



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 March 2012
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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Lavandula angustifolia* Miller, aetheroleum

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	May 2010 July 2010 November 2010 January 2011
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BG (bългарски): лавандулово масло CS (čeština): levandulová silice DA (dansk): Lavendelolie DE (Deutsch): lavendelöl EL (elliniká): αιθέριο έλαιο λαβαντίδος EN (English): lavender oil ES (español): Lavanda, aceite esencial de ET (eesti keel): tähklavendli eeterlik õli FI (suomi): laventeliöljy FR (français): lavande (huile essentielle de) HU (magyar): levendulaolaj IT (italiano): Lavanda essenza	LT (lietuvių kalba): LV (latviešu valoda): Lavandas ēteriskā eļļa MT (malti): NL (nederlands): lavendelolie PL (polski): Olejek eteryczny lawendowy PT (português): Óleo essencial de alfavema RO (română): ulei volatil de levănțică SK (slovenčina): Levanduľová silica SL (slovenščina): eterično olje prave sivke SV (svenska): lavendelolja IS (íslenska): NO (norsk): lavendelolje
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Community herbal monograph on *Lavandula angustifolia* Miller, aetheroleum

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>Lavandula angustifolia</i> Miller, aetheroleum (lavender oil) i) Herbal substance Not applicable. ii) Herbal preparations Essential oil obtained by steam distillation from the flowering tops of <i>Lavandula angustifolia</i> Miller

3. Pharmaceutical form

Well-established use	Traditional use
	Herbal preparation in liquid dosage form for oral use and as a bath additive. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

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 the specified indication

¹ The material complies with the Ph. Eur. monograph (ref.: 07/2010:1338).

² The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

Well-established use	Traditional use
	exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology <i>Adolescents, adults and elderly</i> - Oral use Daily dose³: 20–80 mg - Use as bath additive 1 to 3 g per full bath once 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. Use as bath additive: recommended temperature of bath: 35–38 °C during 10–20 minutes.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance(s). Full baths are contraindicated in cases of open wounds, large skin injuries, acute skin diseases, high fever, severe infections, severe circulatory disturbances and cardiac insufficiency.

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.

³ It is expected that for the finished product, the amount will be expressed in a number of drops. As this number depends upon the droplet counter and the oil itself, it is up to the applicant to convert the weight in a number of drops.

Well-established use	Traditional use
	If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

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 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. 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. Adequate tests on genotoxicity, carcinogenicity and reproductive toxicity of lavender oil have not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

27 March 2012