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Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Agropyron repens* (L.) P. Beauv., rhizoma

Draft

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	September 2010 November 2010 January 2011
Adopted by Committee on Herbal Medicinal Products (HMPC) for release for consultation	27 January 2011
End of consultation (deadline for comments)	15 June 2011
Re-discussion in MLWP	September 2011
Adoption by HMPC Monograph (EMA/HMPC/563408/2010) AR (EMA/HMPC/563395/2010) List of references (EMA/HMPC/563402/2010) HMPC Opinion (EMA/HMPC/888911/2011)	22 November 2011
First systematic review	
Discussion in HMPC	March 2021 May 2021 July 2021
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Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Agropyron repens* (L.) Beauv., rhizoma, *Elymus repens* (L.) Gould, rhizoma, Agropyri repentis rhizoma, Graminis rhizoma, Couch grass rhizome

BG (bulgarski): Пирей, коренище	LT (lietuvių kalba): Varpučių šakniastiebiai
CS (čeština): oddenek pýru	LV (latviešu valoda): Vārpatas saknenis
DA (dansk): Kvikgræs rhizom	MT (Malti): għerq tan-niġem
DE (Deutsch): Queckenwurzelstock	NL (Nederlands): Kweek
EL (elliniká): ριζωμα αγρωστίδος της έρπουσας (αγριάδας) - ριζωμα αγρώστιδος	PL (polski): Kłącze perzu
	PT (português): grama francesa, rizoma
EN (English): Couch grass rhizome	RO (română): rizom de pir
ES (español): grama de las boticas, rizoma de	SK (slovenčina): podzemok pýru
ET (eesti keel): orasheina juurikas	SL (slovenščina): korenika plazeče pirnice
FI (suomi): juolavehnä, juurakko	SV (svenska): kvickrot, jordstam
FR (français): chiendent (rhizome de)	IS (íslenska):
HR (hrvatski): pirikin podanak	NO (norsk): kvekerot
HU (magyar): tarackbúza gyökértörzs	
IT (italiano): Gramigna rizoma	

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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 *Agropyron repens* (L.) P. Beauv., rhizoma (couch grass rhizome) i) Herbal substance Not applicable. ii) Herbal preparations a) Comminuted herbal substance b) Liquid extract (DER 1: 1-1), extraction solvent ethanol 20-25% V/V c) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 40% V/V

3. Pharmaceutical form

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

[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.: 01/2008:1306). Detailed specifications for the herbal substance shall be given by references to bibliographic sources in absence of a monograph in the European Pharmacopoeia, a national pharmacopoeia or national codex currently used officially in a Member State.

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.

4.2. Posology and method of administration[3]

Well-established use	Traditional use
	Posology *Adolescents, adults and elderly* a) Herbal tea 3-6 g of comminuted herbal substance in 250 ml boiling water as a herbal infusion or decoction 2-4 times daily Single doses 3-6 g. Average daily doses 6-24 g The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use') *Adults and elderly* b) Liquid extract Single dose: 3-8 ml, 2 to 4 times daily c) Tincture Single dose: 5-15 ml, 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** The herbal substance is traditionally used over a period of 2 up to 4 weeks.

[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
	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
	a), b), c) Hypersensitivity to the active substance(s) a) Conditions where a reduced fluid intake is recommended (e.g. severe cardiac or renal disease).

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	a) The use in children under 12 years of age has not been established due to lack of adequate data. b), c) The use in children and adolescents under 18 years of age has not been established due to lack of adequate data. a), b), c) If the symptoms such as fever, dysuria, spasms or blood in urine occur during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. b), c) For tinctures and extracts 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.

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 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

07 July 2021