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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

DRAFT

COMMUNITY HERBAL MONOGRAPH ON *CIMICIFUGA RACEMOSA* (L.) NUTT., RHIZOMA

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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 [1]

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

[1] The declaration of the active substance 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 minor neurovegetative menopausal complaints (such as hot flushes and sweating).	

4.2. Posology and method of administration

Well-established use	Traditional use
Posology *Female adults in the menopause* Daily dose: Extracts equivalent 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 3 months without medical advice. **Method of administration** Daily dosage divided into 1 or 2 single doses; tablets must not be sucked.	

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 with nausea and vomiting, or dark urine). If vaginal bleeding occurs, or if unclear or new 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 any other tumour disease should not use Cimicifuga preparations.	

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
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 effects 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 associated with the use of Cimicifuga containing products. Skin reactions (urticaria, itching, exanthema), facial oedema, peripheral oedema and gastrointestinal symptoms (i. e. dyspeptic disorders, diarrhoea) have been reported. The frequency of undesirable effects 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 minor symptoms of menopausal complaints are known. Clinical pharmacological studies indicate that especially the vasomotor symptoms of menopausal complaints such as hot flushes and 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 was defined with 21.06 mg native extract/kg bodyweight. In Cimicifuga-treated, tumour-bearing, female transgenic mice, the percentage of mice with detectable 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. In an *in vivo* study in rats microvesicular steatosis was	

found in animals treated with > 0.5 mg ethanolic extract/kg bodyweight. There are no conclusive studies on genotoxicity, carcinogenicity and reproductive toxicity.	

6. PHARMACEUTICAL PARTICULARS

Well-established use	Traditional use
Not applicable.	

7. DATE OF COMPILATION/LAST REVISION

17 September 2009