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

DRAFT

**COMMUNITY LIST ENTRY ON
HAMAMELIS VIRGINIANA L., FOLIUM ET CORTEX AUT RAMUNCULUS
DESTILLATUM**

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	November 2009
ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION	12 November 2009
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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 list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products; traditional use; <i>Hamamelis virginiana</i> L.; Hamamelidis folium et cortex aut ramunculus destillatum; hamamelis leaf and bark or twigs distillate
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**ENTRY TO LIST OF HERBAL SUBSTANCES, PREPARATIONS AND
COMBINATIONS THEREOF FOR USE IN
TRADITIONAL HERBAL MEDICINAL PRODUCTS**

**ENTRY TO LIST OF HERBAL SUBSTANCES, PREPARATIONS AND
COMBINATIONS THEREOF FOR USE IN
TRADITIONAL HERBAL MEDICINAL PRODUCTS:**

**HAMAMELIS VIRGINIANA L., FOLIUM ET CORTEX AUT RAMUNCULUS
DESTILLATUM**

Scientific name of the plant	
<i>Hamamelis virginiana</i> L.	
Botanical family	
Hamamelidaceae	
Herbal substance	
Hamamelis leaf and bark or twigs	
Common name in all EU official languages of herbal substance	
BG (bългарski):	IT (italiano):
CS (čeština):	LT (lietuvių kalba):
DA (dansk):	LV (latviešu valoda):
DE (Deutsch):	MT (malti):
ET (eesti keel):	NL (nederlands):
EL (elliniká):	PL (polski):
EN (English): Hamamelis leaf and bark or twigs	PT (português):
ES (español):	RO (română):
FI (suomi):	SK (slovenčina):
FR (français):	SL (slovenščina):
HU (magyar):	SV (svenska):
	<i>IS (íslenska):</i>
	<i>NO (norsk):</i>
Herbal preparation(s)	
Distillate prepared from fresh leaves and bark (1:1.12 – 2.08; ethanol 6% m/m) Distillate prepared from dried twigs (1:2; ethanol 14-15%) ¹	
European Pharmacopoeia monograph reference	
N/A	

¹ According to USP (USP-31- NF 26, 2008 Vol 3:3526)

Indication(s)
<p>a) Traditional herbal medicinal product for relief of minor skin inflammation and dryness of the skin.</p> <p>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.</p> <p>The product is a traditional herbal medicinal product for use in the specified indications exclusively based upon long-standing use.</p>
Type of tradition
European.
Specified strength
Not applicable
Specified posology
<p>Indication a)</p> <p><i>Children over 6 years of age, adolescents, adults and elderly</i> Hamamelis water 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’).</p> <p>Indication b)</p> <p><i>Adolescents, adults and elderly</i> Eye drops²: Hamamelis distillate (2) diluted (1:10), 2 drops/each eye, 3-6 times a day The use is not recommended in children under 12 years of age (see below Special warnings and precautions for use).</p>
Route of administration
Cutaneous or ocular use.
Duration of use or any restrictions on the duration of use
<p>Indication a)</p> <p>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.</p> <p>Indication b)</p> <p>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.</p>

² The medicinal product complies with the Ph. Eur. monograph on eye preparations (01/2008:1163)

Any other information necessary for the safe use

Contra-indications

Hypersensitivity to the active substance.

Special warnings and precautions for 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.

Interactions with other medicinal products and other forms of interaction

None reported.

Pregnancy and lactation

Safety during pregnancy and lactation has not been established.

In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed.

Undesirable effects

Indication a)

Allergic contact dermatitis may occur in sensitive patients. The frequency is not known.

Indication b)

A conjunctivitis case has been reported. The frequency is not known.

Overdose

No case of overdose has been reported.

Pharmaceutical particulars [If necessary]

Not applicable.

Pharmacological effects or efficacy plausible on the basis of long-standing use and experience [If necessary for the safe use of the product]

Not applicable.

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