



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA/HMPC/563725/2010
Committee on Herbal Medicinal Products (HMPC)

Overview of comments received on Community herbal monograph on *Juniperus communis* L., aetheroleum (EMA/HMPC/12402/2010)

Table 1: Organisations and/or individuals that commented on the draft Community herbal monograph> on *Juniperus communis* L., aetheroleum as released for public consultation on 15 March 2010 until 15 August 2010.

| | Organisations and/or individuals |
|---|---|
| 1 | European Scientific Cooperative on Phytotherapy (ESCOP) |



Table 2: Discussion of comments

General comments to draft document

| Interested party | Comment and Rationale | Outcome |
|------------------|-----------------------|---------|
| | | |

SPECIFIC COMMENTS ON TEXT

| Section number and heading | Interested party | Comment and Rationale | Outcome |
|---|------------------|--|--|
| Clinical particulars 4.1. Therapeutic indications | ESCOP | <p>Oral use Indication 1) Comments The wording could be improved and the term “as an adjuvant” appears unnecessary. Proposed change (if any) We propose amendment of the text, to read: Traditional herbal medicinal product to enhance the elimination of urine [<i>or alternatively...</i> to enhance the renal elimination of water...] and hence flushing of the urinary tract in minor urinary tract complaints.</p> | The standard formulation is used as there is no sufficient clinical evidence for a diuretic activity. Not endorsed. |
| Clinical particulars 4.1. Therapeutic indications | ESCOP | <p>Cutaneous use Indication 3) Comments The term “as adjuvant” appears unnecessary. Proposed change (if any) We propose amendment of the text, to read: Traditional herbal medicinal product for the relief of minor</p> | Also here the use of the standard formulation is preferred. The most recent monograph comparable with this indication is the one on the essential oil of <i>Rosmarinus officinalis</i> . Not endorsed. |

| Section number and heading | Interested party | Comment and Rationale | Outcome |
|--|------------------|--|---|
| | | muscular and articular pain. | |
| Clinical particulars 4.2. Posology and method of administration | ESCOP | <p>Posology</p> <p>Cutaneous use</p> <p>Adolescents, adults</p> <p>Comments</p> <p>As well as in the form of a bath additive, juniper oil diluted with a suitable carrier oil can be applied directly to the skin [1,2].</p> <p>Proposed change (if any)</p> <p>After the sentence commencing "Bath additive...", we propose the insertion of an additional sentence:</p> <p>Massage oil, 3-4 times weekly: 10 drops of juniper oil diluted with 5 ml of almond oil, for application to muscles or joints [1].</p> | <p>The mixing with almond oil makes sense.</p> <p>On the other hand it is not clear whether it is based on a long standing use. The original reference should be given in order to check the 30 years of use.</p> <p>Not endorsed.</p> |
| Clinical particulars 4.2. Posology and method of administration | ESCOP | <p>Duration of use</p> <p>Comments</p> <p>A period of 2 weeks is reasonable for oral use in indications 1 and 2, but unjustifiably short for indication 3, which would include chronic rheumatic and arthritic conditions.</p> <p>Proposed change (if any)</p> <p>We propose amendment of the text, to read:</p> <p>If symptoms persist for more than 2 weeks during oral use of the product, or more than 8 weeks during cutaneous use, a doctor or a qualified health care practitioner should be consulted.</p> | <p>ESCOP is right to point to the chronic character of the use. However, the wording reflects upon persisting symptoms. Application of the oil should at least within 2 weeks lessen the symptoms. If no amelioration is seen after 2 weeks one could seriously question whether the patients would want to continue the therapy. If on the contrary the symptoms improve, there may be reason to continue. The actual wording correctly translates this therapeutic concept.</p> <p>Not endorsed.</p> |

References

Ody P. *Juniperus communis* - Juniper. In: Medicinal Herbal: Herbal remedies for common ailments. London-New York: Dorling Kindersley, 2000:80.

Chevallier A. *Juniperus communis* - Juniper. In: Encyclopedia of Medicinal Plants, 2nd ed. London-New York: Dorling Kindersley, 2001:224.