



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Herbal medicine: summary for the public

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### Valerian root

*Valeriana officinalis* L., radix

This is a summary of the scientific conclusions reached by the Committee on Herbal Medicinal Products (HMPC) on the medicinal uses of valerian root. The HMPC conclusions are taken into account by EU Member States when evaluating applications for the licensing of herbal medicines containing valerian root.

This summary is not intended to provide practical advice on how to use medicines containing valerian root. For practical information about using valerian root medicines, patients should read the package leaflet that comes with the medicine or contact their doctor or pharmacist.

#### **What is valerian root?**

Valerian root is the common name for the underground parts of the plant *Valeriana officinalis* L.

The HMPC conclusions only cover valerian root preparations which are obtained by drying and comminuting (reducing into tiny pieces) or powdering the underground parts of the plant, by expressing the juice of the fresh root, and as dry or liquid extracts. Extracts are prepared using a technique to extract compounds by putting the plant material in a solvent (such as ethanol, methanol or water) to dissolve compounds and form a liquid extract. For dry extracts, the solvent is then evaporated off.

Herbal medicines containing comminuted valerian root are usually available as herbal tea to be drunk or as bath additives. The other herbal preparations of valerian root are available in solid or liquid form to be taken by mouth.

Valerian root preparations may also be found in combination with other herbal substances in some herbal medicines. These combinations are not covered in this summary.



## **What are the HMPc conclusions on its medicinal uses?**

The HMPc concluded that a specific valerian root preparation obtained as dry ethanol extract<sup>1</sup> can be used for the relief of mild nervous tension and sleep disorders.

The HMPc also concluded that, on the basis of its long-standing use, the other valerian root preparations described above can be used for relief of mild symptoms of mental stress and to aid sleep.

Valerian root medicines should be used only in adults and adolescents over the age 12 years. A doctor or healthcare practitioner should be consulted if symptoms persist during treatment for mental stress and to aid sleep. When used for the relief of mild nervous tension and sleep disorders, if symptoms persist or worsen after 2 weeks of continued use with the medicine, a doctor should be consulted.

Detailed instructions on how to take valerian root medicines and who can use them can be found in the package leaflet that comes with the medicine.

## **How does valerian root work as a medicine?**

The way valerian root medicines work is not fully known, but from some experiments it is thought that effects on the brain leading to relaxation and sleepiness might play a role.

## **What evidence supports the use of valerian root medicines?**

The HMPc conclusions on the use of a specific valerian root preparation obtained as dry ethanol extract for the relief of mild nervous tension and sleep disorders are based on their 'well-established use'. This means that there are bibliographic data providing scientific evidence of their effectiveness and safety when used in this way, covering a period of at least 10 years in the EU.

The HMPc considered that clinical studies with dry ethanol extracts support its use for relief of mild nervous tension and in sleep disorders. Results showed improvements in the time it takes to fall asleep and sleep quality.

The HMPc conclusions on the use of other valerian medicines for relief of mild symptoms of mental stress and to aid sleep are based on their 'traditional use'. This means that, although there is insufficient evidence from clinical studies, the effectiveness of these herbal medicines is plausible and there is evidence that they have been used safely in this way for at least 30 years (including at least 15 years within the EU). Moreover, the intended use does not require medical supervision.

In its assessment, the HMPc also considered clinical studies involving patients with mild symptoms of mental stress and insomnia (difficulty sleeping). Although a possible effect in these conditions was observed, several shortcomings were identified. Therefore, the HMPc conclusions on these uses of valerian root medicines are based on their long-standing use.

For detailed information on the studies assessed by the HMPc, see the HMPc assessment report.

## **What are the risks associated with valerian root medicines?**

Side effects have been reported with valerian root. These include nausea and abdominal cramps.

Patients with open wounds, skin problems, high fever, severe infections and severe heart and circulation problems should not have baths with valerian root medicines.

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<sup>1</sup> Dry extract (DER 3-7.4:1), extraction solvent: ethanol 40-70% (V/V). DER or drug extract ratio is the ratio between the amount of herbal substance used and the quantity of extract obtained.

Further information on the risks associated with valerian root medicines, including the appropriate precautions for their safe use, can be found in the monograph under the tab 'All documents' on the Agency's website: [ema.europa.eu/Find medicine/Herbal medicines for human use](http://ema.europa.eu/Find%20medicine/Herbal%20medicines%20for%20human%20use).

## **How are valerian root medicines approved in the EU?**

Any applications for the licensing of medicines containing valerian root have to be submitted to the national authorities responsible for medicinal products, which will assess the application for the herbal medicine and take into account the scientific conclusions of the HMPC.

Information on the use and licensing of valerian root medicines in EU Member States should be obtained from the relevant national authorities.

## **Other information about valerian root medicines**

Further information on the HMPC assessment of valerian root medicines, including details of the Committee's conclusions, can be found under the tab 'All documents' on the Agency's website: [ema.europa.eu/Find medicine/Herbal medicines for human use](http://ema.europa.eu/Find%20medicine/Herbal%20medicines%20for%20human%20use). For more information about treatment with valerian root medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.