22 September 2021
EMA/HMPC/486551/2020
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Orthosiphon aristatus* (Blume) Miq. var. *aristatus*, folium

Final – Revision 1

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	March 2009 May 2009 July 2009
Adopted by Committee on Herbal Medicinal Products (HMPC) for release for consultation	16 July 2009
End of consultation (deadline for comments).	15 December 2009
Re-discussion in MLWP	January 2010 March 2010
Adoption by HMPC Monograph (EMA/HMPC/281496/2009) Assessment Report (EMA/HMPC/135701/2009) List of references (EMA/HMPC/281529/2009) Overview of comments received during the public consultation (EMA/HMPC/143067/2010) HMPC Opinion (EMA/HMPC/153982/2010)	11 March 2010
Revision	
Discussion in HMPC	March 2020 September 2020 November 2020 January 2021
Adopted by HMPC for release for consultation	13 January 2021
End of consultation (deadline for comments).	30 April 2021
Re-discussion in HMPC	July 2021 September 2021
Adoption by HMPC	22 September 2021

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Orthosiphon aristatus* (Blume) Miq. var. *aristatus*; Orthosipnonis folium; Java tea

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

BG (bălgarski): Ортосифон, лист CS (čeština): trubkovcový list DA (dansk): Javate DE (Deutsch): Orthosiphonblätter EL (elliniká): τέϊον ιάβης EN (English): Java tea ES (espanol): ortosifón, hoja de ET (eesti keel): vurrumündileht FI (suomi): jaavalainen tee, lehti FR (français): orthosiphon (feuille d') HU (magyar): jávaitea levél IT (italiano): Thè di Giava (Ortosifon)	LT (lietuvių kalba): Arbatinių inkstažolių lapai LV (latviešu valoda): Ortosifona lapas MT (malti): werqa tat-te ta' ġava NL (nederlands): Kattensnor PL (polski): Liść ortosyfonu PT (português): chá-de-java RO (română): frunză de orthosiphon SK (slovenčina): list ortosifónu SL (slovenščina): javanski čaj SV (svenska): javate IS (íslenska): NO (norsk): java-te

European Union herbal monograph on *Orthosiphon aristatus* (Blume) Miq. var. *aristatus*, 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 *Orthosiphon aristatus* (Blume) Miq. var. *aristatus*, folium (Java tea) i) Herbal substance Not applicable ii) Herbal preparations a) Comminuted herbal substance b) Powdered herbal substance c) Liquid extract (DER 1:1), extraction solvent ethanol 25% m/m d) Dry extract (DER 5-7:1), extraction solvent water e) Dry extract (DER 8-12:1), extraction solvent ethanol 60% V/V f) Dry extract (DER 7-8:1), extraction solvent ethanol 70% V/V g) Dry extract (DER 5-7:1), extraction solvent ethanol 30% V/V

3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea for oral use. Herbal preparations in liquid or solid dosage forms for oral use.

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.: 1229).

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 used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary tract complaints. 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

Well-established use	Traditional use
	Posology *Adults and Elderly* a) Herbal tea: 2-3 g comminuted herbal substance in 150 ml of boiling water as a herbal infusion Daily dose: 6-12 g b) Powdered herbal substance Single dose: 500-750 mg Daily dose: 1000-1500 mg c) Liquid extract (DER 1:1), extraction solvent ethanol 25% m/m Single dose: 2 g Daily dose: 2-4 g d) Dry extract (DER 5-7:1), extraction solvent water Single dose: 360 mg Daily dose: 1080-1440 mg e) Dry extract (DER 8-12:1), extraction solvent ethanol 60% V/V Single dose: 200-400 mg

Well-established use	Traditional use
	Daily dose: 600-1200 mg f) Dry extract (DER 7-8:1), extraction solvent ethanol 70% V/V Single dose: 280 mg Daily dose: 840 mg g) Dry extract (DER 5-7:1), extraction solvent ethanol 30% V/V Single dose: 200 mg Daily dose: 400 mg The 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 2 weeks during the use of the medicinal product a doctor or a qualified health care practitioner should be consulted. **Method of administration** Oral use. To ensure an increase of the amount of urine, adequate fluid intake is required during treatment.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance. Conditions where a reduced fluid intake is recommended (e.g. severe cardiac or renal disease).

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	The use in children and adolescents under 18 years of age has not been established due to lack of adequate data. If complaints of symptoms such as fever, dysuria, spasms or blood in the urine occur during the use of the medicinal product, a

Well-established use	Traditional use
	doctor or a qualified health care practitioner should be consulted. For liquid 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
	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
	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, unless necessary for the safe use of the product. Adequate tests on genotoxicity have not been performed. Tests on reproductive toxicity and carcinogenicity have not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

22 September 2021