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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Orthosiphon stamineus* Benth., folium

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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 *Orthosiphon stamineus* Benth., folium (Java tea) i) Herbal substance Dried, fragmented leaf ii) Herbal preparations a) Liquid extract (DER 1:1, ethanol 25% m/m) b) Dry extract (DER 5-7:1, water) c) Dry extract (DER 8-12:1 ethanol 60% V/V) d) Dry extract (DER 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. 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

1 The material complies with the Ph. Eur. monograph (ref.: 01/2008 : 1229 corrected 6.0).
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
	urinary tract complaints. 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 *Adults and Elderly* i) Herbal substance for tea preparation: 6 to 12 g daily in divided doses. ii) Herbal preparations: a) Liquid extract: 2 g, 1 to 2 times daily. b) Dry extract (5-7:1): 360 mg, 3 to 4 times daily. c) Dry extract (8-12:1): 200 to 400 mg, 3 times daily. d) Dry extract (7-8:1): 280 mg, 3 times daily. The use is not recommended in children and adolescents under 18 years of age (see section 4.4 Special warnings and precautions for use). **Duration of use** If the symptoms persist 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.

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. Appropriate fluid intake is recommended. 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. The use of this product is not recommended in case of oedema due to limited heart and kidney function. 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.

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 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. 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

11 March 2010