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Evaluation of Medicines for Human Use

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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

DRAFT

COMMUNITY HERBAL MONOGRAPH ON *HARPAGOPHYTUM PROCUMBENS* D.C. AND/OR *HARPAGOPHYTUM ZEYHERI* DECNE, RADIX

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Comments should be provided using this template to hmpc.secretariat@emea.europa.eu
Fax: +44 20 75 23 70 51

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7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 70 51
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

COMMUNITY HERBAL MONOGRAPH ON *HARPAGOPHYTUM PROCUMBENS* D.C. AND / OR *HARPAGOPHYTUM ZEYHERI* DECNE, RADIX

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 *Harpagophytum procumbens* D.C. and / or *Harpagophytum zeyheri* Decne, radix (devil's claw root) i) Herbal substance : cut dried tuberous secondary root ii) Herbal preparations Dried powdered root Liquid extract (1 : 1 ; 30% V/V ethanol) Soft extract (2.5-4.0 : 1 ; 70% V/V ethanol) Dry extract (1.5-2.5 : 1 ; water) Dry extract (5-10 : 1 ; water) Dry extract (2.8-3.4 : 1 ; 30% V/V ethanol) Dry extract (2.6-3.1 : 1 ; 30% m/m ethanol) Dry extract (3-4 : 1 ; 30% m/m ethanol) Dry extract (1.5-2.1 : 1 ; 40% V/V ethanol) Dry extract (3-5 : 1 ; 60% V/V ethanol) Dry extract (4.4-5.0 : 1 ; 60% V/V ethanol) Dry extract (3-6 : 1 ; 80% V/V ethanol) Dry extract (6-12 : 1 ; 90% V/V ethanol)

3. PHARMACEUTICAL FORM

Well-established use	Traditional use
	Herbal substance or herbal preparation in solid or liquid dosage forms or as herbal tea 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.:1095 current edition).

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

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Well-established use	Traditional use
	a) Traditional herbal medicinal product for relief of minor articular pain. b) Traditional herbal medicinal product used for the relief of mild digestive disorders such as bloating and flatulence and where there is loss of appetite. The product is a traditional herbal medicinal product for use in specified indications exclusively based on long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology *Adults* Indication a) Daily dose i) herbal substance Dried root : 4.5 g in 500 ml water as herbal tea divided in 3 doses ii) herbal preparations Dried powdered root : 1.35 g divided in 3 doses Liquid extract (1 : 1 ; 30% V/V ethanol) : 15 ml Soft extract (2.5-4.0 : 1 ; 70% V/V ethanol) : 10 ml Dry extract (1.5-2.5 : 1 ; water): 300 mg to 2.4 g divided in 2 to 3 doses Dry extract (5-10 : 1 ; water) : 600 to 800 mg divided in 2 to 3 doses Dry extract (2.8-3.4 : 1 ; 30% V/V ethanol) : 460 mg divided in 2 doses Dry extract (2.6-3.1 : 1 ; 30% m/m ethanol) : 1.6 g divided in 2 to 4 doses Dry extract (3-4 : 1 ; 30% m/m ethanol) : 1.35 g divided in 3 doses

	Dry extract (1.5-2.1 : 1 ; 40% V/V ethanol): 600 mg to 2.7 g divided in 2 to 3 doses Dry extract (3-5 : 1 ; 60% V/V ethanol) : 960 mg divided in 2 doses Dry extract (4.4-5.0 : 1 ; 60% V/V ethanol) : 960 mg divided in 2 to 4 doses Dry extract (3-6 : 1 ; 80% V/V ethanol): 300 mg divided in 3 doses Dry extract (6-12 : 1 ; 90% V/V ethanol): 90 mg divided in 2 doses Indication b) Daily dose i) herbal substance Dried root: 1.5 g in water divided in several doses ii) herbal preparations Soft extract (2.5-4.0 : 1 ; 70% V/V ethanol) : 10 ml Indications a) and b) Not recommended for use in children and adolescents under 18 years of age (see section 4.4 Special warnings and precautions for use). **Duration of use** Indication a) Note to be taken for more than 4 weeks. Indication b) Duration of use should be restricted to a maximum of two weeks. If the symptoms persist 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 is not recommended because of the lack of available experience. Articular pain accompanied by swelling of joint, redness or fever should be examined by a doctor. Caution should be taken when devil's claw is administered to patient affected by cardiac disorders. As a general precaution, patients with gastric or duodenal ulcer should not use devil's claw preparations. If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. For liquid extracts containing ethanol, the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included.

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

Well-established use	Traditional use
	Not known.

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
	Gastrointestinal disorders: diarrhoea, nausea, vomiting, abdominal pain. Central Nervous system disorders: headache, dizziness. Skin disorders: allergic skin reactions 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 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

10 January 2008