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Evaluation of Medicines for Human Use

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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

FINAL

COMMUNITY HERBAL MONOGRAPH ON *HAMAMELIS VIRGINIANA* L., FOLIUM ET CORTEX AUT RAMUNCULUS DESTILLATUM

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	May 2008 July 2008 September 2008 November 2008
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KEYWORDS	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Hamamelis virginiana* L.; Hamamelidis folium et cortex out ramunculus destillatum; hamamelis leaf and bark or twigs distillate

BG (bălgarski):
CS (čeština):
DA (dansk):
DE (Deutsch):
EL (elliniká):
EN (English): Hamamelis leaf and bark or twigs
ES (espanol): Hamamelis, hoja y corteza de
ET (eesti keel):
FI (suomi):
FR (français):
HU (magyar):
IT (italiano):
LT (lietuvių kalba):
LV (latviešu valoda):
MT (malti):
NL (nederlands):
PL (polski):
PT (português):
RO (română):
SK (slovenčina):
SL (slovenščina):
SV (svenska):
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COMMUNITY HERBAL MONOGRAPH ON
***HAMAMELIS VIRGINIANA* L.,**
FOLIUM ET CORTEX AUT RAMUNCULUS DESTILLATUM

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 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.; Hamamelidis folium et cortex aut ramunculus (hamamelis leaf and bark or twigs) i) Herbal substance Not applicable ii) Herbal preparations 1. Distillate prepared from fresh leaves and bark (1:1.12-2.08; ethanol 6% m/m) 2. Distillate prepared from dried twigs (1:2; ethanol 14-15%)[2]

3. PHARMACEUTICAL FORM

Well-established use	Traditional use
	Herbal preparations in semisolid dosage forms for cutaneous use and liquid dosage forms for ocular use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

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

[2] According to USP (USP-31- NF 26, 2008 Vol 3:3526) Distillate prepared from dried twigs (1:2; ethanol 14-15%).

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 to be used for the temporary relief of eye discomfort due to dryness of the eye or to exposure to wind or sun. 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) *Children over 6 years of age, adolescents, adults and elderly* Distillate in a strength corresponding to 5-30% in semi-solid preparations, several times a day. The use is not recommended in children under 6 years of age (see section 4.4 'Special warnings and precautions for use'). Indication b) *Adolescents, adults and elderly* Eye drops[3]: Distillate (2) diluted (1:10), 2 drops/each eye, 3-6 times daily. The use is not recommended in children under 12 years of age (see section 4.4 'Special warnings and precautions for use').

[3] The medicinal product complies with the Ph. Eur. monograph on eye preparations (01/2008:1163)

	Duration of use Indication a) 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. Indication b) The recommended duration of use is 4 days. If the symptoms persist for more than 2 days during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. **Method of administration** Cutaneous use. Ocular use.

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
	Indication a) The use in children under 6 years of age has not been established due to lack of adequate data. Indication b) Stop use and ask a doctor if you experience eye pain, changes in vision, continued redness, or irritation of the eye, or if the condition worsens or persists for more than 48 hours. The use in children under 12 years of age has not been established due to lack of adequate data. For extracts 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
	Indication a) Allergic contact dermatitis may occur in sensitive patients. The frequency is not known. Indication b) Conjunctivitis cases have 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. Adequate tests on genotoxicity are available for hamamelis distillate preparations. The external (cutaneous and ocular use) application of distillate preparations of *Hamamelis virginiana* can be regarded as safe.

6. PHARMACEUTICAL PARTICULARS

Well-established use	Traditional use
	Not applicable.

7. DATE OF COMPILATION/LAST REVISION

12 November 2009