



London, 5 July 2007
Doc. Ref. EMEA/HMPC/513617/2006

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

DRAFT

COMMUNITY HERBAL MONOGRAPH ON *HUMULUS LUPULUS* L., FLOS

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	January 2007 May 2007 July 2007
ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION	5 July 2007
END OF CONSULTATION (DEADLINE FOR COMMENTS)	15 October 2007
REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	
ADOPTION BY HMPC	

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Fax: +44 20 75 23 70 51

KEYWORDS	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Humulus lupulus</i> L.; Lupuli flos; hop strobiles
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COMMUNITY HERBAL MONOGRAPH ON *HUMULUS LUPULUS* L., FLOS

1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION^{1,2}

<u>Well-established use</u>	<u>Traditional use</u>
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended</p> <p>i) Herbal substance <i>Humulus lupulus</i> L., flos (hop strobiles)</p> <p>ii) Herbal preparations</p> <ul style="list-style-type: none">- Comminuted herbal substance- Liquid extract (1:1) prepared with ethanol/water 45% v/v- Tincture (1:5) prepared with ethanol/water 60% v/v

3. PHARMACEUTICAL FORM

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

¹ The material complies with the Ph. Eur. monograph (ref. 01/2005:1222).

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

<u>Well-established use</u>	<u>Traditional use</u> Traditional herbal medicinal product for relief of mild symptoms of mental stress and to aid sleep. The product is a traditional herbal medicinal product for use in specified indication exclusively based upon long-standing use.
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4.2. Posology and method of administration

<u>Well-established use</u>	<u>Traditional use</u> Posology <i>Adolescents over 12 years of age, adults, elderly</i> Single dose <ul style="list-style-type: none">- 0.5 g dried inflorescences (e.g. as powdered herbal substance)- 0.5-2.0 g dried inflorescences for preparation of an infusion For relief of mild symptoms of mental stress, 0.5-1.0 g, 2-4 times daily To aid sleep, 1.0-2.0 g, a single dose half to one hour before bedtime with an earlier dose during the evening, if necessary <ul style="list-style-type: none">- 0.5-2.0 ml of liquid extract- 1.0-2.0 ml of tincture The use is not recommended in children under 12 years of age (see section 4.4. Special warnings and precautions for use). Duration of use Not to be taken for more than 2 weeks. 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.
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4.3. Contraindications

<u>Well-established use</u>	<u>Traditional use</u> Hypersensitivity to the active substance.
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4.4. Special warnings and precautions for use

<u>Well-established use</u>	<u>Traditional use</u> The use is not recommended in children under 12 years of age due to lack of adequate data. For tinctures and extracts 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.
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4.5. Interactions with other medicinal products and other forms of interaction

<u>Well-established use</u>	<u>Traditional use</u> Concomitant use with synthetic sedatives is not recommended unless advised by a doctor.
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4.6. Pregnancy and lactation

<u>Well-established use</u>	<u>Traditional use</u> Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.
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4.7. Effects on ability to drive and use machines

<u>Well-established use</u>	<u>Traditional use</u> May impair ability to drive and use machines. Affected patients should not drive or operate machinery.
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4.8. Undesirable effects

<u>Well-established use</u>	<u>Traditional use</u> None known. If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.
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4.9. Overdose

<u>Well-established use</u>	<u>Traditional use</u> No case of overdose has been reported.
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5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

<u>Well-established use</u>	<u>Traditional use</u> Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.
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5.2. Pharmacokinetic properties

<u>Well-established use</u>	<u>Traditional use</u> Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.
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5.3. Preclinical safety data

<u>Well-established use</u>	<u>Traditional use</u> 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 genotoxicity were not performed for water extracts. Tests on water/ethanolic extracts were negative. Tests on reproductive toxicity and carcinogenicity have not been performed.
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6. PHARMACEUTICAL PARTICULARS

<u>Well-established use</u>	<u>Traditional use</u> Not applicable.
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7. DATE OF COMPILATION/LAST REVISION

5 July 2007