



London, 14 January 2009  
Doc. Ref.: EMEA/HMPC/591648/2007

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

**FINAL**

**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>	November 2008 January 2009
<b>ADOPTION BY HMPC</b>	14 January 2009

<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 Dry extract (5:1, aqueous)

### 3. PHARMACEUTICAL FORM

<u>Well-established use</u>	<u>Traditional use</u>
	Herbal substance or herbal preparations for oral use as herbal tea or in solid dosage forms.  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 indications 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.  Dry extract (5:1, aqueous): up to 400 mg 2 times daily.  The use in children and adolescents under 18 years of age 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.  <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 under 18 years of age 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

14 January 2009

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<sup>3</sup>Where herbal preparations 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.