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**COMMITTEE ON HERBAL MEDICINAL PRODUCTS
(HMPC)**

DRAFT

COMMUNITY HERBAL MONOGRAPH ON *HAMAMELIS VIRGINIANA* L., FOLIUM

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	May 2008 July 2008 September 2008
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REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	
ADOPTION BY HMPC	

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KEYWORDS

Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Hamamelis virginiana* L.; Hamamelidis folium; hamamelis leaf

COMMUNITY HERBAL MONOGRAPH ON *HAMAMELIS VIRGINIANA L., FOLIUM*

1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION^{1,2}

<u>Well-established use</u>	<u>Traditional use</u>
<p>With regard to the marketing authorisation application of Article 10(a) of Directive 2001/83/EC as amended</p>	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended</p> <p><i>Hamamelis virginiana L., folium</i> (hamamelis leaf) dried or fresh leaf</p> <p>i) Herbal substance Not applicable</p> <p>ii) Herbal preparations</p> <ul style="list-style-type: none"> - Dried comminuted herbal substance for herbal tea Tincture prepared from fresh leaves³ (1:10), extraction solvent ethanol 45% - Liquid extract prepared from fresh leaves³ (1:1) extraction solvent ethanol 45% V/V - Liquid extract from dried leaves (1:1) extraction solvent ethanol 30% m/m - Liquid extract from dried leaves (1:2) extraction solvent ethanol 60% V/V

3. PHARMACEUTICAL FORM

<u>Well-established use</u>	<u>Traditional use</u>
	<p>Comminuted herbal substance as herbal tea for oromucosal or cutaneous use. Herbal preparations in semisolid or liquid dosage forms for cutaneous or oromucosal use. Herbal preparations in solid dosage forms for rectal use.</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

¹ The dried material complies with the Ph. Eur. monograph (ref. 04/2008:0909)

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

³ The fresh material complies with Ph. Eur. after dried

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

<u>Well-established use</u>	<u>Traditional use</u> a) Traditional herbal medicinal product for relief of minor skin inflammation and dryness of the skin. b) Traditional herbal medicinal product for the temporary relief of the symptoms associated with hemorrhoids, such as itching, burning sensation or pain. c) Traditional herbal medicinal product used as gargle for relief of minor inflammatory conditions of the oral mucosa. The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.
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4.2. Posology and method of administration

<u>Well-established use</u>	<u>Traditional use</u> Posology <i>Adults, elderly, adolescents and children from 6 to 12 years</i> Indication a) <u>For cutaneous use:</u> Tincture or liquid extracts (1:1) in a strength corresponding to 5-10% in semisolid and liquid preparations, several times daily. Liquid extract (1:2) extraction solvent ethanol 60% V/V in a strength corresponding to 20% as a semi-solid preparation The use in children under 6 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). <i>Adults and elderly</i> Indication b) <u>For cutaneous use:</u> Tincture or liquid extracts in a strength corresponding to 5-10% in semisolid and liquid preparations, several times daily. Liquid extract (1:2) extraction solvent ethanol 60% V/V in a strength corresponding to 20% as a semi-solid preparation, several times daily.
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	<p>Comminuted herbal substance as decoction: 5-10 g/250 ml, up to 3 times a day as impregnated dressing.</p> <p><u>For rectal use:</u> Suppository containing 400 mg of liquid extract DER (1:2), 2-3 times a day.</p> <p>The use is not recommended in children and adolescents under 18 years of age (see section 4.4 'Special warnings and precautions for use').</p> <p><i>Adults and elderly</i></p> <p>Indication c) <u>For oromucosal use:</u> Tincture (1:10) in 45% ethanol (diluted (1:3) with water): 2-4 ml, three times daily as gargle</p> <p>Comminuted herbal substance to be used as a herbal tea, for gargle: 2-3 g up to 3 times a day.</p> <p>Duration of use</p> <p>Indications a) and c) The average duration of use is 1 week.</p> <p>Indication b) The recommended duration of use is 4 days.</p> <p>If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Method of administration</p> <p>For rectal administration, and cutaneous or oromucosal application.</p>
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4.3. Contraindications

<u>Well-established use</u>	<u>Traditional use</u> Hypersensitivity to the herbal substance.
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4.4. Special warnings and precautions for use

<u>Well-established use</u>	<u>Traditional use</u>
	<p>Due to the lack of adequate data the cutaneous application is not recommended for children under 6 years of age.</p> <p>The rectal use of hamamelis preparations is not recommended in children and adolescents under 18 years of age due to the lack of adequate data.</p> <p>If symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p>

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

<u>Well-established use</u>	<u>Traditional use</u>
	None reported.

4.6. Pregnancy and lactation

<u>Well-established use</u>	<u>Traditional use</u>
	<p>Safety during pregnancy and lactation has not been established.</p> <p>In the absence of sufficient data, the oral use during pregnancy and lactation is not recommended.</p>

4.7. Effects on ability to drive and use machines

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

4.8. Undesirable effects

<u>Well-established use</u>	<u>Traditional use</u>
	<p>Allergic contact dermatitis has been reported, the frequency is not known.</p> <p>If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.</p>

4.9. Overdose

<u>Well-established use</u>	<u>Traditional use</u>
	No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

<u>Well-established use</u>	<u>Traditional use</u>
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.2. Pharmacokinetic properties

<u>Well-established use</u>	<u>Traditional use</u>
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.3. Preclinical safety data

<u>Well-established use</u>	<u>Traditional use</u>
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended, unless required for the safe use of the product. Available tests on carcinogenicity and genotoxicity did not give any reason for concern. Tests on reproductive toxicity have not been performed.

6. PHARMACEUTICAL PARTICULARS

<u>Well-established use</u>	<u>Traditional use</u>
	Not applicable.

7. DATE OF COMPILATION/LAST REVISION

4 September 2008