



12 July 2016
EMA/HMPC/627057/2015
Committee on Herbal Medicinal Products (HMPC)

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

Final

| | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|
| Initial assessment | |
| Discussion in Working Party on European Union monographs and 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 |
| Re-discussion in MLWP | September 2008 November 2008 |
| Adoption by HMPC Monograph (EMA/HMPC/251323/2006) AR (EMA/HMPC/251324/2006) List of references (EMA/HMPC/476255/2007) Overview of comments received during the public consultation (EMA/HMPC/454136/2008) HMPC Opinion (EMA/HMPC/584717/2008) | 6 November 2008 |
| First systematic review | |
| Discussion in MLWP | September 2015 November 2015 |
| Adoption by HMPC for release for consultation | 2 February 2016 |
| End of consultation (deadline for comments) | 15 May 2016 |
| Re-discussion in MLWP | 1 June 2016 |
| Adoption by HMPC | 12 July 2016 |

| | |
|----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Keywords | Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; <i>Harpagophytum procumbens</i> DC. and/or <i>Harpagophytum zeyheri</i> Decne., radix; Harpagophytum; Devil's Claw root |
|----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|



| | |
|-------------------------------------------------|----------------------------------------------|
| BG (bulgarski): Дяволски нокът, корен | LT (lietuvių kalba): inkaruočių šaknys |
| CS (čeština): harpagofytový kořen | LV (latviešu valoda): harpagofita saknes |
| DA (dansk): djævleklorod | MT (Malti): Gherq ta' I-Harpagofitum |
| DE (Deutsch): Teufelskrallenwurzel | NL (Nederlands): Duivelsklauw |
| EL (elliniká): πιζα αρπαγοφύτου | PL (polski): korzeń hakorośli |
| EN (English): Devil's Claw root | PT (português): harpagófito, raiz |
| ES (español): harpagofito, raíz de | RO (română): rădăcină de ghiara diavolului |
| ET (eesti keel): saatanaküünejuur | SK (slovenčina): koreň harpagofyta |
| FI (suomi): pirunkoura, juuri | SL (slovenščina): korenina vražjega kremplja |
| FR (français): harpagophyton (racine d') | SV (svenska): djävulsklo, rot |
| HR (hrvatski): gomoljasti korijen vražje kandže | IS (íslenska): |
| HU (magyar): ördögcsáklyagyökér | NO (norsk): djevelklorot |
| IT (italiano): arpagofito radice | |

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 |
|----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | <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</p> <p>Not applicable</p> <p>ii) Herbal preparations</p> <p>a) Comminuted herbal substance</p> <p>b) Powdered herbal substance</p> <p>c) Liquid extract (DER 1: 1), extraction solvent ethanol 30% V/V</p> <p>d) Soft extract (DER 2.5-4.0: 1), extraction solvent ethanol 70% V/V</p> <p>e) Dry extract (DER 1.5-2.5: 1), extraction solvent water</p> <p>f) Dry extract (DER 5-10: 1), extraction solvent water</p> <p>g) Dry extract (DER 2.6-4: 1), extraction solvent ethanol 30% V/V</p> <p>h) Dry extract (DER 1.5-2.1: 1), extraction solvent ethanol 40% V/V</p> <p>i) Dry extract (DER 3-5: 1), extraction solvent ethanol 60% V/V</p> <p>j) Dry extract (DER 3-6: 1), extraction solvent ethanol 80% V/V</p> |

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 |
|----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | k) Dry extract (DER 6-12:1), extraction 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 |
|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | <p>Indication 1) Traditional herbal medicinal product for relief of minor articular pain.</p> <p>Indication 2) Traditional herbal medicinal product used for the relief of mild digestive disorders such as bloating and flatulence and where there is temporary loss of appetite.</p> <p>The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.</p> |

4.2. Posology and method of administration³

| Well-established use | Traditional use |
|----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | <p>Posology</p> <p><i>Adults and elderly</i></p> <p>Indication 1)</p> <p>a) Herbal tea: 4.5 g in 500 ml of boiling water as herbal infusion divided in 3 single doses Infusion time: 8 hours</p> <p>b) Single dose: 435 mg, 3 times daily Daily dose: 1.35 g</p> <p>c) Daily dose: 1.03 g extract as single dose</p> <p>d) Daily dose: 240 mg extract as single dose</p> <p>e) Single dose: 100-1200 mg, 2 to 3 times daily Daily dose: up to 2.4 g</p> <p>f) Single dose: 200-400 mg, 2 to 3 times daily Daily dose: 600-800 mg</p> <p>g) Single dose: 400-800 mg, 2 to 4 times daily Daily dose: 800 mg up to 1.6 g</p> <p>h) Single dose: 300-900 mg, 2 to 3 times daily Daily dose: 600 mg up to 2.7 g</p> <p>i) Single dose: 480 mg, 2 times daily Daily dose: 960 mg</p> <p>k) Single dose: 45 mg, 2 times daily Daily dose: 90 mg</p> <p>l) Single dose: 0.5-1 ml, 3 times daily Daily dose: up to 3 ml</p> <p>Indication 2)</p> <p>a) Herbal tea: 1.5 g in 250 ml boiling water as herbal infusion divided in 3 single doses. Infusion time: 8 hours</p> <p>d) Daily dose: 240 mg extract as single dose</p> <p>e) Single dose: 100 mg, 2 to 3 times daily Daily dose: up to 300 mg</p> <p>g) Single dose: 140-280 mg, 3 times daily Daily dose: 420 up to 840 mg</p> <p>i) Single dose: 480 mg, 2 times daily</p> <p>j) Single dose: 100 mg, 3 times daily Daily dose: 300 mg</p> <p>The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> |

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 |
|----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | <p>Duration of use</p> <p>Indication 1)</p> <p>If the symptoms persist longer than 4 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Indication 2)</p> <p>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.</p> <p>Method of administration</p> <p>Oral use</p> |

4.3. Contraindications

| Well-established use | Traditional use |
|----------------------|---------------------------------------------------------------------------------------------------------|
| | <p>Hypersensitivity to the active substance.</p> <p>Patients with active gastric or duodenal ulcer.</p> |

4.4. Special warnings and precautions for use

| Well-established use | Traditional use |
|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | <p>The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.</p> <p>Articular pain accompanied by swelling of joints, redness or fever should be examined by a doctor.</p> <p>Patients with gallstones should consult a physician prior to use devil's claw.</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 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.</p> |

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. |

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

| 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. Adequate 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

12 July 2016