22 November 2016
EMA/HMPC/453725/2016
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Peumus boldus* Molina, folium

Final

Initial assessment	
Discussion in Working Party on European Union monographs and list (MLWP)	January 2008 March 2008 May 2008
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	8 May 2008
End of consultation (deadline for comments)	15 September 2008
Re-discussion in MLWP	November 2008 January 2009
Adoption by HMPC	14 January 2009
First systematic review	
Discussion in Working Party on European Union monographs and list (MLWP)	July 2016 September 2016
Adoption by HMPC	22 November 2016

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Peumus boldus* Molina, folium; Boldi folium; boldo leaf

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BG (bulgarski): Болдо, лист CS (čeština): boldový list DA (dansk): Boldoblad DE (Deutsch): Boldoblätter EL (elliniká): Φύλλο βόλδου EN (English): boldo leaf ES (español): Boldo, hoja de ET (eesti keel): boldopuuleht FI (suomi): boldo, lehti FR (français): boldo (feuille de) HR (hrvatski): boldov list HU (magyar): boldólevél IT (italiano): Boldo foglia	LT (lietuvių kalba): Kvapiųjų čilmedžių lapai LV (latviešu valoda): Boldo lapas MT (Malti): Werqa tal-Boldo NL (Nederlands): boldoblad PL (polski): Liść boldo PT (português): Boldo, folha RO (română): frunză de boldo SK (slovenčina): list boldovníka SL (slovenščina): list boldovca SV (svenska): boldo, blad IS (íslenska): NO (norsk): boldoblad

European Union 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[1, 2]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC *Peumus boldus* Molina, folium (boldo leaf) i) Herbal substance Not applicable ii) Herbal preparations a) Comminuted herbal substance b) Dry extract (DER 5:1), extraction solvent water

3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea for oral use. Herbal preparation in solid dosage forms for oral use. 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 used for symptomatic relief of dyspepsia and mild

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

[2] The material complies with the Ph. Eur. monograph (ref.: 1396)

Well-established use	Traditional use
	spasmodic disorders of the gastrointestinal tract. The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.

4.2. Posology and method of administration[3]

Well-established use	Traditional use
	Posology *Adults and elderly* a) Comminuted herbal substance Herbal tea: 1–2 g of the comminuted herbal substance in 150 ml of boiling water as a herbal infusion, 2-3 times daily b) Dry extract (DER 5:1) extraction solvent water Single dose: 200-400 mg, 2 times daily Daily dose: 400-800 mg 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 longer 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(s). Obstruction of bile duct, cholangitis, liver disease, gallstones and any other biliary disorders that require medical supervision and advice.

[3] For guidance on herbal substance/herbal preparation administered as herbal tea or as infusion/decoction/macerate preparation, please refer to the HMPC 'Glossary on herbal teas' (EMA/HMPC/5829/2010 Rev.1).

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	The use in children and adolescents under 18 years of age has not been established due to lack of adequate data and because of concerns requiring medical advice. If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

4.5. Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
	None reported

4.6. Fertility, 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 is not recommended. No fertility data available.

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.

5.2. Pharmacokinetic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC.

5.3. Preclinical safety data

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC, 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.

6. Pharmaceutical particulars

Well-established use	Traditional use
	The levels of ascaridole in herbal preparations and herbal medicinal products should be determined.

7. Date of compilation / last revision

22 November 2016