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Valerian root and hop strobile

Valeriana officinalis L., radix and *Humulus lupulus* L., flos

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

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

What is valerian root and hop strobile?

Valerian root is the common name for the underground parts of the plant *Valeriana officinalis* L. and hop strobile is the common name for the flowers of the plant *Humulus lupulus* L.

The HMPC conclusions only cover valerian root and hop strobile preparations that are obtained by putting the plant material in a solvent (such as ethanol or methanol) to dissolve compounds and form a liquid extract. In some cases the solvent is then partially evaporated to obtain a dry extract.

Herbal medicines containing these valerian root and hop strobile preparations are usually available in solid or liquid forms to be taken by mouth.

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

What are the HMPC conclusions on their medicinal uses?

The HMPC concluded that certain valerian root and hop strobile preparations can be used for the relief of sleep disorders.

The HMPC also concluded that other valerian root and hop strobile preparations can be used for relief of mild symptoms of mental stress and to aid sleep, based on the long-standing use of these medicines.



Valerian root and hop strobile medicines should only be used in adults and adolescents over the age of 12 years. If symptoms last or worsen after 4 weeks of taking the medicine for relief of sleep disorders, a doctor should be consulted. If symptoms last or worsen after 4 weeks of taking the medicine for relief of mild symptoms of mental stress and to aid sleep, a doctor or healthcare practitioner should be consulted. Detailed instructions on how to take valerian root and hop strobile medicines and who can use them can be found in the package leaflet that comes with the medicine.

How do valerian root and hop strobile work as a medicine?

The way valerian root works is not fully known, but based on some experimental work it is thought that effects on the brain leading to relaxation and sleepiness might play a role. It is not known whether hop strobile acts either as a mild sedative independently or increases the effect of valerian root to aid sleep.

What evidence supports the use of valerian root and hop strobile medicines?

The HMPC conclusions on the use of these valerian root and hop strobile medicines for the relief of 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.

In its assessment, the HMPC considered various small clinical studies in patients with sleeping disorders and insomnia involving valerian root and hop strobile medicines. The available evidence from valerian root medicines and hop strobile medicines given alone was also considered.

The HMPC conclusions on the use of these valerian root and hop strobile 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 trials, 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 other clinical studies on sleep. However, firm conclusions could not be drawn because the studies had shortcomings such as small numbers of patients, limited information on the preparations used, involvement of healthy people and poor study design. Therefore, the HMPC conclusions on the use of these valerian root and hop strobile 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 and hop strobile medicines?

Gut symptoms may occur such as nausea and tummy cramps. The frequency is not known.

Further information on the risks associated with these valerian root and hop strobile medicines, including the appropriate precautions for their safe use, can be found in the monograph which is published on the Agency's website under the section

'Documents': ema.europa.eu/medicines/herbal/valerian-root-hop-strobile.

How are valerian root and hop strobile medicines approved in the EU?

Any applications for the licensing of medicines containing valerian root and hop strobile 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 and hop strobile medicines in EU Member States should be obtained from the relevant national authorities.

Other information about valerian root and hop strobile medicines

Further information on the HMPC assessment of valerian root and hop strobile medicines, including details of the Committee's conclusions, can be found in the section 'Documents' on the Agency's website: ema.europa.eu/medicines/herbal/valerian-root-hop-strobile. For more information about treatment with valerian root and hop strobile medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.