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Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Ononis spinosa* L., radix

Draft – Revision 1

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Adoption by HMPC Monograph (EMA/HMPC/138317/2013) Assesment Report (EMA/HMPC/138316/2013) List of References (EMA/HMPC/138319/2013) Overview of Comments received during the public consultation (EMA/HMPC/35010/2014) HMPC Opinion (EMA/HMPC/283233/2014)	25 March 2014
First revision	
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Keywords	Committee on Herbal medicinal products; HMPC; European Union herbal monographs; traditional herbal medicinal products; traditional use; *Ononis spinosa* L., radix; Ononidis radix; Restharrow root

BG (bălgarski): Бодлив гръмотрън, корен	LT (lietuvių kalba): Dirvenių šaknys
CS (čeština): jehlicový kořen	LV (latviešu valoda): Blaktenes sakne
DA (dansk): Strand-kragеklorod	MT (malti): Għerq tal-Broxka
DE (Deutsch): Hauhechelwurzel	NL (nederlands): Kattendoorn
EL (elliniká): ονωνίδος ακανθώδους ρίζα	PL (polski): Korzeń wilżyny
EN (English): Restharrow root	PT (português): gatunha, raiz
ES (espanol): gatuña, raíz de	RO (română): rădăcină de osul iepurelui
ET (eesti keel): jooksjarohujuur	SK (slovenčina): koreň ihlice
FI (suomi): ruusuorakko, juuri	SL (slovenščina): korenina navadnega gladeža
FR (français): Bugrane, Bugrane épineuse, Arrête-boeuf (racine de)	SV (svenska): busktörne, rot
HU (magyar): tövises iglice gyökér	*IS (íslenska)*:
HR (hrvatska): korijen zečjeg trna	*NO (norsk):* Tornbeinurtrot
IT (italiano): Ononide radice	

European Union 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 *Ononis spinosa* 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 for the relief of symptoms associated with minor urinary complaints in addition to the general recommendation of a sufficient fluid intake to increase the amount of urine. The product is a traditional herbal medicinal

[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.:07/2014:1879).

Well-established use	Traditional use
	product for use in specified indications exclusively based upon long-standing use.

4.2. Posology and method of administration[3]

Well-established use	Traditional use
	Posology *Adolescents, adults and elderly* Herbal tea: 2 – 4 g of comminuted herbal substance in 150 ml of boiling water as an herbal infusion up to 3 - 4 times daily corresponding to the maximum daily dose of 12 g. The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **Duration of use** If the symptoms persist longer than one week 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.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	The use in children under 12 years of age has not been established due to lack of adequate data. 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.

[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
	Because adequate fluid intake is required during treatment, the use of *Ononis spinosa* L., radix, is not recommended for patients with conditions where reduced fluid intake was advised.

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

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 genotoxicity have not been performed. Tests on reproductive toxicity and carcinogenicity have not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable

7. Date of compilation/last revision

7 May 2025