EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Harpagophytum procumbens* DC. and/or *Harpagophytum zeyheri* Decne., radix

Draft - Revision

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	October 2006 October 2007 January 2008
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	10 January 2008
End of consultation (deadline for comments).	15 April 2008
Rediscussion in MLWP	September 2008 November 2008
Adoption by HMPC Monograph (EMEA/HMPC/251323/2006) AR (EMEA/HMPC/251324/2006) List of references (EMEA/HMPC/476255/2007) Overview of comments received during the public consultation (EMEA/HMPC/454136/2008) HMPC Opinion (EMEA/HMPC/584717/2008)	6 November 2008
First systematic review	
Discussion in MLWP	September 2015 November 2015
Adopted by HMPC for release for consultation	2 February 2016
Start of public consultation	15 February 2016
End of consultation (deadline for comments).Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	15 May 2016
Rediscussion in MLWP	
Adoption by HMPC	

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Harpagophytum procumbens* DC. and/or *Harpagophytum zeyheri* Decne.; Harpagophyti radix; devils claw root

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BG (bulgarski): Дяволски нокът, корен CS (čeština): harpagofytový kořen DA (dansk): Djævleklorod DE (Deutsch): Teufelskrallenwurzel EL (elliniká): Ρίζα Αρπαγοφύτου EN (English): Devil's Claw root ES (español): Harpagofito, raíz de ET (eesti keel): saatanaküünejuur FI (suomi): pirunkoura, juuri FR (français): Harpagophyton (racine d') HR (hrvatski): gomoljasti korijen vražje kandže HU (magyar): ördögcsáklyagyökér IT (italiano): Arpagofito radice	LT (lietuvių kalba): Inkaruočių šaknys LV (latviešu valoda): Harpagofita saknes MT (Malti): Gherq ta' l-Harpagofitum NL (Nederlands): Duivelsklauw PL (polski): Korzeń hakorośli PT (português): Harpagófito, raiz RO (română): rădăcină de ghiara diavolului SK (slovenčina): Koreň harpagofyta SL (slovenščina): korenina vražjega kremplja SV (svenska): Djävulsklo, rot IS (íslenska): NO (norsk): Djevelklorot

European Union herbal monograph on *Harpagophytum procumbens* DC. 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* DC. and/or *Harpagophytum zeyheri* Decne., radix (devil's claw root) i) Herbal substance Not applicable. ii) Herbal preparations a) Comminuted herbal substance b) Powdered herbal substance c) Liquid extract (DER 1:1), extraction solvent ethanol 30% V/V d) Soft extract (DER 2.5-4.0:1), extraction solvent ethanol 70% V/V e) Dry extract (DER 1.5-2.5:1), extraction solvent water f) Dry extract (DER 5-10:1), extraction solvent water g) Dry extract (DER 2.6-4:1), extraction solvent ethanol 30% V/V h) Dry extract (DER 1.5-2.1:1), extraction solvent ethanol 40% V/V i) Dry extract (DER 3-5:1), extraction solvent ethanol 60% V/V j) Dry extract (DER 3-6:1), extraction solvent ethanol 80% V/V k) Dry extract (DER 6-12:1), extraction

[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.: 1095)

Well-established use	Traditional use
	solvent ethanol 90% V/V l) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent: ethanol 25% (V/V)

3. Pharmaceutical form

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

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Indication 1) Traditional herbal medicinal product for relief of minor articular pain. Indication 2) 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 the specified indication exclusively based upon long-standing use.

4.2. Posology and method of administration[3]

Well-established use	Traditional use
	Posology *Adults and elderly* Indication 1) a) Herbal tea: 4.5 g in 500 ml of boiling water

[3] For guidance on herbal substance/herbal preparation administered as herbal tea or as infusion/decoction/macerate preparation, please refer to the HMPC 'Glossary on herbal teas' (EMA/HMPC/5829/2010 Rev.1).

Well-established use	Traditional use
	as herbal infusion divided in 3 single doses Infusion time: 8 hours b) Single dose: 435 mg, 3 times daily Daily dose: 1.35 g c) Daily dose: 1.03 g extract as single dose d) Daily dose: 240 mg extract as single dose e) Single dose: 750-800 mg, 3 times daily Daily dose: 2.25-2.4 g f) Single dose: 200-400 mg, 2 to 3 times daily Daily dose: 600-800 mg g) Single dose: 400 -800 mg; 2 to 4 times daily Daily dose: 800 mg up to 1.6 g h) Single dose: 300-900 mg, 2 to 3 times daily i) Single dose: 480 mg, 2 times daily k) Single dose: 45 mg; 2 times daily l) Single dose: 0.5-1 ml, 3 times daily Indication 2) a) Herbal tea: 1.5 g in 250 ml boiling water as herbal infusion divided in 3 single doses. Infusion time: 8 hours d) Daily dose: 240 mg extract as single dose e) Single dose: 100 mg; 2 to 3 times daily g) Single dose: 140-280 mg, 3 times daily i) Single dose: 480 mg, 2 times daily Single dose: 100 mg; 3 times daily The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **Duration of use** Indication 1) Not to be used for more than 4 weeks. Indication 2) Not to be used for more than 2 weeks.

Well-established use	Traditional use
	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. Articular pain accompanied by swelling of joints, redness or fever should be examined by a doctor. Patients with gallstones should consult a physician prior to use the devil's claw.

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. Articular pain accompanied by swelling of joints, redness or fever should be examined by a doctor. Patients with gallstones should consult a physician prior to use the devil's claw. If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. For liquid preparations 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
	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
	Gastrointestinal symptoms (diarrhoea, nausea, vomiting, abdominal pain) have been reported. Central nervous system effects (headache, vertigo) have been reported. Hypersensitivity reactions (e.g. rash, hives, facial oedema) 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.

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

2 February 2016