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Evaluation of Medicines for Human Use

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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

FINAL

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
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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]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended i) Herbal substance *Humulus lupulus* L., flos (hop strobile) ii) Herbal preparations A) Comminuted[3] herbal substance B) Liquid extract (1:1) prepared with ethanol/water 45% v/v C) Liquid extract (1:10) prepared with sweet wine D) Tincture (1:5) prepared with ethanol/water 60% v/v

3. PHARMACEUTICAL FORM

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

[1] The material complies with the Eur. Ph. monograph (ref. no : 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
[3] Comminuted is understood to include powdered herbal substance.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Well-established use	Traditional use
	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 indications exclusively based on long standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology *Adolescents over 12 years of age, adults, elderly* Single dose A) 0.5-1.0 g dried inflorescences (e.g. as comminuted herbal substance) 0.5-2.0 g dried inflorescences for preparation of an infusion B) 0.5-2.0 ml of liquid extract (1:1), ethanol 45% v/v C) Liquid extract (1:10), sweet wine corresponding to 1.25 g herbal substance. D) 2.0-4.0 ml of tincture (1:5), ethanol/water 60% v/v For relief of mild symptoms of mental stress, a single dose up to 4 times daily. To aid sleep, 1 to 2 single doses half to one hour before bedtime with an earlier dose during the evening, if necessary. 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** If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be should consulted. **Method of administration** Oral use.

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 is not recommended in children under 12 years of age due to lack of adequate data. For tinctures and 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 the ability to drive and use machines

Well-established use	Traditional use
	May impair ability to drive and use machines. Affected patients should not drive or operate machinery.

4.8. Undesirable effects

Well-established use	Traditional use
	None known. If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.

4.9. Overdose

Well-established use	Traditional use
	No case of overdose has been reported.

4. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Well-established use	Traditional use
	Not required as per Article 16(c)(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. Adequate tests on genotoxicity were not performed. Tests on reproductive toxicity and carcinogenicity have not been performed.

6. PHARMACEUTICAL PARTICULARS

Well-established use	Traditional use
	Not applicable.

7. DATA OF COMPILATION/LAST REVISION

11 July 2008