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Evaluation of Medicines for Human Use

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COMMITTEE ON HERBAL MEDICINAL PRODUCTS

COMMUNITY HERBAL MONOGRAPH ON *AESCULUS HIPPOCASTANUM* L., SEMEN

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COMMUNITY HERBAL MONOGRAPH ON *AESCULUS HIPPOCASTANUM* L., SEMEN

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 marketing authorisation application of Article 10(a) of Directive 2001/83/EC as amended	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended
Aesculus hippocastanum L., semen (horse chestnut seed)	*Aesculus hippocastanum* L., semen (horse chestnut seed)
1) Herbal substance Not applicable	1) Herbal substance Not applicable
2) Herbal preparations	2) Herbal preparations
Dry extracts[2] (40-80% (v/v) ethanol) standardised to contain 16-28% triterpene glycosides, calculated as aescin (photometric method).	• Dry extract (ethanol 25-50% v/v) in a strength corresponding to ca 1% aescin in an ointment/gel base • Tincture (1:5; extraction solvent: 50% ethanol (v/v)), 20% in an ointment/gel base

3. PHARMACEUTICAL FORM

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

[1] The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.
[2] The composition of the extraction solvent and the content of aescin must be specified in the individual extract.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Well-established use	Traditional use
Herbal medicinal product for treatment of chronic venous insufficiency, which is characterised by swollen legs, varicose veins, a feeling of heaviness, pain, tiredness, itching, tension and cramps in the calves.	A) Traditional herbal medicinal product to relieve symptoms of discomfort and heaviness of legs related to minor venous circulatory disturbances. B) Traditional herbal medicinal product for relief of signs of bruises, such as local oedema and haematoma. The product is a traditional herbal medicinal product for use in the specified indications exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
Posology *Adults and elderly* Extract (standardised to a content of 50 mg triterpene glycosides calculated as aescin) 2 times daily. The product is not intended for children and adolescents under 18 years of age. **Duration of use** At least 4 weeks of treatment may be required before any beneficial effect is observed. Long-term use is possible in consultation with a doctor. **Method of administration** Oral use.	**Posology** Indication A) *Adults and elderly* Apply a thin layer on the affected area 1-3 times per day. The product is not intended for children and adolescents under 18 years of age. Indication B) *Adolescents, adults and elderly* Apply a thin layer on the affected area 1-3 times per day. The use in children under 12 years of age is not recommended (see section 4.4 ‘Special warnings and precautions for use’). **Duration of use** Indication A) 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.

	Indication B) If the symptoms persist longer than 5 days during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. **Method of administration** Cutaneous use.

4.3. Contraindications

Well-established use	Traditional use
Hypersensitivity to the active substance.	Hypersensitivity to the active substance.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
If there is inflammation of the skin, thrombophlebitis or subcutaneous induration, severe pain, ulcers, sudden swelling of one or both legs, cardiac or renal insufficiency, a doctor should be consulted.	Indication A) If there is inflammation of the skin, thrombophlebitis or subcutaneous induration, severe pain, ulcers, sudden swelling of one or both legs, cardiac or renal insufficiency, a doctor should be consulted. Indication B) The product should not be used on broken skin, around the eyes or on mucous membranes. In the absence of sufficient safety data, the use in children below 12 years of age is not recommended. Indications A) and B) If symptoms worsen or signs of skin infections occur during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

4.5. Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
None reported.	None reported.

4.6. 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.	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.	Not relevant.

4.8. Undesirable effects

Well-established use	Traditional use
Gastrointestinal complaints, headache, vertigo, itching and allergic reactions have been reported. The frequency is not known. If other adverse reactions not mentioned above occur, a doctor or a pharmacist should be consulted.	Hypersensitivity reactions of the skin (itching and erythema) have 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.	No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Well-established use	Traditional use
Pharmacotherapeuticgroup: Vasoprotectives ATC code: C05 The exact mechanism of action is not known, but preclinical and clinical pharmacological studies indicate that an effect on venous tone and capillary filtration rate is involved.	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

Based on a systematic review (meta analysis) of 17 clinical trials, it can be concluded that horse chestnut seed extract (standardised on aescin) significantly reduces symptoms of chronic venous insufficiency, such as oedema, pain and itching compared to placebo.	

5.2. Pharmacokinetic properties

Well-established use	Traditional use
Available data on pharmacokinetic parameters for aescin are of limited validity and not considered relevant for the dosing regimen of the herbal preparation.	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
Available preclinical data indicate low toxicity following oral administration of the herbal preparation. Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.	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.	Not applicable.

7. DATE OF COMPILATION/LAST REVISION

16 July 2009