European Medicines Agency
Evaluation of Medicines for Human Use

London, 12 November 2009
Doc. Ref.: EMA/HMPC/114586/2008

COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

FINAL

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
ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION	4 September 2008
END OF CONSULTATION (DEADLINE FOR COMMENTS)	15 January 2009
REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	May 2009 July 2009 September 2009 November 2009
ADOPTION BY HMPC	12 November 2009

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

BG (bălgarski):	LT (lietuvių kalba):
CS (čeština):	LV (latviešu valoda):
DA (dansk):	MT (malti):
DE (Deutsch):	NL (nederlands):
EL (elliniká):	PL (polski):
EN (English): Hamamelis leaf	PT (português):
ES (espanol): Hamamelis, hoja de	RO (română):
ET (eesti keel):	SK (slovenčina):
FI (suomi):	SL (slovenščina):
FR (français):	SV (svenska):
HU (magyar):	*IS (íslenska)*:
IT (italiano):	*NO (norsk):*

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 70 51
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

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]

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., folium;Hamamelidis folium (hamamelis leaf), dried or fresh leaf. i) Herbal substance Not applicable ii) Herbal preparations - Dried comminuted herbal substance - Tincture (fresh leaves) (Ratio of herbal substance to extraction solvent 1:10, extraction solvent ethanol 45% v/v) - Liquid extract (fresh leaves) (DER 1:1), extraction solvent ethanol 45% v/v - Liquid extract (DER 1:1), extraction solvent ethanol 30% m/m - Liquid extract (DER 1:2), extraction solvent ethanol 60% v/v

3. PHARMACEUTICAL FORM

Well-established use	Traditional use
	Comminuted herbal substance for decoction for oromucosal or cutaneous use. Herbal preparations in semisolid or liquid dosage forms for cutaneous, anorectal or oromucosal use. Herbal preparations in solid dosage forms for rectal use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

[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.

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 symptomatic relief of itching and burning associated with haemorrhoids. c) Traditional herbal medicinal product used as a mouthwash and gargles for relief of minor inflammation of mucous membranes of the oral cavity. 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 Indication a) *Children over 6 years of age, adolescents, adults and elderly* Tincture or liquid extracts (1:1, ethanol 45% v/v or ethanol 30% m/m) in a strength corresponding to 5-10% in semisolid and liquid preparations, several times daily. Liquid extract (1:2, 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'). Indication b) *Adults and elderly* Tincture or liquid extracts (1:1, ethanol 45% v/v or ethanol 30% m/m) in a strength corresponding to 5-10% in semisolid and liquid preparations, several times daily. Liquid extract (1:2, ethanol 60% v/v) in a strength corresponding to 20% as a semi-solid preparation, several times daily.

	Comminuted herbal substance as a decoction: 5-10 g/250 ml, up to 3 times a day as impregnated dressing. Rectal use Suppositories containing 400 mg of liquid extract (1:2, ethanol 60% v/v), one suppository 2-3 times a day. The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). Indication c) *Adolescents, adults and elderly* Tincture (diluted 1:3 with water) 2-4 ml, three times daily for gargles. Comminuted herbal substance to be used as a decoction, for gargles: 2-3 g up to 3 times a day. The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **Duration of use** Indication a) and c) If the symptoms persist for more than 1 week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. Indication b) If the symptoms persist for more than 2 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. **Method of administration** Cutaneous use. Rectal use. Anorectal use. Oromucosal use.

4.3. Contraindications

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

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	Indication a) The use in children under 6 years of age has not been established due to lack of adequate data. Indication b) The use in children and adolescents under 18 years of age has not been established due to lack of adequate data. If rectal bleeding occurs a doctor should be consulted. Indication c) The use in children under 12 years of age has not been established due to lack of adequate data. If symptoms persist or worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. For extracts and tinctures containing ethanol, the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use' must be included.

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.

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 required for the safe use of the product. The external application of preparations of *Hamamelis virginiana* L. can be regarded as safe. One test on carcinogenicity has been performed with an aqueous extract. No carcinogenetic effect has been identified. Tests on genotoxicity and reproductive toxicity have not been performed.

6. PHARMACEUTICAL PARTICULARS

Well-established use	Traditional use Not applicable.

7. DATE OF COMPILATION/LAST REVISION

12 November 2009