



EUROPEAN MEDICINES AGENCY
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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Cinnamomum verum* J.S. Presl (*Cinnamomum zeylanicum* Nees), aetheroleum

Draft

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BG (bългарски): CS (čeština): DA (dansk): Ceylonkanel barkolie DE (Deutsch): Zimtöl EL (elliniká): EN (English): ES (español): ET (eesti keel): FI (suomi): FR (français): Cannelle de Ceylan (huile essentielle de) HU (magyar): ceyloni fahéjfa kéreg olaj IT (italiano):	LT (lietuvių kalba): LV (latviešu valoda): Kanēļkoka ēteriskā eļļa MT (malti): NL (nederlands): PL (polski): PT (português): Óleo essencial de canela de Ceilão RO (română): SK (slovenčina): Škoricovníková silica SL (slovenščina): SV (svenska): IS (islenska): NO (norsk): kanelolje
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Community herbal monograph on *Cinnamomum verum* J.S. Presl (*Cinnamomum zeylanicum* Nees), 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 (<i>Cinnamomum zeylanicum</i> Nees), aetheroleum corticis (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. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

¹ The material complies with the Ph. Eur. monograph (ref.: 01/2008:1501).

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

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
	<p>Hypersensitivity to the active substance or to Peru balsam.</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 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. 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
	<p>Local irritation of the oral mucosa has been reported. The frequency is not known.</p> <p>If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.</p>

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
	<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>

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

15 July 2010