



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 May 2012
EMA/HMPC/354156/2011
Committee on Herbal Medicinal Products (HMPC)

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

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	May 2011 July 2011
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	September 2011
End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	15 February 2012
Rediscussion in Working Party on Community monographs and Community list (MLWP)	March 2012
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Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Aesculus hippocastanum</i> L., cortex; Hippocastani cortex; horse chestnut bark
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BG (bългарски): Див кестен, кора CS (čeština): kůra kaštanu koňského DA (dansk): Hestekastanjabark 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): hevostkastanja, kuori FR (français): Marronnier d'Inde (écorce de) HU (magyar): Vadgesztenyekéreg 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 IS (islenska): NO (norsk): Hestekastanjabark
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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>Indication 1)</p> <p>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>Indication 2)</p> <p>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>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>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>None known.</p> <p>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

22 May 2012