



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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
End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	15 March 2009
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Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Hamamelis virginiana</i> L.; Hamamelidis cortex; hamamelis bark
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BG (bългарски): Хамамелис, кора CS (čeština): Vilínová kůra DA (dansk): Hamamelisbark DE (Deutsch): Hamamelisrinde EL (elliniká): Φλοιός Αμμελίδος EN (English): Hamamelis Bark ES (español): Hamamelis, corteza de ET (eesti keel): Nõiapuukoor FI (suomi): FR (français): Hamamélis de Virginie (écorce d') HU (magyar): Nagylevelű csodamogyoró kéreg IT (italiano): Amamelide corteccia	LT (lietuvių kalba): LV (latviešu valoda): Burvjlazdas miza MT (malti): Qoxra tal-Hamamelis NL (nederlands): Toverhazelaar PL (polski): Kora oczaru PT (português): Hamamélia, casca RO (română): Scoarță de hamamelis SK (slovenčina): Hamamelová kôra SL (slovenščina): Skorja virginskega nepozebnika SV (svenska): Hamamelisbark IS (islenska): NO (norsk): Hamamelisbark
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¹ Changes introduced in June 2011 in substance names in EU languages and section 4.2.

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 75237150
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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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^{2,3}

Well-established use	Traditional use
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended</p> <p><i>Hamamelis virginiana</i> L., cortex; Hamamelidis cortex (hamamelis bark)</p> <p>i) Herbal substance</p> <p>Not applicable</p> <p>ii) Herbal preparations</p> <ul style="list-style-type: none">- 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
	<p>Comminuted herbal substance for decoction for oromucosal and anorectal use.</p> <p>Herbal preparations in semi-solid dosage forms for cutaneous use.</p> <p>Herbal preparations in semi-solid or liquid dosage forms for anorectal use.</p> <p>Herbal preparations in solid dosage forms for rectal use.</p>

² "Hamamelidis cortex" consists of 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.

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

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	<p>a) Traditional herbal medicinal product for relief of minor skin inflammation and dryness of the skin.</p> <p>b) Traditional herbal medicinal product for symptomatic relief of itching and burning associated with haemorrhoids.</p> <p>c) Traditional herbal medicinal product used as a mouthwash and gargles for relief of minor inflammation of mucous membranes of the oral cavity.</p> <p>The product is a traditional herbal medicinal product for use in the specified indications exclusively based upon long-standing use.</p>

4.2. Posology and method of administration

Well-established use	Traditional use
	<p>Posology</p> <p>Indication a)</p> <p><i>Adolescents, adults and elderly</i></p> <p><u>Cutaneous use</u></p> <p>Tincture in a strength corresponding to 5-10% in semi-solid preparations, several times daily.</p> <p>Dry extract (5-7.7:1; ethanol 30% m/m) in a strength corresponding to 1.3% as an ointment, several times daily.</p> <p>The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p>

Well-established use	Traditional use
	<p data-bbox="810 255 967 286">Indication b)</p> <p data-bbox="810 313 1034 344"><i>Adults and elderly</i></p> <p data-bbox="810 371 979 403"><u>Anorectal use</u></p> <p data-bbox="810 430 1410 528">Tincture in a strength corresponding to 5-10% in semisolid and liquid preparations, several times daily.</p> <p data-bbox="810 555 1375 654">Comminuted herbal substance as a decoction: 5-10 g/250 ml, up to 3 times a day as impregnated dressings.</p> <p data-bbox="810 680 1401 779">Dry extract (5-7.7:1; ethanol 30% m/m) in a strength corresponding to 1.3% as an ointment, several times daily.</p> <p data-bbox="810 806 938 837"><u>Rectal use</u></p> <p data-bbox="810 864 1378 963">Suppositories containing 66 mg of dry extract (5-7.7:1; ethanol 30% m/m), one suppository two or three times daily.</p> <p data-bbox="810 990 1417 1088">The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p data-bbox="810 1182 963 1214">Indication c)</p> <p data-bbox="810 1240 1193 1272"><i>Adolescents, adults and elderly</i></p> <p data-bbox="810 1299 1420 1361">Tincture (1:10), ethanol 45% v/v (diluted 1:3, with water): 2-4 ml, three times daily for gargles.</p> <p data-bbox="810 1388 1407 1451">Comminuted herbal substance to be used as a decoction, for gargles: 2-3 g up to 3 times daily.</p> <p data-bbox="810 1478 1410 1576">The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p data-bbox="810 1671 1021 1702">Duration of use</p> <p data-bbox="810 1729 1062 1760">Indications a) and c)</p> <p data-bbox="810 1787 1414 1921">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.</p>

Well-established use	Traditional use
	<p data-bbox="810 259 970 286">Indication b)</p> <p data-bbox="810 318 1414 452">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 data-bbox="810 483 1155 510">Method of administration</p> <p data-bbox="810 542 999 568">Cutaneous use.</p> <p data-bbox="810 600 1015 627">Oromucosal use.</p> <p data-bbox="810 658 948 685">Rectal use.</p> <p data-bbox="810 716 986 743">Anorectal use.</p>

4.3. Contraindications

Well-established use	Traditional use
	<p data-bbox="810 922 1337 949">Hypersensitivity to the active substance(s).</p>

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p data-bbox="810 1140 970 1167">Indication a)</p> <p data-bbox="810 1198 1404 1301">The cutaneous use in children under 12 years of age has not been established due to lack of adequate data.</p> <p data-bbox="810 1332 970 1359">Indication b)</p> <p data-bbox="810 1391 1401 1494">The use in children and adolescents under 18 years of age has not been established due to lack of data.</p> <p data-bbox="810 1525 1340 1583">If rectal bleeding occurs a doctor should be consulted.</p> <p data-bbox="810 1615 970 1641">Indication c)</p> <p data-bbox="810 1673 1423 1731">The use in children under 12 years of age has not been established due to lack of data.</p> <p data-bbox="810 1762 1404 1865">If symptoms persist or worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p data-bbox="810 1897 1430 2022">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.</p>

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