EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 January 2023
EMA/HMPC/596130/2022
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Aesculus hippocastanum* L., cortex

Draft – Revision 1

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	May 2011 July 2011
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	01 September 2011
End of consultation (deadline for comments).	15 February 2012
Re-discussion in MLWP	March 2012
Adoption by HMPC Monograph (EMA/HMPC/354156/2011) Assessment Report (EMA/HMPC/354157/2011) List of references (EMA/HMPC/354158/2011) Overview of Comments (EMA/HMPC/198422/2012) HMPC Opinion (EMA/HMPC/332116/2012)	22 May 2012
First revision	
Discussion in HMPC	July 2022 September 2022 November 2022 January 2023
Adoption by HMPC for release for consultation	25 January 2023

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Aesculus hippocastanum* L., cortex; Hippocastani cortex; Horse-chestnut bark

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BG (bălgarski): Див кестен, кора CS (čeština): kůra kaštanu koňského DA (dansk): Hestekastanjebark DE (Deutsch): Rosskastanienrinde EL (elliniká): φλοιός ιπποκαστανέας EN (English): Horse-chestnut bark ES (espanol): Castaño de indias, corteza de ET (eesti keel): hobukastanikoor FI (suomi): hevoskastanja, kuori FR (français): marronnier d'Inde (écorce de) HR (hrvatski): kora divljeg kestena HU (magyar): vadgesztenyekéreg IT (italiano): Ippocastano corteccia	LT (lietuvių kalba): Kaštonų žievė LV (latviešu valoda): Zirgkastaņa miza MT (malti): qoxra tas-siġra tal-qastan NL (nederlands): Paardenkastanje PL (polski): Kora kasztanowca PT (português): castanheiro-da-índia, casca RO (română): scoarţă de castan SK (slovenčina): kôra pagaštanu SL (slovenščina): skorja navadnega divjega kostanja SV (svenska): hästkastanj, bark *IS (íslenska)*: *NO (norsk):* Hestekastanjebark

European Union 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 composition[1]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *Aesculus hippocastanum* L., cortex (horse-chestnut bark) i) Herbal substance Not applicable. ii) Herbal preparations Powdered herbal substance Dry extract (DER 7.0-8.5:1), extraction solvent water

3. Pharmaceutical form

Well-established use	Traditional use
	Herbal preparations in solid dosage forms for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Indication 1) Traditional herbal medicinal product for relief of symptoms of discomfort and heaviness of legs

[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
	related to minor venous circulatory disturbances. Indication 2) Traditional herbal medicinal product for symptomatic relief of itching and burning associated with haemorrhoids, after serious conditions have been excluded by a medical doctor. The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology Indication 1) and 2) *Adults and elderly* Powdered herbal substance Single dose: 550 mg, 2 to 3 times daily. Daily dose: 1100 mg to 1650 mg Dry extract Single dose: 200 mg, 2 times daily Daily dose: 400 mg The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **Duration of use** 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. **Method of administration** Oral 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
	The use in children and adolescents under 18 years of age has not been established due to lack of adequate data. Indication 1) 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. Indication 2) If rectal bleeding occurs, a doctor should be consulted.

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. No fertility data available.

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
	None known. If adverse reactions 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

25 January 2023