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Evaluation of Medicines for Human Use

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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

DRAFT

COMMUNITY HERBAL MONOGRAPH ON *QUERCUS ROBUR* L., *QUERCUS PETRAEA* (MATT.) LIEBL. AND *QUERCUS PUBESCENS* WILLD., CORTEX

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	March 2009 September 2009 January 2010
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ADOPTION BY HMPC	

Comments should be provided using this template to hmpc.secretariat@ema.europa.eu
Fax: +44 20 75 23 70 51

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7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 70 51
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

COMMUNITY HERBAL MONOGRAPH ON *QUERCUS ROBUR* L., *QUERCUS PETRAEA* (MATT.) LIEBL. AND *QUERCUS PUBESCENS* WILLD., CORTEX

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 *Quercus robur* L., *Quercus petraea* (Matt.) Liebl. and *Quercus pubescens* Willd., cortex (oak bark) i) Herbal substance Not applicable ii) Herbal preparations - Comminuted herbal substance - Powdered herbal substance - Dry extract (DER 5.0-6.5:1), extraction solvent ethanol 50% V/V

3. PHARMACEUTICAL FORM

Well-established use	Traditional use
	Comminuted herbal substance as a decoction for oral use. Herbal preparation in solid or liquid dosage forms for oral use. Comminuted herbal substance as a decoction, for oromucosal or cutaneous use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

[1] The material complies with the Ph. Eur. monograph (ref. no 01/2008:1887).
[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
	a) Traditional herbal medicinal product for symptomatic treatment of mild diarrhoea. b) Traditional herbal medicinal product for symptomatic treatment of minor inflammation of the oral mucosa or skin. The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology *Adults* Indication a) Single dose - 1 g powdered herbal substance for oral use, 3 times daily - 3 g comminuted herbal substance in 250 ml of water, 3 times daily - Dry extract: 140 mg, 4 times daily Indication b) - Decoction for oromucosal use: 20 g/L. - Decoction for bath preparation: 5 g comminuted herbal substance/1L to be added to the bath (bath duration 20 minutes). For full or partial bath one bath daily. For topical rinses or poultices several 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** Indication a) Not to be used for more than 3 days. If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

	Indication b) Not to be used for more than 1 week. 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** Indication a) Oral use. Indication b) Cutaneous use. Oromucosal use.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance. Use as bath additive: Open wounds, large skin and mucosa injuries and infection of the skin and mucosa.

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 due to lack of adequate data. Indication a) If recurrent diarrhoea or bloody stools occur, a doctor or a qualified health care practitioner should be consulted. Indication b) Hot bath should not be used in case of febrile or infectious illnesses, in heart insufficiency and hypertension.

4.5. Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
	Indication a) Internal absorption of concomitantly administered medicine may be delayed. For this reason, the product should be taken 1 hour or more before or after intake of other medicinal products.

4.6. Pregnancy and lactation

Well-established use	Traditional use
	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
	Allergic reactions are reported. The frequency is not known. If other adverse reactions not mentioned above 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. 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

14 January 2010