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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Humulus lupulus* L., flos

Final

Initial assessment	
Discussion in Working Party on Community monographs and Community list (MLWP)	January 2007 May 2007 July 2007
Adoption by Committee on Herbal Medicinal Products (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)	January 2008 March 2008 May 2008
Adoption by Committee on Herbal Medicinal Products (HMPC) Monograph (EMEA/HMPC/513617/2006) AR (EMEA/HMPC/513618/2006) List of references (EMEA/HMPC/262640/2007) Overview of comments received during the public consultation (EMEA/HMPC/ 577303/2007) HMPC Opinion (EMEA/HMPC/591021/2007)	8 May 2008
First systematic review	
Discussion in Working Party on Community monographs and Community list (MLWP)	November 2013 January 2014 March 2014
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	N/A
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Adoption by Committee on Herbal Medicinal Products (HMPC)	6 May 2014

A search for the versions adopted in May 2008 can be made via the EMA document search function, using the documents' reference number, at:

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Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Humulus lupulus* L.; Lupuli flos; hop strobiles

BG (bălgarski): Хмел, съцветие	IT (italiano): Luppolo fiore
CS (čeština): chmelová šištice	LT (lietuvių kalba): Apynių spurgai
DA (dansk): Humlekopper	LV (latviešu valoda): Apiņa ziedi
DE (Deutsch): Hopfenzapfen	MT (malti): Fjura tal-Lupulu
EL (elliniká): Στρόβιλος λυκίσκου- άνθος λυκίσκου	NL (nederlands): Hopbellen
EN (English): Hop Strobile	PL (polski): Szyszka chmielu
ES (espanol): Lúpulo, flor de	PT (português): Lúpulo, cone
ET (eesti keel): humalakäbi	RO (română): conuri de hamei
FI (suomi): humala, kukka	SK (slovenčina): Chmeľový kvet
FR (français): Houblon (cône de)	SL (slovenščina):cvet navadnega hmelja
HU (magyar): Komlótoboz	SV (svenska): Humlekotte
HR (Croatian):cvijet uzgojenog hmelja	*IS (íslenska)*: *NO (norsk):* Humle

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 *Humulus lupulus* L., flos (hop strobile) i) Herbal substance Not applicable ii) Herbal preparations a) Comminuted herbal substance b) Powdered herbal substance c) Liquid extract (DER 1:1) extraction solvent ethanol 45% v/v d) Liquid extract (DER 1:10) extraction solvent sweet wine e) Tincture (ratio of herbal substance to extraction solvent 1:5) extraction solvent ethanol 60% v/v f) Dry extract (DER 4-5:1) extraction solvent methanol 50% v/v

3. Pharmaceutical form

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

[1]The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.
[2]The material complies with the Ph. Eur. monograph *(ref.:* 1/2011:1222)

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[3]

Well-established use	**Traditional use**
	Posology *Adolescents, adults, elderly* <u>In mental stress</u> *Single dose:* a) Herbal tea: 500 mg of comminuted herbal substance in 150-200 ml of boiling water as a herbal infusion, up to 4 times daily. b) Powdered herbal substance: 400 mg two times daily for adults and 200 mg two times daily for adolescents. c) Liquid extract (1:1): 0.5-2.0 ml, up to 3 times daily. d) Liquid extract (1:10): 19 g, 2-3 times daily. e) Tincture (1:5): 1-2 ml, up to 3 times daily. f) Dry extract (4-5:1): 125 mg, 2-3 times daily. <u>To aid sleep</u> *Single dose:* a) Herbal tea: 500-1000 mg of comminuted herbal substance in 150-200 ml of boiling water as an herbal infusion 30 - 60 min before bedtime. b) Powdered herbal substance: 800–2000 mg, 30-60 minutes before bedtime.

[3] For guidance on herbal substance/herbal preparation administered as herbal tea or as infusion/decoction/macerate preparation, please refer to the HMPC 'Glossary on herbal teas' (EMA/HMPC/5829/2010 Rev.1).

Well-established use	**Traditional use**
	c) Dry extract (4-5:1): 125-250 mg, 60 min before bedtime. The use in children under 12 years of age is not recommended (see section 4.4. Special warnings and precautions for use). **Duration of use** If the symptoms persist longer than two weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be 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 in children under 12 years of age has not been established due to lack of adequate data. If the symptoms worsen during the use of the medicinal product, a doctor or qualified health care practitioner should be consulted. 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. Fertility, 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. No fertility data are available.

4.7. Effects on 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.

5. Pharmacological properties

5.1. Pharmacodynamic properties

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

6. Pharmaceutical particulars

Well-established use	**Traditional use**
	Not applicable.

7. Date of compilation / last revision

6 May 2014