European Medicines Agency
Evaluation of Medicines for Human Use

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COMMITTEE ON HERBAL MEDICINAL PRODUCTS

This document was valid from 14 January 2009 until November 2016. It is now superseded by a new version adopted by the HMPC on 22 November 2016 and published on the EMA website.

COMMUNITY HERBAL MONOGRAPH ON *PEUMUS BOLDUS* MOLINA, FOLIUM

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	January 2008 March 2008 May 2008
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7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 70 51
E-mail: mail@emea.europa.eu http://www.emea.europa.eu
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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
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 *Peumus boldus* 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

Well-established use	Traditional use
	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

Well-established use	Traditional use
	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.

[1] The material complies with the Ph. Eur. monograph (ref. 04/2005: 1396)

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

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4.2. Posology and method of administration

Well-established use	Traditional use
	Posology *Adults and elderly* 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'). **Duration of use** 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. **Method of administration** Oral use.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance. Obstruction of bile duct, cholangitis, liver disease, gallstones and any other biliary disorders that require medical supervision and advice.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	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

Well-established use	Traditional use
	None reported.

4.6. Pregnancy and lactation

Well-established use	Traditional use
	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.

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
	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.

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.

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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[3]

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. 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.

6. PHARMACEUTICAL PARTICULARS

Well-established use	Traditional use
	Not applicable.

7. DATE OF COMPILATION/LAST REVISION

14 January 2009

[3]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.

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