



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Aesculus hippocastanum* L., cortex

Draft

Discussion in Working Party on Community monographs and Community list (MLWP)	May 2011 July 2011
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Rediscussion in Working Party on Community monographs and Community list (MLWP)	
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BG (bългарски): Див кестен, кора CS (čeština): kůra kaštanu koňského DA (dansk): Hestekastanjebark DE (Deutsch): Rosskastanienrinde EL (elliniká): Φλοιός ιπποκαστανέας EN (English): Horse chestnut bark ES (español): Castaño de Indias, corteza de ET (eesti keel): hobukastanikoor FI (suomi): FR (français): Marronnier d'Inde (écorce de) HU (magyar): IT (italiano): Ippocastano corteccia	LT (lietuvių kalba): LV (latviešu valoda): Zirgkastaņa miza MT (malti): NL (nederlands): Paardenkastanje PL (polski): Kora kasztanowca PT (português): Castanheiro-da-índia, casca RO (română): scoarță de castan SK (slovenčina): List pagaštanu SL (slovenščina): skorja navadnega divjega kostanja SV (svenska): Hästkastanj, bark <i>IS (islenska):</i> <i>NO (norsk):</i> Hestekastanjebark
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Community herbal monograph on *Aesculus hippocastanum* L., cortex

1. Name of the medicinal product

To be specified for the individual finished product.

2. Qualitative and quantitative composition¹

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>Aesculus hippocastanum</i> L., cortex (horse chestnut bark)</p> <p>i) Herbal substance</p> <p>Not applicable.</p> <p>ii) Herbal preparations</p> <p>Powdered herbal substance</p>

3. Pharmaceutical form

Well-established use	Traditional use
	<p>Herbal preparations in solid dosage forms for oral 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>Indication 1)</p> <p>Traditional herbal medicinal product for relief of symptoms of discomfort and heaviness of legs</p>

¹ 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>related to minor venous circulatory disturbances.</p> <p>Indication 2)</p> <p>Traditional herbal medicinal product for symptomatic relief of itching and burning associated with haemorrhoids, after serious conditions have been excluded by a medical doctor.</p> <p>The product is a traditional herbal medicinal product for use in 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><i>Adults and elderly</i></p> <p>Single dose: 275 mg, 3 to 6 times daily.</p> <p>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>Duration of use</p> <p>If the symptoms persist longer than 2 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Method of administration</p> <p>Oral use.</p>

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
	The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.

Well-established use	Traditional use
	<p data-bbox="810 255 970 286">Indication 1)</p> <p data-bbox="810 315 1433 488">If there is inflammation of the skin, thrombophlebitis, varicosis or subcutaneous induration, ulcers, sudden swelling of one or both legs, cardiac or renal insufficiency, a doctor should be consulted.</p> <p data-bbox="810 517 970 548">Indication 2)</p> <p data-bbox="810 577 1353 638">If rectal bleeding occurs, a doctor should be consulted.</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
	<p data-bbox="810 1079 1390 1220">Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</p> <p data-bbox="810 1249 1129 1279">No fertility data available.</p>

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
	<p data-bbox="810 1718 970 1747">None known.</p> <p data-bbox="810 1776 1417 1836">If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.</p>

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

13 September 2011