



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA/HMPC/278053/2015
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Valeriana officinalis* L., aetheroleum

Final

Initial assessment (as part of <i>Valeriana officinalis</i> L., radix) ¹	
Discussion in Working Party on European Union monographs and list (MLWP)	May 2005 June 2005 September 2005
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	20 September 2005
End of consultation (deadline for comments)	31 January 2006
Re-discussion in MLWP	May 2006 July 2006
Adoption by HMPC Monograph (EMA/HMPC/340719/2005) AR (EMA/HMPC/167391/2006) List of references (EMA/HMPC/167392/2006) Overview of comments received during the public consultation (EMA/HMPC/50774/2006) HMPC Opinion (EMA/HMPC/313368/2006)	13 July 2006
First systematic review	
Discussion in MLWP	January 2015 March 2015 May 2015
Adopted by HMPC for release for consultation	7 July 2015
Start of public consultation	22 July 2015
End of consultation (deadline for comments)	31 October 2015
Re-discussion in MLWP	November 2015
Adoption by HMPC	2 February 2016

¹ The herbal preparation *Valerianae aetheroleum* was included in the monograph *Valerianae radix* as valerian root oil, adopted on 13 July 2006. However, during the revision of *Valerianae radix*, a standalone monograph was established for *Valerianae aetheroleum*.



Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; <i>Valeriana officinalis</i> L., aetheroleum; Valerianae aetheroleum; Valerian essential oil	
BG (bulgarski): масло от Валериана	LT (lietuvių kalba): Valerijonų eterinis aliejus	
CS (čeština): kozlíková silice	LV (latviešu valoda): Baldriāna ēteriskā eļļa	
DA (dansk): Baldrianolie	MT (Malti): żejt volatili tal-Valerjana	
DE (Deutsch): Baldrianöl	NL (Nederlands): Valeriaan, etherische olie	
EL (elliniká): Αιθέριο έλαιο βαλεριανής	PL (polski): olejek z korzenia kozłka lekarskiego	
EN (English): Valerian essential oil	PT (português): Óleo essencial de valeriana	
ES (español): Valeriana, aceite esencial de	RO (română): ulei volatil de valeriana	
ET (eesti keel): palderjaniõli	SK (slovenčina): Silica valeriany	
FI (suomi): rohtovirmajuuriöljy	SL (slovenščina): eterično olje zdravilne špajke	
FR (français): Valériane (huile essentielle de)	SV (svenska): Vänderotolja	
HR (hrvatski): odoljenovo eterično ulje	IS (islenska):	
HU (magyar): macskagyökér olaj	NO (norsk): Valerianaolje	
IT (italiano): Valeriana essenza		

European Union herbal monograph on *Valeriana officinalis* L., aetheroleum

1. Name of the medicinal product

To be specified for the individual finished product.

2. Qualitative and quantitative composition^{2, 3}

Well-established use	Traditional use
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended</p> <p><i>Valeriana officinalis</i> L., aetheroleum (Valerian essential oil)</p> <p>i) Herbal substance Not applicable</p> <p>ii) Herbal preparations Essential oil</p>

3. Pharmaceutical form

Well-established use	Traditional use
	<p>Herbal preparations in liquid dosage forms for oral use.</p> <p>Herbal preparations in liquid dosage forms for use as bath additive.</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

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

³ The material complies with the German Pharmacopoeia 6 (DAB 6).

4. Clinical particulars

4.1. Therapeutic indications

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

4.2. Posology and method of administration

Well-established use	Traditional use
	<p>Posology</p> <p><i>Adolescents, adults and elderly</i></p> <p>Oral Use</p> <p>Single dose: 15 mg</p> <p>For relief of mild symptoms of mental stress up to 3 times daily.</p> <p>To aid sleep, two single doses half to one hour before bedtime.</p> <p>Use as bath additive</p> <p>Single dose: 240-400 mg for a full bath, up 3-4 times per week</p> <p>The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p>Duration of use</p> <p>If symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Method of administration</p> <p>Oral use</p> <p>Use as bath additive. Temperature: 34-37°C duration of bath 10-20 minutes.</p>

4.3. Contraindications

Well-established use	Traditional use
	<p>Hypersensitivity to the active substance.</p> <p>Use as bath additive</p> <p>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.</p>

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>The use in children under 12 years of age has not been established due to lack of adequate data.</p> <p>If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p>

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
	<p>Safety during pregnancy and lactation has not been established. In the absence of sufficient data, use during pregnancy and lactation is not recommended.</p> <p>No fertility data available.</p>

4.7. Effects on ability to drive and use machines

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

4.8. Undesirable effects

Well-established use	Traditional use
	<p>Oral use</p> <p>Gastrointestinal symptoms (e.g. nausea, abdominal cramps) may occur after ingestion of valerian root preparations. The frequency is not known.</p> <p>If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.</p> <p>Use as bath additive</p> <p>None known</p> <p>If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.</p>

4.9. Overdose

Well-established use	Traditional use
	<p>Oral use</p> <p>Valerian root at a dose of approximately 20 g caused symptoms, such as fatigue, abdominal cramp, chest tightness, light-headedness, hand tremor and mydriasis, which disappeared within 24 hours. If symptoms arise, treatment should be supportive.</p> <p>Use as bath additive</p> <p>No case of overdose has been reported.</p>

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
	Adequate 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

02 February 2016