



13 January 2021
EMA/HMPC/376770/2019
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Aloysia citrodora* Paláu (syn. *Aloysia triphylla* (L'Hér.) Kuntze; *Verbena triphylla* L'Hér.; *Lippia citriodora* Kunth), folium

Final

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP) and Committee on Herbal Medicinal Products (HMPC)	September 2018
	September 2019
	March 2020
	May 2020
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	6 May 2020
End of consultation (deadline for comments)	31 August 2020
Re-discussion in HMPC	November 2020
	January 2021
Adoption by HMPC	13 January 2021

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; <i>Aloysia citrodora</i> Paláu; <i>Aloysia triphylla</i> (L'Hér.) Kuntze; <i>Verbena triphylla</i> L'Hér.; <i>Lippia citriodora</i> Kunth, folium; Verbenae citriodorae folium; lemon verbena leaf
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<p>BG (bulgarski): Лимонова върбинка, лист CS (čeština): list aloisie citronové DA (dansk): CITRONVERBENABLAD DE (Deutsch): Zitronenverbenablätter EL (elliniká): Αλοΐσιας κτριόσμου (λουίζας) φύλλο EN (English): lemon verbena leaf ES (español): Hierbaluisa, hoja de ET (eesti keel): FI (suomi): sitruunaverbena, lehti FR (français): verveine odorante HR (hrvatski): list limunomirisnog sporiša HU (magyar): citromverbéna levél IT (italiano): Verbena odorosa, foglia</p>	<p>LT (lietuvių kalba): Citrininių aloyzijų lapai LV (latviešu valoda): citrona verbēnas lapas MT (Malti): Weraq tal-Alwiża NL (Nederlands): Citroenverbena, blad PL (polski): Liść witułki cytrynowej (liść werbeny cytrynowej) PT (português): Lúcia-lima, folha RO (română): frunză de verbenă citrată SK (slovenčina): list aloysie citrónovej SL (slovenščina): list citronke SV (svenska): citronverbena, blad IS (íslenska): NO (norsk):</p>
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European Union herbal monograph on *Aloysia citrodora* Paláu (syn. *Aloysia triphylla* (L'Hér.) Kuntze; *Verbena triphylla* L'Hér.; *Lippia citriodora* Kunth), 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
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC</p> <p><i>Aloysia citrodora</i> Paláu (syn. <i>Aloysia triphylla</i> (L'Hér.) Kuntze; <i>Verbena triphylla</i> L'Hér.; <i>Lippia citriodora</i> Kunth), folium; lemon verbena leaf</p> <p>i) Herbal substance</p> <p>As defined in the Ph. Eur. monograph.</p> <p>ii) Herbal preparations</p> <p>Comminuted herbal substance</p>

3. Pharmaceutical form

Well-established use	Traditional use
	<p>Comminuted herbal substance as herbal tea for oral use.</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	<p>Indication 1)</p> <p>Traditional herbal medicinal product for relief of mild symptoms of mental stress and to aid</p>

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.: 1834).

Well-established use	Traditional use
	<p>sleep.</p> <p>Indication 2)</p> <p>Traditional herbal medicinal product for symptomatic treatment of mild gastrointestinal complaints including bloating and flatulence.</p> <p>The product is a traditional herbal medicinal product for use in the specified indications exclusively based upon long-standing use.</p>

4.2. Posology and method of administration³

Well-established use	Traditional use
	<p>Posology</p> <p><i>Adolescents, Adults and Elderly</i></p> <p>Indication 1)</p> <p>Herbal tea</p> <p>For relief of mild symptoms of mental stress: 5 g of the comminuted herbal substance in 100 ml of boiling water as a decoction, 3 times daily.</p> <p>To aid sleep: 1-2 g of the comminuted herbal substance in 200 ml of boiling water as a herbal infusion half an hour before bedtime</p> <p>Indication 2)</p> <p>Herbal tea</p> <p>2-3 g of the comminuted herbal substance in 200 ml of boiling water as a herbal infusion, 1-3 times daily, or 1 g of the comminuted herbal substance in 200 ml of boiling water as a herbal infusion up to 5 times daily.</p> <p>The use in children is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p>Duration of use</p> <p>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.</p>

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
	Method of administration Oral use

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance and to other plants of the Verbenaceae family.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	The use in children has not been established due to lack of adequate data. 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 the absence of sufficient data, 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
	May impair ability to drive and use machines. Affected patients should not drive or operate machinery.

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, unless necessary for the safe use of the product. Adequate 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

13 January 2021