European Medicines Agency
*Evaluation of Medicines for Human Use*

London, 16 July 2009
Doc. Ref.: EMEA/HMPC/281496/2009

**COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)**

**DRAFT**

# COMMUNITY HERBAL MONOGRAPH ON *ORTHOSIPHON STAMINEUS* BENTH., FOLIUM

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| **DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)** | May 2009<br>July 2009 |
| **ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION** | 16 July 2009 |
| **END OF CONSULTATION (DEADLINE FOR COMMENTS)** | 15 December 2009 |
| **REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)** | |
| **ADOPTION BY HMPC** | |

Comments should be provided using this template to hmpc.secretariat@emea.europa.eu
Fax: +44 20 75 23 70 51

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| **KEYWORDS** | Herbal medicinal products; HMPC; Community herbal monographs; traditional use ; *Orthosiphon stamineus* Benth.; Orthosiphonis staminei folium; Java tea |

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 70 51
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

**COMMUNITY HERBAL MONOGRAPH ON *ORTHOSIPHON STAMINEUS* BENTH., 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 stamineus* Benth., folium (Java tea, leaf)<br><br>i) Herbal substance<br>- Dried, fragmented leaf<br><br>ii) Herbal preparations<br>- Powdered herbal substance<br>- Liquid extract (1:1, ethanol 25% m/m)<br>- Dry extract (5-7:1, water)<br>- Dry extract (4-5:1, ethanol 25% m/m)<br>- Dry extract (4:1, ethanol 30% v/v)<br>- Dry extract (5-7:1, ethanol 60% v/v)<br>- Dry extract (7-8:1, ethanol 70% v/v) |

## 3. PHARMACEUTICAL FORM

| Well-established use | Traditional use |
|---|---|
| | Herbal substance or herbal preparation in solid or liquid dosage forms or as herbal tea for oral use.<br><br>The pharmaceutical form should be described by the European Pharmacopoeia full standard term. |

[1] The material complies with the Eur. Ph. monograph (ref.: 04/2009 : 1229).
[2] The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance

## 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 complaints.<br><br>The product is a traditional herbal medicinal product for use in the specified indication exclusively based on long-standing use. |

### 4.2. Posology and method of administration

| Well-established use | Traditional use |
|---|---|
| | **Posology**<br><br>- Herbal substance for tea preparation : 6 to 12 g daily in divided doses<br>- Powdered herbal substance: 650 mg 2 times daily<br>- Liquid extract (1:1, ethanol 25% m/m) : 2 g 1 to 2 times daily<br>- Dry extract (5-7:1, water) : 360 mg 3 to 4 times daily<br>- Dry extract (4-5:1, ethanol 25% m/m) : 200 mg 2 times daily<br>- Dry extract (4:1 ethanol 30% v/v) : 150 to 300 mg 1 to 3 times daily<br>- Dry extract (8-12:1, ethanol 60% v/v) : 200 to 400 mg 3 times daily<br>- Dry extract (7-8:1, ethanol 70% v/v) : 280 mg 3 times daily<br><br>The use in children and adolescents under 18 years of age is not recommended (see section 4.4 ‘Special warnings and precautions for use’).<br><br>**Duration of use**<br><br>If the symptoms persist for more than 2 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. |

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| | **Method of administration**<br><br>Oral use.<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 or obstruction of the urinary tract). |

### 4.4. Special warnings and precautions for use

| Well-established use | Traditional use |
|---|---|
| | The use in children and adolescents under 18 years of age is not recommended due to lack of adequate data.<br><br>If complaints or symptoms such as fever, dysuria, spasms or blood in urine occur during the use of the medicinal product, a doctor or a qualified healthcare practitioner 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.<br><br>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.<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>Conventional tests on reproductive toxicity, genotoxicity, and carcinogenicity have not been performed. |

## 6. PHARMACEUTICAL PARTICULARS

| Well-established use | Traditional use<br><br>Not applicable. |
|---|---|

## 7. DATE OF COMPILATION/LAST REVISION

16 July 2009