EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 January 2014
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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Plantago lanceolata* L., folium

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	July 2010 September 2010 November 2010
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	25 November 2010
End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	15 April 2011
Rediscussion in Working Party on Community monographs and Community list (MLWP)	May 2011 July 2011 September 2011
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Corrigendum[1]	28 January 2014

Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Plantago lanceolata* L., folium; Plantaginis lanceolatae folium; ribwort plantain leaf

BG (bălgarski): Теснолист живовлек, лист	LT (lietuvių kalba):
CS (čeština): jitrocelový list	LV (latviešu valoda): Šaurlapu ceļtekas lapas
DA (dansk): Lancetvejbredblad	MT (malti): Werqa tal-Bisbula Salvaġġa
DE (Deutsch): Spitzwegerichblätter	NL (nederlands): Smalle Weegbree
EL (elliniká): ισπαγούλη (ελλειπές)	PL (polski): Liść babki lancetowatej
EN (English): ribwort plantain	PT (português): Tanchagem menor
ES (espanol): Llantén menor, hoja de	RO (română): frunză de patlagină
ET (eesti keel): süstlehise teelehe leht	SK (slovenčina): List skorocelu kopijovitého
FI (suomi):	SL (slovenščina): list ozkolistnega trpotca
FR (français): Plantain lancéolé (feuille de)	SV (svenska): Svartkämparblad
HU (magyar): lándzsás útifű levél	*IS (íslenska)*:
IT (italiano): Piantaggine foglia	*NO (norsk): Smalkjempeblad*

[1] Corrigendum: correction in section 2 concerning the herbal preparation g) (DER 1:11).

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Community herbal monograph on *Plantago lanceolata* L., folium

1. Name of the medicinal product

To be specified for the individual finished product.

2. Qualitative and quantitative composition[2,3]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *Plantago lanceolata* L., folium (ribwort plantain) i) Herbal substance Not applicable. ii) Herbal preparations a) Comminuted herbal substance b) Powdered herbal substance c) Dry extract (DER 3-6:1); extraction solvent: water d) Liquid extract (DER 1:0.8-1.2); extraction solvent: ethanol 20-40% V/V e) Soft extract (DER 1.5-1.7:1); extraction solvent: ethanol 20% m/m f) Expressed juice (DER 1:0.5-0.9) from the fresh herb g) Syrup according to ÖAB 2009 (formally, the native herbal preparation is a liquid extract (DER 1:11); extraction solvent: water) h) Dry extract (DER 3-5:1); extraction solvent: ethanol 20% m/m i) Liquid extract (DER 1:5.8-5.9); extraction solvent: water

1 The material complies with the Ph. Eur. monograph (ref.:01/2008:1884).
2 The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea for oral use. Powdered herbal substance in a solid dosage form and other herbal preparations in liquid or solid dosage forms for oral and/or oromucosal 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 as a demulcent for the symptomatic treatment of oral or pharyngeal irritations and associated dry cough. 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[4]

Well-established use	Traditional use
	Posology <u>Oral use</u> *Adolescents, adults and elderly* Single dose a) and b) Herbal tea: 2 g of the comminuted herbal substance in 150 ml of boiling water as a herbal infusion, 2-3 times per day. Daily dose: 4-6 g c) 233 mg dry extract, 3 times per day. Daily dose: 699 mg d) 0.4 to 1.9 g liquid extract, administered 3-4 times per day with a minimum dose of 1.2 g and a maximum dose of 5.6 g per day.

[4] 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).

Well-established use	Traditional use
	e) 804 mg soft extract, 4 times per day. Daily dose: 3216 mg f) 10 ml expressed juice, 3 times per day. Daily dose: 30 ml g) 15 ml syrup, 3-4 times per day. Daily dose: 45-60 ml h) 300 mg dry extract, 3-4 times per day. Daily dose: 900-1200 mg i) 4 ml liquid extract, 3-5 times per day. Daily dose: 12-20 ml *Children* c) *5-11 years of age* Single dose of 233 mg dry extract, 2-3 times per day. Daily dose: 466-699 mg *3-4 years of age* Single dose of 117 mg dry extract, 3 times per day. Daily dose: 351 mg d) Only for liquid extracts with a DER 1:1 a traditional use in children has been recorded. *5-11 years of age* Single dose of 1.0 to 1.25 g liquid extract, administered 2-3 times per day with a minimum dose of 2.5 g and a maximum dose of 3.8 g per day. *3-4 years of age* Single dose of 0.5 to 0.625 g, administered 2-3 times per day with a minimum dose of 1.25 g and a maximum dose of 1.9 g per day. e) *5-11 years of age* 804 mg soft extract, 3 times per day. Daily dose: 2412 mg *3-4 years of age* 402 mg soft extract, 3 times per day. Daily dose: 1206 mg f) *4-11 years of age* Single dose 5 ml expressed juice, 2 times

Well-established use	Traditional use
	per day. Daily dose: 10 ml g) *3-11 years of age* 5 ml syrup as single dose, 3-4 times per day. Daily dose: 15-20 ml h) *5-11 years of age* 300 mg dry extract as single dose, 3 times per day. Daily dose: 1200 mg *3-4 years of age* 150 mg dry extract, 3 times per day. Daily dose: 450 mg i) *5-11 years of age* 3 ml liquid extract, 2-4 times per day. Daily dose: 6-12 ml *3-4 years of age* 2 ml liquid extract, 2-3 times per day. Daily dose: 4-6 ml The oral use in children under 3 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). <u>Oromucosal use</u> *Adults and elderly* b) and c) Single dose of 160-190 mg up to a maximum dose of 1280 mg/day administered as coated tablet or lozenge. The oromucosal 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 1 week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. **Method of administration** Oral use. Oromucosal use.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	The oral use in children under 3 years of age is not recommended because of concerns requiring medical advice and due to the lack of adequate data. The oromucosal use in children and adolescents under 18 years of age is not recommended due to the lack of adequate data. If dyspnoea, fever or purulent sputum occurs during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. For extracts containing ethanol, the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included.

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
	No fertility data available. 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

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
	None known. If adverse reactions 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.

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. Tests on reproductive toxicity and carcinogenicity have not been performed. Adequate tests on genotoxicity have not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation / last revision

28 January 2014