



11 March 2010  
EMA/HMPC/143067/2010

**This document was valid from 11 March 2010 until 22 September 2021.**

## Overview of comments received on Community herbal monograph on *Orthosiphon stamineus* Benth., folium (EMA/HMPC/281496/2009)

Table 1: Organisations and/or individuals that commented on the draft Community herbal monograph on *Orthosiphon stamineus* Benth., folium as released for public consultation on 7 September 2009 until 15 December 2009.

	<b>Organisations and/or individuals</b>
1	Kooperation Phytopharmaka, Germany
2	Dr Vaclav Bazata
3	Association of the European Self-Medication Industry - AESGP



Table 2: Discussion of comments

### General comments to draft document

Interested party	Comment and Rationale	Outcome
Kooperation Phytopharmaka	Kooperation Phytopharmaka, a German scientific organisation, in principle welcomes the preparation of the above-mentioned Community herbal monograph. However, we would like to comment as follows on the restriction of age for the use in children/adolescents.	
AESGP	AESGP in principle welcomes the preparation of the above-mentioned Community herbal monograph which should facilitate mutual recognition in Europe by providing harmonised assessment criteria for herbal medicinal products.	

## SPECIFIC COMMENTS ON TEXT

Section number and heading	Interested party	Comment and Rationale	Outcome
2. Qualitative and quantitative composition	AESGP	<p>The product Elusanes orthosiphon is constituted of 200 mg dry extract of <u>final DER 4:1</u> in ethanol 30% v/v. However, this should be corrected using the native DER i.e. 5-7:1 in ethanol 30% v/v.</p> <p><b>Proposed change:</b>  <b>Dry extract (5-7:1, ethanol 30% v/v)</b> instead of Dry extract (4:1, ethanol 30% v/v).</p>	<p>This preparation has not been used for 30 years. Consequently it will not be present in the monograph.</p>
4.1. Therapeutic indications	Dr V. Bazata	<p>The wording of Therapeutic indications in Community Herbal Monographs is generally too soft in case of Traditional use to distinguish it from herbal non-medicinal products.</p> <p>Indication is not reflecting the totality of evidence, f.i. ESCOP Monograph ORTHOSIPHONIS FOLIUM, where is given at heading <b>Therapeutic indications</b>: Irrigation of the urinary tract, especially in cases of inflammation and renal gravel and as adjuvant in the treatment of bacterial infections of the urinary tract.</p> <p>(EMEA draft of Herbal Monograph is mentioning only „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“, despite in Inventory of herbal substances for assessment – Alphabetical order , Doc.Ref.EMA/HMPC/494079/2007 are ESCOP herbal monograph on Orthosiphonis folium 1229/2 listed on page 10 ).</p>	<p>The therapeutic indication of <i>Orthosiphon stamineus</i> Benth, folium is in line with the therapeutic indications of other traditional herbal medicinal products which have similar properties. Of course, herbal non-medicinal products have no monograph and no therapeutic indication.</p>

Section number and heading	Interested party	Comment and Rationale	Outcome
		<p><b>Proposed change (if any):</b>  <b>To include "in cases of inflammation and renal gravel and as adjuvant in the treatment of bacterial infections of the urinary tract"</b> instead of „in minor urinary complaints“, with deleting the words “Traditional herbal medicinal product” as redundant (given in disclaimer of each THMP label).</p>	
4.2. Posology and method of administration	Koop Phytopharmaka	<p>We do not agree with the restriction of age to persons from 18 years onwards. We consider Orthosiphon preparations a useful therapeutic alternative in cases where an antibiotic is not (yet) required. As children and adolescents might suffer of infections of the urinary tract, the use of Orthosiphon is justified. E.g., the HMPC Community Herbal Monograph on <i>Solidago virgaurea</i> also includes the option to use preparations thereof in adolescents from 12 years onwards. We therefore propose to replace “18” by “12” years of age.</p>	<p>Not accepted</p> <p>After review of the overall available literature, no clinical studies have been conducted with Orthosiphonis folium in children and adolescents under 18 years of age.</p> <p>To support the traditional use for children and adolescents under 18 years of age, the herbal product should be used for not less than several decades in this target population. Article 16c of CD 2001/83 requires a documented medicinal use throughout a period of at least 30 years preceding the date of application, including at least 15 years within the EU. The basic requirements encompass that the product has an efficacy that is plausible on the basis of long-standing use. Thus, as these requirements are not fulfilled for children and adolescents under 18 years of age, an indication in this target population can not be granted.</p>

Section number and heading	Interested party	Comment and Rationale	Outcome
4.2. Posology and method of administration	AESGP	The restriction of age to persons from 18 years onwards is not justified. Orthosiphon preparations are a useful therapeutic alternative in case an antibiotic is not (yet) required. Infections of the urinary tract might also occur in children and adolescents. In addition, the HMPC monograph on <i>Solidago virgaurea</i> also includes the option to use preparations thereof in adolescents from 12 years onwards. <b>Proposed change (if any):</b> For the reason presented above "18" should be replaced by "12".	See comments above.
4.2. Posology and method of administration	Dr V. Bazata	Policy of precautionary principle to exclude all children below age of 12 years of age in Posology without any justification or only "lack of data" substantiation is dubious and may be harmful to SME businesses.	
4.4. Special warnings and precautions for use	Koop Phytopharmaka	For the reasons given above we propose to replace "18" by "12" years of age.	Not Accepted. See comments on section 4.2 (Posology and method of administration).
4.4. Special warnings and precautions for use	AESGP	The same comment as for "4.2 Posology and method of administration" applies to this paragraph. <b>Proposed change (if any):</b> We propose to replace "18" by "12" years of age.	See comments above.