



10 May 2011
EMA/HMPC/706229/2009
Committee on Herbal Medicinal Products (HMPC)

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

Final

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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), aetheroleum; Cinnamomi corticis aetheroleum; Cinnamon bark oil
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BG (bългарски): Цейлонско канелено дърво, масло от кора CS (čeština): silice kůry skořicovníku cejlonského DA (dansk): Ceylonkanel barkolie DE (Deutsch): Zimtöl EL (elliniká): έλαιο κινναμώμου (καννέλας) EN (English): Cinnamon Bark Oil ES (español): Canela de Ceilán, aceite esencial de corteza de ET (eesti keel): kaneeliõli FI (suomi): FR (français): Cannelle de Ceylan (huile essentielle de) HU (magyar): ceyloni fahéjfa kéreg olaj IT (italiano): Cannella di Ceylon corteccia, essenza	LT (lietuvių kalba): Cinamonų žievės eterinis aliejus LV (latviešu valoda): Kanēļkoka mizas ēteriskā eļļa MT (malti): NL (nederlands): Kaneelolie PL (polski): olejek eteryczny z kory cynamonowca cejlonskiego PT (português): Óleo essencial de canela-de-Ceilão RO (română): ulei volatil de scorțișoară SK (slovenčina): Škoricovníková silica SL (slovenščina): eterično olje skorje cimetrovca SV (svenska): Kanelolja IS (íslenska): NO (norsk): kanelolje
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Community herbal monograph on *Cinnamomum verum* J.S. Presl., corticis aetheroleum

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, corticis aetheroleum (cinnamon bark oil)</p> <p>i) Herbal substance</p> <p>Not applicable.</p> <p>ii) Herbal preparations</p> <p>Essential oil obtained by steam distillation from the cortex.</p>

3. Pharmaceutical form

Well-established use	Traditional use
	<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>

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	<p>Traditional herbal medicinal product for symptomatic treatment of mild, spasmodic gastrointestinal complaints including bloating and flatulence.</p> <p>The product is a traditional herbal medicinal product for use in a specified indication</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.: 04/2011:1501).

Well-established use	Traditional use
	exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	<p>Posology</p> <p><i>Adults and elderly</i></p> <p>Essential oil: 50 to 200 mg daily, in 2 to 3 doses.</p> <p>In order to avoid local irritation, the use of the undiluted oil is not recommended.</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>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 consulted.</p> <p>Method of administration</p> <p>Oral use.</p>

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>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>

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
	Local irritation of the oral mucosa has 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. 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

10 May 2011