EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Cimicifuga racemosa* (L.) Nutt., rhizoma

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BG (bălgarski): Цимицифуга, коренище	LT (lietuvių kalba):
CS (čeština): ploštičníkový kořen	LV (latviešu valoda): Sudrabsveces saknenis
DA (dansk): Sølvlysrhizom	MT (malti): Riżoma tal-Koħox
DE (Deutsch): Cimicifugawurzelstock	NL (nederlands): Zilverkaars
EL (elliniká):	PL (polski): Kłącze pluskwicy groniastej
EN (English): black cohosh	PT (português): Cimicifuga, rizoma
ES (espanol): Cimicifuga, rizoma de	RO (română): rizom de cimicifuga
ET (eesti keel): lursslillejuurikas	SK (slovenčina): Podzemok ploštičníka
FI (suomi):	SL (slovenščina):
FR (français):	SV (svenska): Läkesilverax, jordstam
HU (magyar): Fürtös poloskavész gyökértörzs	*IS (íslenska)*:
IT (italiano): Cimicifuga rizoma	*NO (norsk)*: Klaseormedruerot

[1] Changes introduced in substance names in EU languages and sections 4.8 and 5.1

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7051
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

Community herbal monograph on *Cimicifuga racemosa* (L.) Nutt., rhizoma

1. Name of the medicinal product

To be specified for the individual finished product.

2. Qualitative and quantitative composition[2]

Well-established use	Traditional use
With regard to the marketing authorisation application of Article 10(a) of Directive 2001/83/EC as amended *Cimicifuga racemosa* (L.) Nutt., rhizoma (black cohosh) i) Herbal substance Not applicable. ii) Herbal preparations a) Dry extract (DER 5-10:1), extraction solvent ethanol 58% (V/V) b) Dry extract (DER 4.5-8.5:1), extraction solvent ethanol 60% (V/V) c) Dry extract (DER 6-11:1), extraction solvent propan-2-ol 40% (V/V)	

3. Pharmaceutical form

Well-established use	Traditional use
Herbal preparation in solid dosage forms for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.	

2 The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
Herbal medicinal product for the relief of menopausal complaints such as hot flushes and profuse sweating.	

4.2. Posology and method of administration

Well-established use	Traditional use
Posology *Female adults in the menopause* Daily dose (divided into 1 or 2 single doses): Dry extracts corresponding to 40 mg of the herbal substance. **Duration of use** If the symptoms persist during the use of the medicinal product, a doctor or a pharmacist should be consulted. Cimicifuga should not be taken for more than 6 months without medical advice. **Method of administration** Oral use.	

4.3. Contraindications

Well-established use	Traditional use
Hypersensitivity to the active substance.	

4.4. Special warnings and precautions for use

Well-established use	Traditional use
Patients with a history of liver disorder should take Cimicifuga preparations with caution (see section 4.8 'Undesirable effects'). Patients should stop taking Cimicifuga preparations and consult their doctor immediately if they develop signs and symptoms suggestive of liver injury (tiredness, loss of appetite, yellowing of skin and eyes or severe upper stomach pain	

Well-established use	Traditional use
with nausea and vomiting or dark urine). If vaginal bleeding occurs or other symptoms occur, a doctor should be consulted. Cimicifuga preparations should not be used together with oestrogens unless advised by a doctor. Patients who have been treated or who are undergoing treatment for breast cancer or other hormone-dependent tumours should not use Cimicifuga preparations without medical advice. Please see section 5.3. 'Preclinical safety data'. If the symptoms worsen during the use of the medicinal product, a doctor or a pharmacist should be consulted.	

4.5. Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
None reported.	

4.6. Pregnancy and lactation

Well-established use	Traditional use
Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended. Women of childbearing potential should consider using effective contraception during treatment.	

4.7. Effects on ability to drive and use machines

Well-established use	Traditional use
No studies on the effect on the ability to drive and use machines have been performed.	

4.8. Undesirable effects

Well-established use	Traditional use
Liver toxicity (including hepatitis, jaundice, disturbances in the liver function tests) is	

Well-established use	Traditional use
associated with the use of Cimicifuga containing products. The frequency is not known. Skin reactions (urticaria, itching, exanthema), facial oedema, peripheral oedema and gastrointestinal symptoms (i.e. dyspeptic disorders, diarrhoea) have been reported. The frequency is not known. If other adverse reactions not mentioned above occur, a doctor or a pharmacist should be consulted.	

4.9. Overdose

Well-established use	Traditional use
No case of overdose has been reported.	

5. Pharmacological properties

5.1. Pharmacodynamic properties

Well-established use	Traditional use
Pharmacotherapeutic group: other gynaecologicals ATC code: G02C Neither the mode of action nor the constituents relevant for the improvement of menopausal complaints are known. Clinical pharmacological studies indicate that menopausal complaints (such as hot flushes and profuse sweating) can improve under treatment with medicinal products from *Cimicifuga racemosa* root.	

5.2. Pharmacokinetic properties

Well-established use	Traditional use
No data available.	

5.3. Preclinical safety data

Well-established use	Traditional use
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

Well-established use	Traditional use
Not applicable.	

7. Date of compilation/last revision

25 November 2010