



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 May 2011
EMA/HMPC/246774/2009
Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Cinnamomum verum* J.S. Presl, cortex

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	May 2009 November 2009 May 2010 July 2010
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Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Cinnamomum verum</i> J. S. Presl, (<i>Cinnamomum zeylanicum</i> Nees), cortex; Cinnamomi cortex; Cinnamon
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BG (bългарski): Канелена кора CS (čeština): Škoricovníková kůra DA (dansk): Ceylonkanel DE (Deutsch): Zimtrinde EL (elliniká): φλοιός κινναμώμου (καννέλας) EN (English): Cinnamon ES (español): Canela de Ceilán, corteza de ET (eesti keel): kaneelikoor FI (suomi): FR (français): Cannelle de Ceylan HU (magyar): Ceyloni fahéjfa kéreg IT (italiano): Cannella di Ceylon corteccia	LT (lietuvių kalba): Cinamonų žievė LV (latviešu valoda): Kanējkoka miza MT (malti): Qoxra tal-Kannella NL (nederlands): Kaneel PL (polski): kora cynamonowca cejlonskiego PT (português): Canela-de-ceilão, casca RO (română): Scortșoară SK (slovenčina): Škoricovníková kôra SL (slovenščina): skorja cimetrovca SV (svenska): Kanel <i>IS (islenska):</i> <i>NO (norsk):</i> Kanel
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Community herbal monograph on *Cinnamomum verum* J. S. Presl., 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>Cinnamomum verum</i> J.S. Presl, cortex (cinnamon)i) Herbal substance</p> <p>Not applicable.</p> <p>ii) Herbal preparations</p> <p>a) Comminuted herbal substance</p> <p>b) Liquid extract (DER 1:1), extraction solvent ethanol 70% V/V</p> <p>c) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 70% V/V</p>

3. Pharmaceutical form

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

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.: 04/2011:0387).

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	<p>Indication 1</p> <p>Traditional herbal medicinal product for symptomatic treatment of mild, spasmodic gastro-intestinal complaints including bloating and flatulence.</p> <p>Indication 2</p> <p>Traditional herbal medicinal product for symptomatic treatment of mild diarrhoea.</p> <p>The product is a traditional herbal medicinal product for use in a specified indications exclusively based upon long-standing use.</p>

4.2. Posology and method of administration³

Well-established use	Traditional use
	<p>Posology</p> <p><i>Adults and elderly</i></p> <p>Indications 1) and 2)</p> <p>a) Herbal tea: 0.5-1 g comminuted herbal substance as an infusion, up to 4 times daily</p> <p>Indication 1)</p> <p>b) Liquid extract: Single dose: 0.5-1 ml, 3 times daily</p> <p>c) Tincture: Daily dose: 2-4 ml</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>If the symptoms persist longer than 2 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be</p>

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).

	<p>consulted.</p> <p>Indication 2)</p> <p>If the symptoms persist longer than two days, a doctor or a qualified health care practitioner should be consulted.</p> <p>Method of administration</p> <p>Oral use.</p>
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4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance or to Peru balsam.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>Indications 1) and 2)</p> <p>The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.</p> <p>If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care professional should be consulted.</p> <p>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.</p> <p>Indication 2)</p> <p>In case of diarrhoea, rehydration should be the first measure.</p> <p>If recurrent diarrhoea or bloody stools occur, a doctor or a qualified health care practitioner should be consulted.</p>

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
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	<p>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.</p> <p>Adequate tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.</p>
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6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

10 May 2011