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**COMMITTEE ON HERBAL MEDICINAL PRODUCTS  
(HMPC)**

**DRAFT**

**COMMUNITY HERBAL MONOGRAPH ON *PEUMUS BOLDUS* MOLINA, FOLIUM**

<b>DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)</b>	January 2008 March 2008 May 2008
<b>ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION</b>	8 May 2008
<b>END OF CONSULTATION (DEADLINE FOR COMMENTS)</b>	15 September 2008
<b>REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)</b>	
<b>ADOPTION BY HMPC</b>	

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<b>KEYWORDS</b>	Herbal medicinal products; HMPC; Community herbal monograph; traditional use; <i>Peumus boldus</i> Molina; Boldi folium; boldo leaf
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## COMMUNITY HERBAL MONOGRAPH ON *PEUMUS BOLDUS* MOLINA, FOLIUM

### 1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION<sup>1, 2</sup>

<u>Well-established use</u>	<u>Traditional use</u>
With regard to the marketing authorisation application of Article 10(a) of Directive 2001/83/EC as amended	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended  <i>Peumus boldus</i> Molina, folium (boldo leaf)  i) Herbal substance whole or fragmented, dried leaf ii) Herbal preparations comminuted herbal substance for tea preparation

### 3. PHARMACEUTICAL FORM

<u>Well-established use</u>	<u>Traditional use</u>
	Herbal substance or herbal preparations as herbal tea for oral use.  The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

### 4. CLINICAL PARTICULARS

#### 4.1. Therapeutic indications

<u>Well-established use</u>	<u>Traditional use</u>
	Traditional herbal medicinal product for symptomatic relief of dyspepsia and mild spasmodic disorders of the gastrointestinal tract. The product is a traditional herbal medicinal product for use in specified indication(s) exclusively based upon long-standing use.

<sup>1</sup> The material complies with the Ph Eur monograph (ref. 04/2005: 1396)

<sup>2</sup> The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

#### 4.2. Posology and method of administration

<u>Well-established use</u>	<u>Traditional use</u>  <b>Posology</b>  <i>Adults and elderly</i>  Comminuted herbal substance for tea preparation: 1–2 g of herbal substance. To be taken 2-3 times daily.  The use in children and adolescents is not recommended (see section 4.4 Special warnings and precautions for use).  <b>Duration of use</b>  If the symptoms persist more than 2 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted (see section 4.4 Special warnings and precautions for use).  <b>Method of administration</b>  Oral use.
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#### 4.3. Contraindications

<u>Well-established use</u>	<u>Traditional use</u>  Hypersensitivity to the active substance.  Obstruction of bile duct, cholangitis, liver disease, gallstones and any other biliary disorders that require medical supervision and advice.
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#### 4.4. Special warnings and precautions for use

<u>Well-established use</u>	<u>Traditional use</u>  The use in children and adolescents is not recommended because data are not sufficient and medical advice should be sought.  If symptoms worsen during the use of the medicinal product, a doctor or a qualified health practitioner should be consulted.
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#### 4.5. Interactions with other medicinal products and other forms of interaction

<u>Well-established use</u>	<u>Traditional use</u>  None reported.
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#### 4.6. Pregnancy and lactation

<u>Well-established use</u>	<u>Traditional use</u> Safety during pregnancy and lactation has not been established. In view of the pre-clinical safety data (see section 5.3), the use during pregnancy and lactation should be avoided.
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#### 4.7. Effects on ability to drive and use machines

<u>Well-established use</u>	<u>Traditional use</u> No studies on the effect on the ability to drive and use machines have been performed.
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#### 4.8. Undesirable effects

<u>Well-established use</u>	<u>Traditional use</u> Hypersensitivity (anaphylaxis) 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.
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#### 4.9. Overdose

<u>Well-established use</u>	<u>Traditional use</u> No case of overdose has been reported.
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### 5. PHARMACOLOGICAL PROPERTIES

#### 5.1. Pharmacodynamic properties

<u>Well-established use</u>	<u>Traditional use</u> Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.
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#### 5.2. Pharmacokinetic properties

<u>Well-established use</u>	<u>Traditional use</u> Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.
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### 5.3. Preclinical safety data<sup>3</sup>

<u>Well-established use</u>	<u>Traditional use</u>  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 have been performed with a dry ethanolic extract of boldo leaf and boldine administered orally to pregnant rats. Results showed anatomical alterations in the fetus and a few cases of abortion at high doses.  Tests on genotoxicity and carcinogenicity have not been performed with preparations of boldo leaf.
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### 6. PHARMACEUTICAL PARTICULARS

<u>Well-established use</u>	<u>Traditional use</u>  Not applicable.
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### 7. DATE OF COMPILATION/LAST REVISION

8 May 2008

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<sup>3</sup>Where herbal teas from Boldo leaf are used, the total exposure to ascaridole should be considered from a safety standpoint. The levels in herbal medicinal products should be quantified. There are no data on ascaridole exposure from other herbal preparations.