



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 September 2010
EMA/HMPC/561942/2010
Committee on Herbal Medicinal Products (HMPC)

Overview of comments received on Community herbal monograph on *Leonurus cardiaca* L., herba (EMA/HMPC/561942/2010)

Table 1: Organisations and/or individuals that commented on the draft Community herbal monograph on *Leonurus cardiaca* L., herba as released for public consultation on 15 May 2010 until 15 August 2010.

| | Organisations and/or individuals |
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| 1 | AESGP (Association of the European Self-Medication Industry) |
| 2 | ESCOP (European Scientific Cooperative on Phytotherapy) |
| 3 | BPI (Bundesverband der Pharmazeutischen Industrie) |



Table 2: Discussion of comments

| GENERAL COMMENTS | | |
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| Interested party | Comment and Rationale | Outcome |
| AESGP ESCOF BPI | Appreciate the draft and welcome the release of draft assessment report | |

| SPECIFIC COMMENTS ON TEXT | | | |
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| Section number and heading | Interested party | Comment and Rationale | Outcome |
| Monograph 4.1. Therapeutic indications | AESGP | <p>We agree with the indication “to relieve symptoms of nervous tension” but we propose to include additionally “e.g. nervous cardiac complaints”. Should this not be accepted, we could suggest adding “after initial diagnosis by a doctor”.</p> <p>The current literature [1,2] includes “nervous cardiac complaints” or “functional cardiac complaints, respectively, as an indication for <i>Leonurus cardiaca</i>. “Cardiac” is also part of the Latin name of the plant and thus points to the use in this area.</p> <p>A traditional German preparation (SALUS Herz-Beruhigungstee) may serve as an example for a combination of herbal substances used as a tea with a respective indication.</p> <p>References Schilcher H, Kammerer S, Wegener T. Leitfaden Phytotherapie. 3rd ed. München-Jena: Urban & Fischer 2007: 120.</p> | <p><i>Accepted, in principle. After clarification of the legal scope of indications for THMP by the European Commission, the following indication has been added:</i></p> <p>“Traditional herbal medicinal product used to relieve symptoms of nervous cardiac complaints such as palpitations, after serious conditions have been excluded by a medical doctor”.</p> <p>No further change in posology etc. is necessary.</p> <p>The references do not add any new information to the literature which is already included in the list of references and that has been addressed in the assessment report.</p> |

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| | | Fintelmann V, Weiss RF. Lehrbuch der Phytotherapie 10th ed. Stuttgart: Hippokrates, 2002:194. | |
| | ESCOP | <p>We propose that the in the indication cardiac complaints have to be evident and suggest the wording "Mild cardiac complaints of nervous origin" [1,2,3,4].</p> <p>Several literature references mention the indication for using motherwort in association with cardiac complaints; e.g.</p> <p>Vegetative Neurose, vegetative Herzbeschwerden[1]</p> <p>Nervous cardiac disorders (nervöse Herzbeschwerden) [2]</p> <p>Neuropathic cardiac disorders, cardiac complaints of nervous origin[3]</p> <p>Nervous and cardiac disorders[4]</p> <p>We propose that the relation of cardiac symptoms and their nervous origin could be made evident in the text of the therapeutic in</p> <ol style="list-style-type: none"> 1. Nahrstedt A. Drogen und Phytopharmaka mit sedierender Wirkung. Z Phytotherapie 1985; 6:101-9. 2. Bradley PR (ed) Motherwort in: British herbal compendium vol 1. British Herbal Medicine Association 1992:161-2. 3. Czygan FC, Hiller K. Leonuri cardiaca herba In: Wichtl M (ed). Teedrogen und Phytopharmaka 4. Aufl. Wissenschaftliche Verlagsgesellschaft mbH Stuttgart 2002:333-4. (Kommision E) 4. Sweetman SC (ed) Motherwort in: Martindale. The complete drug reference. Thirty-fifth edition. Pharmaceutical Press 2007. <p>dication</p> | Accepted, in principle. See above. |

