EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

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

Draft

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| **Initial assessment** | |
| Discussion in Working Party on European Union monographs and European Union list (MLWP) | May 2008<br>July 2008<br>September 2008 |
| Adopted by Committee on Herbal Medicinal Products (HMPC) for release for consultation | 4 September 2008 |
| End of consultation (deadline for comments). | 15 January 2009 |
| Re-discussion in MLWP | May 2009<br>July 2009 |
| Adoption by HMPC<br>Monograph (EMEA/HMPC/225319/2008)<br>AR (EMEA/HMPC/225304/2008)<br>List of references (EMEA/HMPC/225629/2008)<br>Overview of comments received during the public consultation (EMEA/HMPC/262723/2009)<br>HMPC Opinion (EMEA/HMPC/438817/2009) | 16 July 2009 |
| **First systematic review** | |
| Discussion in HMPC | March 2020<br>September 2020<br>November 2020<br>January 2021 |
| Adopted by HMPC for release for consultation | 13 January 2021 |
| Start of public consultation | 1 February 2021 |
| End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu | 30 April 2021 |


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



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|---|---|
| **BG (bălgarski): Ортосифон, лист**<br>**CS (čeština): trubkovcový list**<br>**DA (dansk): Javate**<br>**DE (Deutsch): Orthosiphonblätter**<br>**EL (elliniká): τέϊον ιάβης**<br>**EN (English): java tea**<br>**ES (espanol): ortosifón, hoja de**<br>**ET (eesti keel): vurrumündileht**<br>**FI (suomi): jaavalainen tee**<br>**FR (français): orthosiphon (feuille d')**<br>**HU (magyar): ortosifonov list**<br>**IT (italiano): Thè di Giava (Ortosifon)** | **LT (lietuvių kalba): Arbatinių inkstažolių lapai**<br>**LV (latviešu valoda): Ortosifona lapas**<br>**MT (malti): werqa tat-te ta' ġava**<br>**NL (nederlands): Kattensnor**<br>**PL (polski): Liść ortosyfonu**<br>**PT (português): chá-de-java**<br>**RO (română): frunză de orthosiphon**<br>**SK (slovenčina): list ortosifónu**<br>**SL (slovenščina): javanski čaj**<br>**SV (svenska): javate**<br>***IS (íslenska)*:**<br>***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 as amended<br><br>*Orthosiphon aristatus* (Blume) Miq.var. *aristatus*, folium (Java tea)<br><br>i) Herbal substance<br><br>As defined in the Ph. Eur. Monograph<br><br>ii) Herbal preparations<br><br>a) Comminuted herbal substance<br><br>b) Powdered herbal substance<br><br>c) Liquid extract (DER 1:1), extraction solvent: ethanol 25% m/m<br><br>d) Dry extract (DER 5-7:1), extraction solvent: water<br><br>e) Dry extract (DER 8-12:1), extraction solvent: ethanol 60% V/V<br><br>f) Dry extract (DER 7-8:1), extraction solvent: ethanol 70% V/V<br><br>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. |

1 The material complies with the Ph. Eur. monograph (ref.: 1229).
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 or solid dosage forms for oral use.<br><br>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.<br><br>The product is a traditional herbal medicinal product for use in specified indication exclusively based on long-standing use. |

## *4.2. Posology and method of administration*

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

| Well-established use | **Traditional use** |
|---|---|
| | ethanol 60% V/V<br><br>Single dose:200-400 mg<br>Daily dose: 600-1200 mg<br><br>f) Dry extract (DER 7-8:1), extraction solvent ethanol 70% V/V<br><br>Single dose: 280 mg<br>Daily dose: 840 mg<br><br>g) Dry extract (DER 5-7:1), extraction solvent ethanol 30% V/V<br><br>Single dose: 200 mg<br>Daily dose: 400 mg<br><br>The use is not recommended in children and adolescents under 18 years of age (see section 4.4 Special warnings and precautions for use).<br><br>**Duration of use**<br><br>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.<br><br>**Method of administration**<br><br>Oral use<br><br>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.<br><br>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.<br><br>For extracts, appropriate fluid intake is |

| Well-established use | **Traditional use** |
|---|---|
| | recommended.<br><br>If complaints of symptoms such as fever, dysuria, spasms or blood in the urine occur during the use of the medicinal product, a doctor or a qualified health care professional should be consulted.<br><br>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. 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.<br><br>No fertility data are 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.<br><br>If adverse reactions occur, a doctor or a qualified health 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.<br><br>Adequate tests on genotoxicity have not been performed<br><br>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

13 January 2021