



6 May 2020
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

Draft

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	September 2018 September 2019 March 2020 May 2020
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	6 May 2020
Start of public consultation	31 May 2020
End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	31 August 2020
Re-discussion in MLWP	
Adoption by HMPC	

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; <i>Aloysia triphylla</i> (L'Hérit.) Britt.; <i>Aloysia citriodora</i> Ortega; <i>Lippia citriodora</i> H.B. y K.; <i>Verbena triphylla</i> L'Hérit, folium; Aloysiae 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 κιτριόσμου (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 aloyzių 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 citronată 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>THMP product for relief of mild symptoms of mental stress and to aid sleep.</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 data-bbox="810 255 965 284">Indication 2)</p> <p data-bbox="810 311 1423 376">TMHP for symptomatic treatment of mild digestive complaints including bloating and flatulence.</p> <p data-bbox="810 405 1347 506">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 data-bbox="810 696 935 725">Posology</p> <p data-bbox="810 752 1193 781"><i>Adolescents, Adults and Elderly</i></p> <p data-bbox="810 808 965 837">Indication 1)</p> <p data-bbox="810 864 938 893">Herbal tea</p> <p data-bbox="810 920 1417 1133">For relief of mild symptoms of mental stress: 1-2 g of the comminuted herbal substance in 200 ml of boiling water as a herbal infusion up to 5 times daily or 5 g of the comminuted herbal substance in 100 ml of boiling water as a decoction up to 3 times daily.</p> <p data-bbox="810 1160 1417 1339">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 or 1-5 g of the comminuted herbal substance in 100 ml of water as a decoction half an hour before bedtime.</p> <p data-bbox="810 1366 965 1395">Indication 2)</p> <p data-bbox="810 1422 938 1451">Herbal tea</p> <p data-bbox="810 1478 1417 1655">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 data-bbox="810 1682 1417 1783">The use in children is not recommended (see section 4.4 'Special warnings and precautions for use').</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
	<p data-bbox="807 259 1018 286">Duration of use</p> <p data-bbox="807 315 1410 454">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> <p data-bbox="807 483 1142 510">Method of administration</p> <p data-bbox="807 539 916 566">Oral use</p>

4.3. Contraindications

Well-established use	Traditional use
	<p data-bbox="807 754 1378 819">Hypersensitivity to the active substance and to other plants of the Verbenaceae family.</p>

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p data-bbox="807 1010 1410 1075">The use in children has not been established due to lack of adequate data.</p> <p data-bbox="807 1104 1398 1205">If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p>

4.5 Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
	<p data-bbox="807 1431 986 1458">None reported</p>

4.6. Fertility, pregnancy and lactation

Well-established use	Traditional use
	<p data-bbox="807 1648 1390 1787">Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</p> <p data-bbox="807 1816 1123 1843">No fertility data available.</p>

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

6 May 2020