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| <p>Assessment report</p> <p>4.3 Overall conclusions on clinical pharmacology and efficacy</p> | <p>AESGP</p> | <p>Section 4.3 of the Draft Assessment Report, ends with the following statement: „<i>As specific expressions of symptoms of nervous tension such as cardiac symptoms, climacteric symptoms, hyperthyreosis, or other indications such as anxiety require intervention by a medical doctor for diagnosis, treatment and follow-up, such a differentiation is not appropriate, although a traditional use could be easily extracted from literature.</i>“</p> <p>We would like to point out that <u>climacteric symptoms</u> do not necessarily require intervention by a medical doctor for diagnosis, treatment and follow-up. Climacteric symptoms are a benign, self-limiting condition not resulting in persistent or medically significant disability/incapacity. There is no general warning that women experiencing climacteric symptoms should consult a doctor, because such symptoms could origin from an undetected serious medical condition. In line with this general medical principle, the draft HMPC monograph on <i>Cimicifuga racemosa</i> L. NUTT., rhizome (EMA/HMPC/600717/2007) does not stipulate consultation of a doctor before treatment: “<i>If the symptoms persist during the use of the medicinal product, a doctor or a pharmacist should be consulted. Cimicifuga should not be taken for more than 3 months without medical advice.</i>“</p> <p>This draft monograph reflects the current European regulatory practice, as illustrated by the existing herbal or homeopathic non-prescription medicines on the market indicated for the treatment of mild climacteric symptoms (e.g. <i>Cimicifuga racemosa</i> dry extracts in the U.K.¹, Sweden² or Germany³; homoeopathic preparations in Germany⁴). Intervention of a</p> | <p>Agreed in principle.</p> <p>New wording: “Cardiac complaints are consistently and widely mentioned in the literature and such use may even be reflected by the plant's name. Nervous cardiac complaints were included under the condition that initial diagnosis by a doctor has ruled out any serious condition such as arrhythmia, hyperthyreosis, organic heart diseases, etc.</p> <p>As specific expressions of symptoms of nervous tension such as hyperthyreosis, or other indications such as anxiety may indicate a serious condition and require intervention by a medical doctor for diagnosis, treatment and follow-up, such a differentiation is not appropriate, although a traditional use could be extracted from literature”.</p> |
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¹ Kira® meno film coated tablets,

² Klimadynon® tablets

³ Remifemin® tablets

⁴ Bomaklim Complex; Cefakliman®; Klimaktoplant® N, Sepia comp

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| | | <p>medical doctor is only required, if a prescription medicine is to be used, like hormone replacement therapy.</p> <p>With reference to our comment on the draft monograph, the mention of cardiac symptoms should also be qualified. Cardiac symptoms associated with nervous tension can fall in the remit of collaborative care i.e. be self-managed after an initial diagnosis by a doctor has cleared any possible underlying serious cause and/or pathology requiring doctor's supervision.</p> <p>Hence, we would like to ask to reword this sentence as follows:</p> <p><i>„As specific expressions of symptoms of nervous tension such as hyperthyreosis, or other indications such as anxiety require intervention by a medical doctor for diagnosis, treatment and follow-up, such a differentiation is not appropriate, although a traditional use could be easily extracted from literature. Cardiac symptoms might be included after initial diagnosis by a doctor.</i></p> | |
| | BPI | <p>In chapter 4.3.the draft report reads: „As specific expressions of symptoms of nervous tension such as cardiac symptoms, climacteric symptoms, hyperthyreosis, or other indications such as anxiety require intervention by a medical doctor for diagnosis, treatment and follow-up, such a differentiation is not appropriate, although a traditional use could be easily extracted from literature.“</p> <p>We ask to change the wording into</p> <p><i>„As specific expressions of symptoms of nervous tension such as cardiac symptoms, hyperthyreosis, or other indications such as anxiety require intervention by a medical doctor for diagnosis, treatment and follow-up, such a differentiation is not</i></p> | Agreed in principle. See above. |

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| | | <p><i>appropriate, although a traditional use could be easily extracted from literature."</i></p> <p><i>Rationale</i></p> <p>Climacteric symptoms do not necessarily require intervention by a medical doctor for diagnosis, treatment and follow-up. Climacteric symptoms are a benign, self-limiting condition not resulting in persistent or medically significant disability/incapacity. There is no general warning that women experiencing climacteric symptoms should consult a doctor, because such symptoms could origin from an undetected serious medical condition.</p> | |
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