EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 September 2019
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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Hamamelis virginiana* L., cortex

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	May 2008 July 2008 September 2008 November 2008
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	6 November 2008
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Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Hamamelis virginiana* L.; Hamamelidis cortex; hamamelis bark

1 Changes introduced in June 2011 in substance names in EU languages and section 4.2. A footnote introduced in September 2019 (section 2 for reference to new Ph. Eur. monograph)

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BG (bălgarski): Хамамелис, кора	LT (lietuvių kalba):
CS (čeština): Vilínová kůra	LV (latviešu valoda): Burvjlazdas miza
DA (dansk): Hamamelisbark	MT (malti): Qoxra tal-Ħamamelis
DE (Deutsch): Hamamelisrinde	NL (nederlands): Toverhazelaar
EL (elliniká): Φλοιός Αμαμελίδος	PL (polski): Kora oczaru
EN (English): Hamamelis Bark	PT (português): Hamamélia, casca
ES (espanol): Hamamelis, corteza de	RO (română): Scoarţă de hamamelis
ET (eesti keel): Nõiapuukoor	SK (slovenčina): Hamamelová kôra
FI (suomi):	SL (slovenščina): Skorja virginskega nepozebnika
FR (français): Hamamélis de Virginie (écorce d')	SV (svenska): Hamamelisbark
HU (magyar): Nagylevelű csodamogyoró kéreg	*IS (íslenska)*:
IT (italiano): Amamelide corteccia	*NO (norsk):* Hamamelisbark

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[2,3]

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

3. Pharmaceutical form

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

2 The material complies with the Ph. Eur. monograph (2532).
3 The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

Well-established use	Traditional use
	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 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 the specified indications exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	**Traditional use**
	Posology Indication a) *Adolescents, adults and elderly* <u>Cutaneous use</u> Tincture in a strength corresponding to 5-10% in semi-solid preparations, several times daily. Dry extract (5-7.7:1; ethanol 30% m/m) 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'). Indication b)

Well-established use	**Traditional use**
	Adults and elderly Anorectal use Tincture in a strength corresponding to 5-10% in semisolid and liquid preparations, several times daily. Comminuted herbal substance as a decoction: 5-10 g/250 ml, up to 3 times a day as impregnated dressings. Dry extract (5-7.7:1; ethanol 30% m/m) in a strength corresponding to 1.3% as an ointment, several times daily. Rectal use Suppositories containing 66 mg of dry extract (5-7.7:1; ethanol 30% m/m), one suppository two or three times daily. 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 (1:10), ethanol 45% v/v (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 daily. 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** Indications 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

Well-established use	**Traditional use**
	during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. **Method of administration** Cutaneous use. Oromucosal use. Rectal use. 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**
	Indication a) The cutaneous use in children under 12 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 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 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 tinctures 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. Fertility, 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. Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6. Pharmaceutical particulars

Well-established use	**Traditional use**
	Not applicable.

7. Date of compilation / last revision

6 June 2011