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Evaluation of Medicines for Human Use

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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

FINAL

COMMUNITY HERBAL MONOGRAPH ON *RUSCUS ACULEATUS* L., RHIZOMA

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	July 2007 September 2007
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COMMUNITY HERBAL MONOGRAPH ON *RUSCUS ACULEATUS* L., RHIZOMA

1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION[1, 2]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *Ruscus aculeatus* L., rhizoma (butcher's broom) i) Herbal substance Not applicable ii) Herbal preparations[3] Dried powdered root Dry extract (2.5-6.5 : 1 ; water) Dry extract (5-8.5 : 1 ; 80% V/V ethanol) Dry extract (6-9 : 1 ; primary solvent 96 % V/V ethanol followed by water.) Dry extract (15-20 : 1 ; 60% V/V methanol)

3. PHARMACEUTICAL FORM

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

[1] The material complies with the Ph. Eur. monograph (ref. 01/2005 : 1847)
[2] The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.
[3] Quantified for ruscogenins as determined by the total amount of ruscogenin and neoruscogenin

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Well-established use	Traditional use
	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 symptomatic relief of itching and burning associated with haemorrhoids. The product is a traditional herbal medicinal product for use in specified indication exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology *Adults, elderly* Dried powdered root: 350 mg 3 times daily Dry extract (2.5-6.5 : 1 ; water):140 to 200 mg 1 to 3 times daily Dry extract (5-8.5 : 1 ; 80 % V/V ethanol): 86 mg 1 to 2 times daily Dry extract (6-9 : 1 ; primary solvent 96 % V/V ethanol followed by water): 45 mg 2 times daily Dry extract (15-20 : 1; 60% V/V methanol): 37 mg 2 times daily Recommendations given for dried powdered root or dry extracts (7-11 mg daily) of quantified ruscogenins as determined by the total amount of ruscogenin and neoruscogenin. *Children, adolescents* There is no relevant indication for children and adolescents. **Duration of use** 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. **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
	If there is inflammation of the skin or subcutaneous induration, ulcers, sudden swelling of one or both legs, cardiac or renal insufficiency, a doctor should be consulted. If diarrhoea develops, treatment should be discontinued. 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. 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
	Nausea, gastrointestinal complaints, diarrhea, lymphocytic colitis may occur. 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 genotoxicity, carcinogenicity, and reproductive toxicity have not been performed.

6. PHARMACEUTICAL PARTICULARS

Well-established use	Traditional use
	Not applicable.

7. DATE OF COMPILATION/LAST REVISION

4 September 2008