EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

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

Draft

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DE (Deutsch):	NL (nederlands):
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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[1,2]

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 whole or fragmented, dried leaf and scape (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) Liquid extract (DER 1:11); extraction solvent: water

3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea, powdered herbal substance in a solid dosage form and other herbal preparations in liquid or solid dosage forms for oral and/or oromucosal use.

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.

Well-established use	Traditional 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 specified indications exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology Oral use *Adolescents, adults and elderly* a) Single dose of 2 g, 2-3 times per day. c) Single dose of 233 mg dry extract, 3 times per day. d) Single dose of 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. e) 804 mg soft extract, 4 times per day. f) Single dose 10 ml, 3 times per day. g) 15 ml as single dose, 3-4 times per day. *Children* c) *5 - 11 years of age* Single dose of 233 mg dry extract, 2-3 times per day. *3 - 4 years of age* Single dose of 117 mg dry extract, 3 times per day.

Well-established use	Traditional use
	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. *3-4 years of age* 402 mg soft extract, 3 times per day. f) *4-11 years of age* Single dose 5 ml, 2 times per day. g) *3-11 years of age* 5 ml as single dose, 3-4 times per day. The use in children under 3 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). Oromucosal use *Adults and elderly* b) and c) Single dose of 160-190 mg up to a maximum dose of 1.280 mg/d 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 for more than 1 week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

Well-established use	Traditional use
	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 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 between the age of 3 and 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. Pregnancy and lactation

Well-established use	Traditional use
	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.	Not applicable.

7. Date of compilation/last revision

25 November 2010