



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Quercus robur* L., *Quercus petraea*.(Matt.) Liebl., *Quercus pubescens* Willd., cortex

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	March 2009 September 2009 January 2010
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BG (bългарски): CS (čeština): DA (dansk): DE (Deutsch): EL (ελληνικά): EN (English): oak bark ES (español): ET (eesti keel): FI (suomi): FR (français): HU (magyar): IT (italiano):	LT (lietuvių kalba): LV (latviešu valoda): MT (malti): NL (nederlands): PL (polski): PT (português): RO (română): SK (slovenčina): SL (slovenščina): SV (svenska): <i>IS (íslenska):</i> <i>NO (norsk):</i>
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Community herbal monograph on *Quercus robur* L., *Quercus petraea*.(Matt.) Liebl., *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
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended</p> <p><i>Quercus robur</i> L., <i>Quercus petraea</i> (Matt.) Liebl. and <i>Quercus pubescens</i> Willd., cortex (oak bark)</p> <p>i) Herbal substance</p> <p>Not applicable</p> <p>ii) Herbal preparations</p> <ul style="list-style-type: none">a) Comminuted herbal substanceb) Powdered herbal substancec) Dry extract (DER 5.0-6.5:1), extraction solvent ethanol 50% m/m

3. Pharmaceutical form

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

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
	<p data-bbox="810 405 967 434">Indication 1)</p> <p data-bbox="810 461 1326 524">Traditional herbal medicinal product for symptomatic treatment of mild diarrhoea.</p> <p data-bbox="810 551 967 580">Indication 2)</p> <p data-bbox="810 607 1414 710">Traditional herbal medicinal product for symptomatic treatment of minor inflammation of the oral mucosa or skin.</p> <p data-bbox="810 736 967 766">Indication 3)</p> <p data-bbox="810 792 1350 969">Traditional herbal medicinal product for symptomatic relief of itching and burning associated with haemorrhoids, after serious conditions have been excluded by a medical doctor.</p> <p data-bbox="810 996 1425 1099">The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.</p>

4.2. Posology and method of administration

Well-established use	Traditional use
	<p data-bbox="810 1292 935 1321">Posology</p> <p data-bbox="810 1348 991 1377"><i>Adults, elderly</i></p> <p data-bbox="810 1404 967 1433">Indication 1)</p> <ul style="list-style-type: none"> <li data-bbox="858 1460 1409 1523">a) 3 g comminuted herbal substance in 250 ml of water, three times daily. <li data-bbox="858 1550 1414 1653">b) 1 g powdered herbal substance in capsules/tablets for oral use, three times daily. <li data-bbox="858 1680 1342 1709">c) Dry extract: 140 mg, 4 times daily. <p data-bbox="810 1736 967 1765">Indication 2)</p> <ul style="list-style-type: none"> <li data-bbox="858 1792 1374 1821">a) Decoction for oromucosal use: 20 g/L. <p data-bbox="810 1848 1067 1877">Indications 2) and 3)</p> <ul style="list-style-type: none"> <li data-bbox="858 1904 1390 2007">b) Decoction for bath preparation: 5 g comminuted herbal substance/1L to be added to the bath (bath duration 20

Well-established use	Traditional use
	<p>minutes).</p> <p>One full or partial bath daily.</p> <p>Topical rinses or poultices several times daily.</p> <p>The use in children and adolescents under 18 years of age is not recommended (see section 4.4. 'Special warnings and precautions for use').</p> <p>Duration of use</p> <p>Indication 1)</p> <p>Not to be used for more than 3 days.</p> <p>If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Indications 2) and 3)</p> <p>Not to be used for more than 1 week.</p> <p>If the symptoms persist 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> <p>Cutaneous use.</p> <p>Oromucosal use.</p> <p>Anorectal use.</p>

4.3. Contraindications

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

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>The use in children and adolescents under 18 years of age is not recommended due to lack of adequate data.</p> <p>Indication 1)</p> <p>If recurrent diarrhoea or bloody stools occur, a doctor or a qualified health care practitioner should be consulted.</p> <p>Indications 2) and 3)</p> <p>Hot bathes should not be used in case of febrile or infectious illnesses, in heart insufficiency and hypertension.</p> <p>Indication 3)</p> <p>If rectal bleeding occurs during the treatment of haemorrhoids a doctor should be consulted.</p>

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

Well-established use	Traditional use
	<p>Indication 1)</p> <p>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.</p>

4.6. Pregnancy and lactation

Well-established use	Traditional use
	<p>Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</p>

4.7. Effects on ability to drive and use machines

Well-established use	Traditional use
	<p>No studies on the effect on the ability to drive and use machines have been performed.</p>

4.8. Undesirable effects

Well-established use	Traditional use
	Allergic reactions have been 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

25 November 2010