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SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

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

Final

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<b>Keywords</b>	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<sup>1,2</sup>

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>

<sup>1</sup> The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

<sup>2</sup> 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><b>Posology</b></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><b>Duration of use</b></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><b>Method of administration</b></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**

<b>Well-established use</b>	<b>Traditional use</b>
	None reported.

#### **4.6. Fertility, pregnancy and lactation**

<b>Well-established use</b>	<b>Traditional use</b>
	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**

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

#### **4.8. Undesirable effects**

<b>Well-established use</b>	<b>Traditional use</b>
	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**

<b>Well-established use</b>	<b>Traditional use</b>
	No case of overdose has been reported.

## **5. Pharmacological properties**

### **5.1. Pharmacodynamic properties**

<b>Well-established use</b>	<b>Traditional use</b>
	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