



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

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| 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): Οωννίδος 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 |
|---|--|



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