



European Medicines Agency  
Evaluation of Medicines for Human Use

London, 24 October 2005  
Doc. Ref. EMEA/HMPC/340779/2005

**COMMITTEE ON HERBAL MEDICINAL PRODUCTS  
(HMPC)**

**DRAFT**

**ENTRY TO LIST OF HERBAL SUBSTANCES, PREPARATIONS AND  
COMBINATIONS THEREOF FOR USE IN  
TRADITIONAL HERBAL MEDICINAL PRODUCTS:  
VALERIAN ROOT (VALERIANA, RADIX)**

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| <b>DISCUSSION IN THE DRAFTING GROUP ON SAFETY &amp;<br/>EFFICACY</b> | May 2005<br>June 2005<br>September 2005 |
| <b>ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION</b>                 | September 2005                          |
| <b>END OF CONSULTATION (DEADLINE FOR COMMENTS )</b>                  | 31 January 2006                         |

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| <b>KEYWORDS</b> | Herbal medicinal products; HMPC; List of herbal substances, preparations and combinations thereof; traditional use. |
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| Scientific name of the plant                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                       |
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| <i>Valeriana officinalis</i> L.                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                       |
| Botanical family                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                       |
| Valerianaceae                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                       |
| Common name in all EU official languages                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                       |
| ES (español): raíz de Valeriana; hierba de los gatos<br>CS (ceština): kozlíkový kořen<br>DA (dansk): Valerianerod<br>DE (Deutsch): Baldrian<br>ET (eesti keel): Palderjani juur<br>EL (elliniká):<br>EN (English): Valerian root<br>FR (français): racine de Valériane<br>IT (italiano): Valeriana radice<br>LV (latviešu valoda): baldriāna saknes<br>LT (lietuviu kalba):<br>HU (magyar): macskagyökér | MT (Malti): Gherq tal-Valerjana<br>NL (Nederlands): valeriaanwortel<br>PL (polski): korzeń kozłka<br>PT (português): Raiz de Valeriana<br>SK (slovenčina):<br>SL (slovenscina): zdravilna špajka<br>FI (suomi): rohtovirmajuuri<br>SV (svenska): valerianarot<br>IS (islenska):<br>NO (norsk): Legevendelrot<br>BG (bulgarski):<br>RO (romana): radacina de valeriana |
| Herbal preparation(s)                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                       |
| Dried Valerian root<br>Fresh plant juice<br>Valerian root oil                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                       |
| European Pharmacopoeia monograph reference                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                       |
| Valerianae radix (01/2005:0453)                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                       |
| Traditional use                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                       |
| Traditional herbal medicinal product for support of mental relaxation and normal sleep exclusively based on long-standing use.                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                       |
| Specified strength                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                       |
| Please see 'Specified posology'                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                       |
| Specified posology                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                       |
| <p><i>Adolescents over 12 years of age, adults, elderly</i></p> <p>Single dose:<br/>0.3 to 1 g dried Valerian root (e.g. as powdered drug or as herbal tea, according to British Herbal Pharmacopoeia, 1976).</p>                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                       |

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| <p>15 ml of fresh plant juice<br/>15 mg of Valerian root oil</p> <p>For relaxation up to 3 times daily<br/>To aid sleep, a single dose half to one hour before bedtime with an earlier dose during the evening if necessary.</p> <p>Maximum daily dose: 4 single doses.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Route of administration</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Oral use                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Duration of use</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| To achieve optimal efficacy, continued use over 2 - 4 weeks is recommended.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Pharmacological effects or efficacy plausible on the basis of long-standing use and experience</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Sedative and anxiolytic effect plausible on the basis of long-standing use and experience.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Any other information necessary for the safe use</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <p><b>Contraindications</b><br/>Patients with known hypersensitivity to Valerian should not use Valerian root preparations.</p> <p><b>Special warnings and precautions for use</b><br/>Because there is no experience available, use of this product is not recommended in children below the age of 12 years.<br/>If symptoms persist during the use of the medicinal product or if adverse effects not mentioned in the package leaflet occur, a doctor or a qualified health care practitioner should be consulted.</p> <p><b>Interactions with other medicinal products and other forms of interaction</b><br/>Only limited data on pharmacological interactions with other medicinal products are available. Clinically relevant interaction with drugs metabolised by the CYP 2D6 or CYP 3A4 pathway is unlikely.<br/>An additive effect with barbiturates is possible and could result in excessive sedation. Co-medication with barbiturates is therefore not recommended.<br/>Since additive effects with other sedatives cannot be excluded, co-medication is not recommended as a general precaution.<br/>The effect of Valerian preparations may be potentiated by alcohol. Excessive concomitant consumption of alcohol should therefore be avoided.</p> <p><b>Pregnancy and lactation</b><br/>Safety during pregnancy and lactation has not been established definitely. No adverse effects have been reported from the common use of Valerian root as a medicinal product. As a precautionary measure, because of lack of data, use during pregnancy and lactation is not recommended.</p> <p><b>Effects on ability to drive and use machines</b><br/>[Preparation] should not be taken up to 2 hours before driving or operating machinery.</p> <p><b>Undesirable effects</b><br/>Very rarely (<math>\leq 1:10000^1</math>) gastro-intestinal symptoms (e.g. nausea, abdominal cramps) may occur after ingestion of Valerian root preparations.</p> |

<sup>1</sup> Data derived from spontaneous reports

**Any other information necessary for the safe use (continued)****Overdose**

Valerian root at a dose of approximately 20 g caused benign symptoms (fatigue, abdominal cramp, chest tightness, lightheadedness, hand tremor and mydriasis), which disappeared within 24 hours. If symptoms arise, treatment should be supportive. After intake of very high doses of Valerian root over several years (daily consumption corresponding to approximately 30 g of the drug) withdrawal symptoms (delirium) have been reported.