EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Lavandula angustifolia* P. Mill., flos

Draft

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BG (bălgarski): Лавандула, цвят	LT (lietuvių kalba):
CS (čeština): levandulový květ	LV (latviešu valoda): Lavandas ziedi
DA (dansk):	MT (malti):
DE (Deutsch): Lavendelblüten	NL (nederlands):
EL (elliniká):	PL (polski): Kwiat lawendy
EN (English): lavender	PT (português):
ES (espanol):	RO (română): floare de levănţică
ET (eesti keel): tähklavendli õis	SK (slovenčina): Levanduľový kvet
FI (suomi):	SL (slovenščina):
FR (français): lavande (fleur de)	SV (svenska): Lavendelblomma
HU (magyar): Levendulavirág	*IS (íslenska)*:
IT (italiano):	*NO (norsk)*: lavendelblomst

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Community herbal monograph on *Lavandula angustifolia* P. Mill., 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 *Lavandula angustifolia* P. Mill., flos (lavender flower) i) Herbal substance As defined in the Ph. Eur. monograph. ii) Herbal preparations a) Comminuted herbal substance b) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 50-60% v/v

3. Pharmaceutical form

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

1 The material complies with the Ph. Eur. monograph (ref.: 01/2008:1534).
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

Well-established use	Traditional use
	Traditional herbal medicinal product for relief of mild symptoms of mental stress and exhaustion and to aid sleep. The product is a traditional herbal medicinal product for use in specified indication exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology *Adolescents, adults and elderly* a) An infusion is made of herbal substance or comminuted herbal substance (approximately 1 to 2 g) in 150 ml of water: 3 times daily b) Tincture Single dose: 2-4 ml, 3 times daily. 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 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(s).

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	The use in children under 12 years of age has not

Well-established use	Traditional use
	been established due to lack of adequate data. If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. For tinctures 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 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. No studies on the effect on the ability to drive and use machines have been performed.

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. Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

27 January 2011