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Evaluation of Medicines for Human Use

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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

DRAFT

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

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

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KEYWORDS	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Hamamelis virginiana* L.; Hamamelidis cortex; hamamelis bark

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

1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION[1, 2]

Well-established use	Traditional use
With regard to the marketing authorisation application of Article 10(a) of Directive 2001/83/EC as amended	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *Hamamelis virginiana* L., cortex (hamamelis bark) i) Herbal substance Not applicable ii) Herbal preparations - Dried comminuted herbal substance - Tincture (1:10; extraction solvent ethanol 45% v/v) - Dry extract (5-7.7:1; extraction solvent ethanol 30% m/m)

3. PHARMACEUTICAL FORM

Well-established use	Traditional use
	Comminuted herbal substance as decoction for anorectal use and as herbal tea for oromucosal use. Herbal preparations in semisolid dosage forms for cutaneous use. Herbal preparations in semisolid or liquid dosage forms for anorectal use. Herbal preparations in solid dosage forms for rectal use.

[1] "Hamamelidis Cortex" consists in the dried bark from the stems, branches and twigs of *Hamamelis virginiana* L. (Fam. Hamamelidaceae), collected in spring. It contains not less than 4.0% of hide powder-precipitable tannins, expressed as pyrogallol and calculated with reference to the dried drug.

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

	Herbal preparations in liquid dosage forms for oromucosal use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Well-established use	Traditional use
	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 a mouthwash for relief of minor inflammatory conditions of the oral mucosa. The product is a traditional herbal medicinal product for use in specified indication exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology *Adolescents, adults and elderly* Indication a) For cutaneous use Tincture in a strength corresponding to 5-10% in semisolid preparations, several times daily. Dry extract in a strength corresponding to 1.3% as an ointment, several times daily. The use in children under 12 years of age is not recommended (see section 4.4 “Special warnings and precautions for use”).

	Adults and elderly Indication b) For anorectal use Tincture in a strength corresponding to 5-10% in semisolid and liquid preparations, several times daily. Comminuted herbal substance as decoction: 5-10g/250 ml, up to 3 times a day as impregnated dressings. For rectal use One suppository containing 66 mg of dry extract (5-7.7:1; ethanol 30% m/m) two or three times a day. *Adults and elderly* Indication c) Tincture (1:10; ethanol 45% (diluted (1:3) with water) 2-4 ml, three times daily for gargles) Comminuted herbal substance to be used as herbal tea, for gargles: 2-3 g up to 3 times a day. Indications b) and c) The use in children and adolescents under 18 years of age is not recommended (see section 4.4 “Special warnings and precautions for use”). **Duration of use** Indications a) and c) The average duration of use is 1 week. Indication b) The recommended duration of use is 4 days. If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. **Method of administration** For cutaneous, oromucosal, rectal and anorectal use.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance(s)

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	If symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. Indication a) Due to the lack of adequate data the use is not recommended in children under 12 years of age. Indications b) and c) Due to the lack of adequate data the use is not recommended in children and adolescents under 18 years of age.

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.

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
	Allergic contact dermatitis has been reported. The frequency is not known. If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner 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
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.2. Pharmacokinetic properties

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

5.3. Preclinical safety data

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended, unless necessary 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

Well-established use	Traditional use Not applicable.

7. DATE OF COMPILATION/LAST REVISION

6 November 2008