20 November 2018
EMA/HMPC/188804/2017
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Ruscus aculeatus* L., rhizoma

Final

Initial assessment	
Discussion in Working Party on European Union monographs and list (MLWP)	July 2007 September 2007
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	7 September 2007
End of consultation (deadline for comments)	15 December 2007
Re-discussion in MLWP	March 2009 May 2008 September 2008
Adoption by HMPC Monograph (EMA/HMPC/261938/2007) Assessment Report (EMA/HMPC/2619389/2007) List of references (EMA/HMPC/372915/2007) Overview of comments received during public consultation (EMA/HMPC/112990/2008) HMPC Opinion (EMA/HMPC/188003/2008)	4 September 2008
First systematic review	
Discussion in Working Party on European Union monographs and list (MLWP)	March 2017 May 2017 July 2017 September 2017
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	30 January 2018
End of consultation (deadline for comments).	31 May 2018
Re-discussion in MLWP	September 2018

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Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Ruscus aculeatus* L. rhizoma, Butcher's broom

BG (bulgarski): Бодлив залист, коренище	LT (lietuvių kalba): Pelžiedžių šakniastiebiai
CS (čeština): listnatcový kořen	LV (latviešu valoda): Ruskusa saknenis
DA (dansk): Musetorn rhizom	MT (Malti): riżoma tan-niġġiżet il-far
DE (Deutsch): Mäusedornwurzelstock	NL (Nederlands): (stekelige) muizendoorn, wortelstok
EL (elliniká): ριζωμα ρούσκου	PL (polski): Klącze ruszczyka
EN (English): butcher's broom	PT (português): gilbardeira
ES (español): brusco, rizoma de	RO (română): rizom de ghimpe
ET (eesti keel): ruskusejuurikas	SK (slovenčina): podzemok listnatca
FI (suomi): rautamyrtti, juurakko	SL (slovenščina): korenika bodeče lobodike
FR (français): petit houx (rhizome de)	SV (svenska): stickmyrten, rot
HR (hrvatski): veprinov podanak	IS (íslenska):
HU (magyar): szúrós csodabogyó gyökértörzs	NO (norsk): Musetornerot
IT (italiano): Rusco (Pungitopo) rizoma	

European Union 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. *Ruscus aculeatus* L., rhizoma (Butcher's broom). i) Herbal substance Not applicable ii) Herbal preparations a) Powdered herbal substance b) Dry extract (DER 2.5-6.5:1); extraction solvent: water c) Dry extract (DER 5-8.5:1); extraction solvent: ethanol 80% V/V d) Dry extract (DER 6-9:1); extraction solvent: ethanol 96% V/V

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 declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

[2] The material complies with the Ph. Eur. monograph (ref.: 1847).

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Indication 1) Traditional herbal medicinal product to relieve symptoms of discomfort and heaviness of legs 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) a) Powdered herbal substance *Adults:* Single dose: 350 mg, 3 times daily b) Dry extract (DER 2.5-6.5:1); extraction solvent: water *Adults:* Single dose: 150 to 200 mg, Daily dose to maximum 450 mg c) Dry extract (DER 5.0-8.5:1), extraction solvent, ethanol 80% (V/V) *Adults:* Single dose: 86 mg, 1-2 times daily d) Dry extract (DER 6-9:1); extraction solvent: ethanol 96 % V/V *Adults*:

Well-established use	Traditional use
	Single dose: 45 mg, 2 times daily **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. There is no relevant use in children and adolescents. Indication 2) a) Powdered herbal substance *Adults:* Single dose: 350 mg, 3 times daily. b) Dry extract (DER 2.5-6.5:1); extraction solvent: water *Adults:* Single dose: 150 to 200 mg Daily dose to maximum 450 mg c) Dry extract (DER 5.0-8.5:1), extraction solvent, ethanol 80% (V/V) *Adults:* Single dose: 86 mg, 1-2 times daily **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. The use in children and adolescents is not recommended (see section 4.4 special warnings and precaution for use). **Method of administration** Oral use

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance(s).

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 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. If the symptoms worsen 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

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.

5.2. Pharmacokinetic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC.

5.3. Preclinical safety data[3]

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC, 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

20 November 2018