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FINAL

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

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	October 2006 October 2007 January 2008
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**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}

<u>Well-established use</u>	<u>Traditional use</u>
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended</p> <p><i>Harpagophytum procumbens</i> DC. and/or <i>Harpagophytum zeyheri</i> Decne, radix (devil's claw root)</p> <p>i) Herbal substance Cut dried tuberous secondary root</p> <p>ii) Herbal preparations Powdered herbal substance Comminuted herbal substance 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 (2.6-4 : 1 ; 30% V/V ethanol) Dry extract (1.5-2.1 : 1 ; 40% V/V ethanol) Dry extract (3-5 : 1 ; 60% V/V ethanol) Dry extract (3-6 : 1 ; 80% V/V ethanol) Dry extract (6-12 : 1 ; 90% V/V ethanol)</p>

3. PHARMACEUTICAL FORM

<u>Well-established use</u>	<u>Traditional use</u>
	<p>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.</p>

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

<u>Well-established use</u>	<u>Traditional use</u> 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.
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4.2. Posology and method of administration

<u>Well-established use</u>	<u>Traditional use</u> Posology <i>Adults</i> 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 A) Comminuted herbal substance: 4.5 g in 500 ml water as herbal tea divided in 3 doses B) Powdered herbal substance: 1.35 g divided in 3 doses C) Liquid extract (1 : 1 ; 30% V/V ethanol): 15 ml D) Soft extract (2.5-4.0 : 1 ; 70% V/V ethanol): 10 ml E) Dry extract (1.5-2.5 : 1 ; water): 300 mg to 2.4 g divided in 2 to 3 doses F) Dry extract (5-10 : 1 ; water): 600 to 800 mg divided in 2 to 3 doses G) Dry extract (2.6-4: 1 ; 30% V/V ethanol): 460 mg up to 1.6 g divided in 2 to 4 doses
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	<p>H) Dry extract (1.5-2.1 : 1 ; 40% V/V ethanol): 600 mg to 2.7 g divided in 2 to 3 doses</p> <p>I) Dry extract (3-5: 1 ; 60% V/V ethanol): 960 mg divided in 2 to 4 doses</p> <p>J) Dry extract (3-6 : 1 ; 80% V/V ethanol): 300 mg divided in 3 doses</p> <p>K) Dry extract (6-12 : 1 ; 90% V/V ethanol): 90 mg divided in 2 doses</p> <p>Indication b) Daily dose</p> <p>i) Herbal substance Dried root: 1.5 g in water divided in three doses</p> <p>ii) Herbal preparations Soft extract (2.5-4.0 : 1 ; 70% V/V ethanol): 10 ml</p> <p>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').</p> <p>Duration of use</p> <p>Indication a) Note to be taken for more than 4 weeks.</p> <p>Indication b) Duration of use should be restricted to a maximum of 2 weeks.</p> <p>If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Method of administration</p> <p>Oral use.</p>
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4.3. Contraindications

<u>Well-established use</u>	<u>Traditional use</u> Hypersensitivity to the active substance.
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4.4. Special warnings and precautions for use

<u>Well-established use</u>	<u>Traditional use</u>
	<p>The use in children and adolescents under 18 years of age is not recommended because of the lack of available experience.</p> <p>Articular pain accompanied by swelling of joints, redness or fever should be examined by a doctor.</p> <p>As a general precaution, patients with gastric or duodenal ulcer should not use devil's claw root preparations.</p> <p>Caution should be taken when Harpagophytum is administered to patients affected by cardiovascular disorders.</p> <p>If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>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.</p>

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

<u>Well-established use</u>	<u>Traditional use</u>
	Not known.

4.6. Pregnancy and lactation

<u>Well-established use</u>	<u>Traditional use</u>
	<p>Safety during pregnancy and lactation has not been established.</p> <p>In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</p>

4.7. Effects on ability to drive and use machines

<u>Well-established use</u>	<u>Traditional use</u>
	No studies on the effect on the ability to drive and use machines have been performed.

4.8. Undesirable effects

<u>Well-established use</u>	<u>Traditional use</u>
	<p>Gastrointestinal disorders: diarrhoea, nausea, vomiting, abdominal pain.</p> <p>Central Nervous system disorders: headache, dizziness.</p> <p>Skin disorders: allergic skin reactions</p> <p>The frequency is not known.</p> <p>If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.</p>

4.9. Overdose

<u>Well-established use</u>	<u>Traditional use</u>
	No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

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

5.2. Pharmacokinetic properties

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

5.3. Preclinical safety data

<u>Well-established use</u>	<u>Traditional use</u> 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.
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6. PHARMACEUTICAL PARTICULARS

<u>Well-established use</u>	<u>Traditional use</u> Not applicable.
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7. DATE OF COMPILATION/LAST REVISION

6 November 2008

Superseded