUSIONS

It is recommended that a Traditional Herbal Registration can be granted.

OVERALL CONCLUSION AND RISK ASSESSMENT

QUALITY

English Herbal Medicines Black Cohosh Rumatix is identical to an already licensed product. It is, therefore, pharmaceutically satisfactory.

PRECLINICAL

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

EFFICACY

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

SAFETY

No new or unexpected safety concerns arose from this application.

RISK ASSESSMENT

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

ENGLISH HERBAL MEDICINES BLACK COHOSH RUMATIX

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STEPS TAKEN FOR ASSESSMENT

- 1 The MHRA received the Traditional Herbal Registration application on 2 October 2009.
- 2 Following standard checks and communication with the applicant the MHRA considered the application valid on 27 October 2009.
- 3 Following assessment of the application the MHRA requested further information relating to the quality and clinical dossiers on 21 April 2010.
- 4 The applicant responded to the MHRA's requests, providing further information on the quality and clinical dossiers on 29 November 2010.
- 5 Following assessment of the response the MHRA requested further information relating to the quality and clinical dossiers on 29 November 2010.
- 6 The applicant responded to the MHRA's requests, providing further information on the quality and clinical dossiers on 7 January 2011.
- 7 A THR was granted on 21 January 2011.

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

English Herbal Medicines Black Cohosh Rumatix

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml of oral liquid contains 1 ml of liquid extract from dried Black Cohosh rhizome and root (*Cimicifuga racemosa* (L.) Nutt.) (1:1). Extraction solvent: ethanol 82 % v/v.

1 ml of oral liquid also contains approximately 647 mg of ethanol (alcohol).
(See section 4.4 'Special warnings and precautions for use'.
For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral Liquid.
Medium brown liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

Women of childbearing potential should use effective contraception.

4.2 Posology and method of administration

For oral use only

Adults and the elderly

Take 0.2ml (six drops) three times a day in water or fruit juice if desired.

Children and adolescents less than 18 years

This product is not indicated in children and adolescents less than 18 years (see section 4.4).

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 impairment or renal impairment.

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

4.3 Contraindications

Hypersensitivity to Black Cohosh or any of the excipients.
Children and adolescents under 18 years.
Pregnancy and lactation.
Patients with active liver disease or a history of liver damage.
Patients currently receiving treatment for or with a history of an oestrogen dependent tumour.

4.4 Special warnings and precautions for use

Do not exceed the stated dose.

There have been rare cases of hepatic reactions associated with the use of Black Cohosh. Patients taking this product should immediately stop the use of the product and consult their doctor if they develop signs and symptoms that suggest 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 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 effect may be intensified by Black Cohosh.

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

Contains alcohol – up to 129 mg ethanol per dose (equivalent to 3.2 ml of beer or 1.4 ml of wine). Harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver-disease, or epilepsy.

4.5 Interaction with other medicinal products and other forms of interaction

No studies have been carried out to determine if drug interactions occur with this product.

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

4.6 Pregnancy and lactation

The safety of the product during pregnancy and lactation has not been established, therefore it should not be used during pregnancy or lactation or by women attempting to become pregnant.

4.7 Effects on ability to drive and use machines

No studies on the effect of this product on the ability to drive or use machinery have been performed.

This product contains alcohol (see Section 2).

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.

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

4.9 Overdose

In the event of an overdose, patients should contact a doctor, pharmacist or qualified healthcare practitioner. Treatment should be symptomatic and supportive.

Overdose of this product may result in alcohol intoxication and should be treated accordingly. Amount of ethanol in a full bottle – 32.3 g in 50 ml equivalent to 2 large glasses of wine and 161.7 g in 250ml equivalent to 10 large glasses of wine.

Older herbal texts state that doses of over 5g unprocessed drug (equivalent to 5ml of this product or 25 individual doses) 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

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

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

Ethanol

Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Three years.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Glass bottle with polyethylene dropper cap: 50ml

Glass bottle with butyl-rubber bulb and HDPE plastic cap: 50ml

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Rutland Biodynamics Ltd, Town Park Farm, Brooke, Rutland, LE15 8DG.

8 MARKETING AUTHORISATION NUMBER(S)

THR 28255/0018

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

08/02/2011

10 DATE OF REVISION OF THE TEXT

08/02/2011

PATIENT INFORMATION LEAFLET/LABELLING

A combined Patient Information Leaflet and labelling is provided for this product:

ENGLISH HERBAL MEDICINES

Black Cohosh Rumatix

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

50ml

Ingredients: 1 ml of oral liquid contains 1 ml of liquid extract from dried Black Cohosh rhizome and root (*Cimicifuga racemosa* (L.) Nutt.) (1:1). Extraction solvent: ethanol 82 % v/v. This product also contains the following ingredients: Ethanol (from extract)

HOW TO TAKE THIS PRODUCT: For oral use only. **Adults and the elderly:** Take 0.2ml (six drops) three times a day in water or fruit juice if desired.

This formulation is not suitable for those under 18, pregnant or breastfeeding women, patients who are allergic to any of the ingredients, patients who have liver or kidney disease or patients who have ever had or are suffering from an oestrogen dependent tumour. **Keep all medicines out of the reach and sight of children. Do not exceed the stated dose.**

Manufacturer and Traditional Herbal Registration Holder: English Herbal Medicines Ltd., Brooke, Rutland LE15 8DG. **THR No: 28255/0018.** Prepared Feb 2011

PEEL HERE BUT DO NOT REMOVE

Batch No:
Expiry:

ENGLISH HERBAL MEDICINES

BLACK COHOSH RUMATIX

BEFORE YOU TAKE THIS PRODUCT

Do not take this product if you:

- have ever had or are suffering from liver or kidney disease (eg hepatitis, cirrhosis or jaundice)
- have ever had or are suffering from an oestrogen dependent tumour
- are of child-bearing potential and do not use contraception
- are pregnant or breastfeeding
- are allergic to any of the ingredients
- are under 18 years of age

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.

Tell your doctor before you take this product if you are currently taking a medicine containing oestrogen.

If your symptoms worsen or do not improve after 4 weeks, or adverse reactions not mentioned in the leaflet occur, speak to your doctor, pharmacist or qualified healthcare practitioner.

You should also know: This product contains approximately 129 mg of ethanol (alcohol) per dose equivalent to 3.2 ml of beer or 1.4 ml of wine. Harmful for people suffering from alcoholism or liver disease.

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

POSSIBLE SIDE EFFECTS

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

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

- 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 or become troublesome stop taking the product. These uncommon side effects are often temporary. Stop taking this product immediately if you experience any allergic skin reaction.

Black Cohosh may rarely cause liver problems. If you notice symptoms such as yellowing skin/eyes, nausea, vomiting, dark urine, abdominal pain, unusual tiredness, stop taking the product immediately and seek medical advice. Tell your doctor or pharmacist if you notice any other side effects.

STORING THIS PRODUCT

Do not use after the expiry date shown on the bottle. Return any out of date medicine to your pharmacist who will dispose of it for you. This product does not require any special storage conditions. Keep the bottle tightly closed.

FURTHER INFORMATION

If you take too much of this product (overdose): If you take more than the recommended dose, speak to a doctor, pharmacist or qualified 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 would like further information about this product, contact:

English Herbal Medicines Ltd, Town Park Farm, Brooke, Rutland LE15 8DG.

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



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