EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

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

Draft

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BG (bălgarski): Пирей, коренище	LT (lietuvių kalba):
CS (čeština): oddenek pýru	LV (latviešu valoda): Vārpatas saknenis
DA (dansk):	MT (malti):
DE (Deutsch): Queckenwurzelstock	NL (nederlands): kweek
EL (elliniká):	PL (polski): Kłącze perzu
EN (English): Couch grass rhizome	PT (português):
ES (espanol):	RO (română): rizom de pir
ET (eesti keel): orasheina juurikas	SK (slovenčina): Pýrový podzemok
FI (suomi):	SL (slovenščina):
FR (français): chiendent (rhizome de)	SV (svenska): Kvickrot, jordstam
HU (magyar): Tarackbúza gyökértörzs	IS (íslenska):
IT (italiano):	NO (norsk): Kvekerot

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

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 *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), 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 material complies with the Ph. Eur. monograph (ref.: 01/2008:1306 corrected 6.0).
2 The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Traditional herbal medicinal product 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 specified indication exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology *Adults and elderly* a) Comminuted herbal substance as infusion Single dose: 3-6 g Daily dose: 10-20 g b) Liquid extract Single dose: 4-8 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. 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
	Hypersensitivity to the active substance(s). 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
	The use in children and adolescents under 18 years of age is not recommended because of concerns requiring medical advice. If complaints or 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. 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. 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 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
	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. 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

27 January