



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

7 July 2015  
EMA/HMPC/150849/2015  
Committee for Herbal Medicinal Products (HMPC)

## European Union list entry on *Valeriana officinalis* L., radix Draft

Discussion in Working Party on European Union monographs and European Union list (MLWP)	January 2015 March 2015 May 2015
Adopted by Committee on Herbal Medicinal Products (HMPC) for release for consultation	7 July 2015
Start of public consultation	22 July 2015
End of consultation (deadline for comments). Comments should be provided using this <a href="#">template</a> to <a href="mailto:hmpc.secretariat@ema.europa.eu">hmpc.secretariat@ema.europa.eu</a>	31 October 2015
Rediscussion in MLWP	
Adoption by HMPC	

<b>Keywords</b>	Herbal medicinal products; HMPC; European Union list of herbal substance(s), preparation(s) and combinations thereof for use in traditional herbal medicinal products; traditional use; <i>Valeriana officinalis</i> L., radix; Valerianae radix; valerian root
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## Entry to list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products on *Valeriana officinalis* L., radix

<b>Scientific name of the plant</b>	
<i>Valeriana officinalis</i> L.	
<b>Botanical family</b>	
Valerianaceae	
<b>Herbal substance</b>	
Not applicable.	
<b>Common name of herbal substance in all EU official languages</b>	
BG (bulgarski): Валериана, корен CS (čeština): kozlíkový kořen DA (dansk): Baldrianrod DE (Deutsch): Baldrianwurzel EL (elliniká): Ρίζα βαλεριανής EN (English): Valerian root ES (español): Valeriana, raíz de ET (eesti keel): palderjanijuur FI (suomi): rohtovirmajuuri, juuri FR (français): Valériane (racine de) HR (hrvatski): odoljenov korijen HU (magyar): Macskagyökér IT (italiano): Valeriana radice	LT (lietuvių kalba): Valerijonų šaknys LV (latviešu valoda): Baldriāna saknes MT (Malti): Għerq tal-Valerjana NL (Nederlands): Valeriaanwortel PL (polski): Korzeń kozłka PT (português): Valeriana, raiz RO (română): rădăcină de valeriană SK (slovenčina): Koreň valeriány SL (slovenščina): korenina zdravilne špajke SV (svenska): Vänderot, rot IS (íslenska): NO (norsk): Valerianarot
<b>Herbal preparation(s)</b>	
a) Comminuted herbal substance b) Powdered herbal substance c) Expressed juice from fresh root (1:0.60-0.85) d) Dry extract (DER 4-6:1), extraction solvent: water e) Liquid extract (DER 1:4-6), extraction solvent: water f) Dry extract (DER 4-7:1), extraction solvent methanol 45% (V/V) g) Dry extract (DER 5.3-6.6:1), extraction solvent: methanol 45% (m/m) h) Liquid extract (DER 1:7-9), extraction solvent: sweet vine i) Dry extract (DER 4-5:1), extraction solvent: ethanol 35% (m/m) j) Liquid extract (DER 1:1), extraction solvent: ethanol 60% (V/V) k) Tincture (ratio of herbal substance to extraction solvent 1:8), extraction solvent ethanol 60% (V/V) l) Tincture (ratio of herbal substance to extraction solvent 1:10), extraction solvent ethanol 56% m) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent: ethanol 70% (V/V)	

n) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 60-80% (V/V)
o) Dry extract (DER 5.5-7.4:1), extraction solvent: ethanol 70-90% (V/V)
<b>European Pharmacopoeia monograph reference</b>
Valerianae radix, Ph. Eur. monograph 0453
<b>Indication(s)</b>
Traditional herbal medicinal product used for relief of mild symptoms of mental stress and to aid sleep.  The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.
<b>Type of tradition</b>
European
<b>Specified strength</b>
Please see 'Specified posology'.
<b>Specified posology</b>
<i>Adolescents, adults and elderly</i>  <b>Oral Use</b>  a) single dose: 0.3-3 g For relief of mild symptoms of mental stress up to 3 times daily. To aid sleep, a single dose half to one hour before bedtime with an earlier dose during the evening if necessary. Herbal tea: 0.3-3 g of the comminuted herbal substance in 150 ml of boiling water as a herbal infusion  b) single dose: 0.76-2.0 g, up to 3 times daily  c) single dose: 10 ml For relief of mild symptoms of mental stress up to 3 times daily. To aid sleep, a single dose half to one hour before bedtime with an earlier dose during the evening if necessary.  d) single dose: 420 mg For relief of mild symptoms of mental stress up to 3 times daily. To aid sleep, a single dose half to one hour before bedtime with an earlier dose during the evening if necessary.  e) single dose: 20 ml For relief of mild symptoms of mental stress up to 3 times daily. To aid sleep, a single dose half to one hour before bedtime.  f) single dose: 144-288 mg For relief of mild symptoms of mental stress up to 4 times daily. To aid sleep, a single dose half to one hour before bedtime with an earlier dose during the evening if necessary.

<p>g) single dose: 380-570 mg For relief of mild symptoms of mental stress up to 3 times daily. To aid sleep, a single dose half to one hour before bedtime with an earlier dose during the evening if necessary.</p> <p>h) single dose: 10 ml, up to 3 times daily</p> <p>i) single dose: 427-599 mg, up to 3 times daily</p> <p>j) single dose: 0.3-1.0 ml, up to 3 times daily</p> <p>k) single dose: 4-8 ml, up to 3 times daily</p> <p>l) single dose: 0.84 ml For relief of mild symptoms of mental stress 3-5 times daily. To aid sleep, a single dose half an hour before bedtime.</p> <p>m) single dose: 1.5 ml (mental stress), 3 ml (to aid sleep) For relief of mild symptoms of mental stress up to 3 times daily. To aid sleep, a single dose half an hour before bedtime.</p> <p>n) single dose: 10 ml, up to 3 times daily</p> <p>o) single dose: 322-441.35 mg, up to 3 times daily</p> <p><b>Use as bath additive</b></p> <p>a) single dose: 100 g for a full bath, up to 1 bath daily</p>
<p><b>Route of administration</b></p>
<p>Oral use.</p> <p>Bath additive.</p>
<p><b>Duration of use or any restrictions on the duration of use</b></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><b>Any other information necessary for the safe use</b></p>
<p><b>Contraindications</b></p> <p>Hypersensitivity to the active substance.</p> <p><b>Use as bath additive</b></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> <p><b>Special warnings and precautions for use</b></p> <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> <p>For tinctures and extracts containing ethanol, the appropriate labelling for ethanol, taken from the</p>

'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included

#### **Interactions with other medicinal products and other forms of interaction**

None reported.

#### **Fertility, pregnancy and lactation**

Safety during pregnancy and lactation has not been established. In the absence of sufficient data, use during pregnancy and lactation is not recommended.

No fertility data available.

#### **Effects on ability to drive and use machines**

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

#### **Undesirable effects**

##### ***Oral use***

Gastrointestinal symptoms (e.g. nausea, abdominal cramps) may occur after ingestion of valerian root preparations. The frequency is not known.

If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.

##### ***Use as bath additive***

None known.

If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.

#### **Overdose**

##### ***Oral use***

Valerian root at a dose of approximately 20 g caused symptoms, such as fatigue, abdominal cramp, chest tightness, lightheadedness, hand tremor and mydriasis, which disappeared within 24 hours. If symptoms arise, treatment should be supportive.

##### ***Use as bath additive***

No case of overdose has been reported.

#### **Pharmaceutical particulars [If necessary]**

Not applicable.

#### **Pharmacological effects or efficacy plausible on the basis of long-standing use and experience [If necessary for the safe use of the product]**

Not applicable.

**Date of compilation/Last revision**

7 July 2015