



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 March 2014
EMA/HMPC/138317/2013
Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Ononis spinosa* L., radix

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	March 2013 May 2013
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Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Ononis spinosa</i> L., Ononidis radix; Restharrow root
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BG (bългарски): Бодлив гръмотрън, корен CS (čeština): jehlicový kořen DA (dansk): Krageklo DE (Deutsch): Hauhechelwurzel EL (elliniká): Οωνιδίδος ακανθώδους ρίζα EN (English): Restharrow root ES (español): Gatuña, raíz de ET (eesti keel): jooksjarohujuur FI (suomi): ruusuorakko, juuri FR (français): Bugrane, Arrête-boeuf HU (magyar): tövises iglice gyökér HR (hrvatska): korijen zečjeg trna IT (italiano): Ononide radice	LT (lietuvių kalba): Dirvenių šaknys LV (latviešu valoda): Blaktenes sakne MT (malti): Għerq tal-Broxka NL (nederlands): Kattendoornwortel PL (polski): Korzeń wilżyny PT (português): Gatunha RO (română): rădăcină de osul iepurelui SK (slovenčina): ihlica trnitá SL (slovenščina): korenina navadnega gladeža SV (svenska): busktörnerot <i>IS (íslenska):</i> <i>NO (norsk):</i> Beinurtrot
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Community herbal monograph on *Ononis spinosa* L., 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 <i>Ononis spinosa</i> L., radix (Restharrow root) i) Herbal substance Not applicable. ii) Herbal preparations Comminuted herbal substance.

3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea 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
	Traditional herbal medicinal product used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints. The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.

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.: 01/2008:1879).

4.2. Posology and method of administration³

Well-established use	Traditional use
	<p>Posology</p> <p><i>Adolescents, adults and elderly</i></p> <p>Herbal tea: 2 – 3 g of comminuted herbal substance in 150 ml of boiling water as a herbal infusion up to 3 - 4 times daily corresponding to the maximum daily dose of 12 g.</p> <p>The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p>Duration of use</p> <p>If the symptoms persist longer than 1 week 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>Conditions where a reduced fluid intake is recommended (e.g. severe cardiac or renal disease).</p>

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>The use in children under 12 years of age has not been established due to lack of adequate data.</p> <p>To ensure an increase of the amount of urine, adequate fluid intake is required during the treatment.</p> <p>If urinary tract complaints worsen and symptoms such as fever, dysuria, spasm, or blood in the urine occur during the use of medicinal product, a doctor or a qualified health care practitioner should be consulted.</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).

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 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
	<p>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.</p> <p>Adequate tests on genotoxicity have not been performed.</p> <p>Tests on reproductive toxicity and carcinogenicity have not been performed.</p>

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

25 March 2014