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

Draft

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
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<tbody>
<tr>
<td>Adopted by Committee on Herbal Medicinal Products (HMPC) for release for consultation</td>
<td>7 July 2015</td>
</tr>
<tr>
<td>Start of public consultation</td>
<td>22 July 2015</td>
</tr>
<tr>
<td>End of consultation (deadline for comments). Comments should be provided using this template to <a href="mailto:hmpc.secretariat@ema.europa.eu">hmpc.secretariat@ema.europa.eu</a></td>
<td>31 October 2015</td>
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<tr>
<td>Rediscussion in MLWP</td>
<td></td>
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<tr>
<td>Adoption by HMPC</td>
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**Keywords**

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; *Valeriana officinalis* L., radix; Valerianeae radix; valerian root
## Entry to list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products on *Valeriana officinalis* L., radix

<table>
<thead>
<tr>
<th>Scientific name of the plant</th>
<th>Valeriana officinalis L.</th>
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</thead>
<tbody>
<tr>
<td><strong>Botanical family</strong></td>
<td>Valerianaceae</td>
</tr>
<tr>
<td><strong>Herbal substance</strong></td>
<td>Not applicable.</td>
</tr>
<tr>
<td><strong>Common name of herbal substance in all EU official languages</strong></td>
<td></td>
</tr>
<tr>
<td>BG (bulgarski): Валериана, корен</td>
<td>LT (lietuvų kalba): Valerijonų šaknys</td>
</tr>
<tr>
<td>CS (čeština): kozlíkový kořen</td>
<td>LV (latviešu valoda): Baldriāna saknes</td>
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<tr>
<td>DA (dansk): Baldrianrod</td>
<td>MT (Malti): Gherq tal-Valeriana</td>
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<tr>
<td>DE (Deutsch): Baldrianwurzel</td>
<td>NL (Nederlands): Valeriaanwortel</td>
</tr>
<tr>
<td>EL (elliniká): Ρίζα βαλεριανής</td>
<td>PL (polski): Korzeń kozlka</td>
</tr>
<tr>
<td>EN (English): Valerian root</td>
<td>PT (português): Valeriana, raiz</td>
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<tr>
<td>ES (español): Valeriana, raíz de</td>
<td>RO (română): rădăcină de valeriană</td>
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<tr>
<td>ET (eesti keel): palderjanijuur</td>
<td>SK (slovenčina): Koreň valeriány</td>
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<tr>
<td>FI (suomi): rohtovirmajuuri, juuri</td>
<td>SL (slovenščina): korenina zdravilne špajke</td>
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<td>FR (français): Valériane (racine de)</td>
<td>SV (svenska): Vänderot, rot</td>
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<tr>
<td>HR (hrvatski): odoljenov korijen</td>
<td>IS (íslenska):</td>
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<td>HU (magyar): Macskagyökér</td>
<td>NO (norsk): Valerianaarot</td>
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<td>IT (italiano): Valeriana radice</td>
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</tbody>
</table>

### Herbal preparation(s)

- **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)

**European Pharmacopoeia monograph reference**

Valerianae radix, Ph. Eur. monograph 0453

**Indication(s)**

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.

**Type of tradition**

European

**Specified strength**

Please see 'Specified posology'.

**Specified posology**

*Adolescents, adults and elderly*

**Oral Use**

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.
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.

h) single dose: 10 ml, up to 3 times daily

i) single dose: 427-599 mg, up to 3 times daily

j) single dose: 0.3-1.0 ml, up to 3 times daily

k) single dose: 4-8 ml, up to 3 times daily

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.

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.

n) single dose: 10 ml, up to 3 times daily

o) single dose: 322-441.35 mg, up to 3 times daily

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**Use as bath additive**

a) single dose: 100 g for a full bath, up to 1 bath daily

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**Route of administration**

Oral use.
Bath additive.

**Duration of use or any restrictions on the duration of use**

If symptoms persist during the use of the medicinal product, a doctor or a qualified health care 
practitioner should be consulted.

**Any other information necessary for the safe use**

**Contraindications**

Hypersensitivity to the active substance.

**Use as bath additive**

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.

**Special warnings and precautions for 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 a qualified health care 
practitioner should be consulted.

For tinctures and extracts containing ethanol, the appropriate labelling for ethanol, taken from the
### 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