



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

09 July 2025
EMA/HMPC/887979/2022
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Plantago lanceolata* L., folium

Final – Revision 1

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	July 2010 September 2010 November 2010
Adopted by Committee on Herbal Medicinal Products (HMPC) for release for consultation	25 November 2010
End of consultation (deadline for comments)	15 April 2011
Rediscussion in MLWP	May 2011 July 2011 September 2011
Adoption by HMPC Monograph (EMA/HMPC/437858/2010) Assessment Report (EMA/HMPC/437859/2010) List of References (EMA/HMPC/437860/2010) Overview of Comments received during the public consultation (EMA/HMPC/353910/2011) HMPC Opinion (EMA/HMPC/888909/2011)	22 November 2011
First revision	
Discussion in HMPC	November 2022 January 2023 March 2023 May 2023 May 2024 July 2024
Adopted by HMPC for release for consultation	24 July 2024
Start of public consultation	15 August 2024
End of consultation (deadline for comments)	15 November 2024
Re-discussion in HMPC	January 2025 May 2025 July 2025
Adoption by HMPC	09 July 2025

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Keywords	Committee on Herbal medicinal products; HMPC; European Union herbal monographs; herbal medicinal products; traditional use; <i>Plantago lanceolata</i> L., folium; Plantaginis lanceolatae folium; Ribwort plantain
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BG (bългарски): Теснолист живовлек, лист	LT (lietuvių kalba): Siauralapių gysločių lapai
CS (čeština): jitrocelový list	LV (latviešu valoda): Šaurlapu ceļtekas lapa
DA (dansk): Lancetvejbreddblad	MT (malti): werqa tal-bisbula salvaġġa
DE (Deutsch): Spitzwegerichblätter	NL (nederlands): Smalle Weegbree
EL (elliniká): ισπαγούλης φύλλο	PL (polski): Liść babki lancetowatej
EN (English): Ribwort plantain	PT (português): tanchagem menor
ES (español): llantén menor, hoja de	RO (română): frunză de patlagină
ET (eesti keel): süstlelise teelehe leht	SK (slovenčina): list skorocelu kopijovitého
FI (suomi): heinäratamo, lehti	SL (slovenščina): list ozkolistnega trpotca
FR (français): Plantain lancéolé (feuille de)	SV (svenska): svartkämpar, blad
HR (hrvatski): list trpuca	IS (íslenska):
HU (magyar): lándzsás útifű levél	NO (norsk): smalkjempeblad
IT (italiano): Piantaggine foglia	

European Union 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 <i>Plantago lanceolata</i> 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 1:0.9-1.1), extraction solvent: ethanol 24-35% 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 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 j) Liquid extract (DER 1:0.8-1.2), extraction solvent: ethanol 40% V/V k) Liquid extract (DER 1:3) extraction solvent: ethanol 60% (V/V)

3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea for oral and oromucosal use. Comminuted herbal substance as macerate for oromucosal and cutaneous 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
	Herbal preparations in liquid, semi-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
	<u>Indication 1)</u> Traditional herbal medicinal product as a demulcent for the symptomatic treatment of oral or pharyngeal irritations and associated dry cough. <u>Indication 2)</u> Traditional herbal medicinal product used for the relief of cough associated with cold. <u>Indication 3)</u> Traditional herbal medicinal product used for the treatment of minor inflammation of the skin. 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 administration³

Well-established use	Traditional use
	Posology <u>Indications 1) and 2)</u> <u>Oral use</u> Preparation a) <i>Adolescents, adults and elderly</i> Herbal tea: 1.4 - 2 g of the comminuted herbal substance in 150-250 ml of boiling water as an herbal infusion Dosage frequency: 2-3 times daily Daily dose: 4 - 6 g

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).

Well-established use	Traditional use
	The oral use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). Preparation c) <i>Adolescents, adults and elderly</i> Single dose: 233 mg Dosage frequency: 3 times daily Daily dose: 699 mg <i>Children 5-11 years of age</i> Single dose: 233 mg Dosage frequency: 2-3 times daily Daily dose: 466 - 699 mg <i>Children 3-4 years of age</i> Single dose: 117 mg Dosage frequency: 3 times daily Daily dose: 351 mg The oral use in children under 3 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). Preparation d) <i>Adolescents, adults and elderly</i> Single dose: 0.94 - 2.6 g Dosage frequency: 3-6 times daily Daily dose: 3.75 - 7.5 g <i>Children 5-11 years of age</i> Single dose: 0.31 - 1.3 g Dosage frequency: 2-6 times daily Daily dose: 1.25 - 3.9 g <i>Children 3-4 years of age</i> Single dose: 0.16 - 1.3 g Dosage frequency: 2-6 times daily Daily dose: 0.62 - 2.6 g The oral use in children under 3 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). Preparation e)

Well-established use	Traditional use
	<i>Adolescents, adults and elderly</i> Single dose: 804 mg Dosage frequency: 4 times daily Daily dose: 3216 mg <i>Children 5-11 years of age</i> Single dose: 804 mg Dosage frequency: 3 times daily Daily dose: 2412 mg <i>Children 3-4 years of age</i> Single dose: 402 mg Dosage frequency: 3 times daily Daily dose: 1206 mg The oral use in children under 3 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). Preparation f) <i>Adolescents, adults and elderly</i> Single dose: 10 ml Dosage frequency: 3 times daily Daily dose: 30 ml <i>Children 3-11 years of age</i> Single dose: 5 ml Dosage frequency: 2 times daily Daily dose: 10 ml The oral use in children under 3 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). Preparation g) <i>Adolescents, adults and elderly</i> Single dose: 7.5 g Dosage frequency: 3-4 times daily Daily dose: 22.5 - 30.0 g <i>Children 3-11 years of age</i> Single dose: 2.5 g

Well-established use	Traditional use
	Dosage frequency: 3-4 times daily Daily dose: 7.5 - 10 g The oral use in children under 3 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). Preparation h) <i>Adolescents, adults and elderly</i> Single dose: 300 mg Dosage frequency: 3-4 times daily Daily dose: 900 - 1200 mg <i>Children 5-11 years of age</i> Single dose: 300 mg Dosage frequency: 3 times daily Daily dose: 900 mg <i>Children 3-4 years of age</i> Single dose: 150 mg Dosage frequency: 3 times daily Daily dose: 450 mg The oral use in children under 3 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). Preparation i) <i>Adolescents, adults and elderly</i> Single dose: 2.1 g Dosage frequency: 3-5 times daily Daily dose: 6.3 - 10.6 g <i>Children 5-11 years of age</i> Single dose: 1.6 g Dosage frequency: 2-4 times daily Daily dose: 3.2 - 6.4 g <i>Children 3-4 years of age</i> Single dose: 1.1 g Dosage frequency: 2-3 times daily Daily dose: 2.2 - 3.3 g

Well-established use	Traditional use
	The oral use in children under 3 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). Preparation k) <i>Adolescents, adults and elderly</i> Single dose: 1.9 g Dosage frequency: 3-4 times daily Daily dose: 5.8 - 7.8 g <i>Children 6-11 years of age</i> Single dose: 0.65 g Dosage frequency: 3-4 times daily Daily dose: 1.9 – 2.6 g The oral use in children under 6 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). <u>Indication 2)</u> <u>Oral use</u> Preparation j) <i>Adolescents, adults and elderly</i> Single dose: 0.4-1.26 g liquid extract Dosage frequency: 3-4 times daily Daily dose: 1.2-4.8 mg The oral use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). <u>Indication 1)</u> <u>Oromucosal use</u> Preparation a) as macerate in 150 ml of cold water <i>Children from 3 years of age, adolescents, adults and elderly:</i> Single dose: 1.4 g Dosage frequency: 3-4 times daily Daily dose: 4.2-5.6 g The oromucosal use in children under 3 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). Preparation b)

Well-established use	Traditional use
	<i>Adolescents, adults and elderly</i> Single dose: 190 mg Dosage frequency: 9 times daily Daily dose: 1.71 g The oromucosal use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). Preparation c) <i>Adolescents, adults and elderly</i> Single dose: 160 mg Dosage frequency: 4-8 times daily (every 2 h) Daily dose: 640-1280 mg The oromucosal use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). <u>Indication 3)</u> <u>Cutaneous use</u> <i>Children from 3 years of age, adolescents, adults and elderly:</i> Preparation a) as macerate in 150 ml of cold water Single dose: 1.4 g Dosage frequency: 3-4 times daily Daily dose: 4.2-5.6 g The macerate is applied on the affected area with a clean dressing. The cutaneous use in children under 3 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. Cutaneous use. The macerate should be used immediately after preparation.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance or to ribwort plantain pollen.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	The oral and oromucosal use in children under 3 years of age is not recommended because of concerns requiring medical advice. Preparation a) The oral use in children under 12 years of age is not recommended due to the lack of adequate data. The cutaneous use in children under 3 years of age is not recommended due to the lack of adequate data. Preparations b) and c) The oromucosal use in children under 12 years of age is not recommended due to the lack of adequate data. Preparation j) The oral use in children under 12 years of age is not recommended due to the lack of adequate data. Preparation k) The oral use in children under 6 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.

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.

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 as amended, unless necessary for the safe use of the product. Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

09 July 2025