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Committee on Herbal Medicinal Products (HMPC)

Assessment Report Summary for the Public (ARSP)

Valerian root

Valeriana officinalis L., radix

Other names

BG (bulgarski): Валериана, корен	LT (lietuvių kalba): Valerijonų šaknys
CS (čeština): kozlíkový kořen	LV (latviešu valoda): Baldriāna sakne
DA (dansk): Baldrianrod	MT (Malti): gherq tal-valerjana
DE (Deutsch): Baldrianwurz	NL (Nederlands): Valeriaanwortel
EL (elliniká): βαλεριανής ρίζα	PL (polski): Korzeń kozłka
EN (English): Valerian root	PT (português): valeriana, raiz
ES (español): valeriana, raíz de	RO (română): rădăcină de valeriană
EE (eesti keel): palderjanijuur	SK (slovenčina): koreň valerjány
FI (suomi): rohtovirmajuuri, juuri	SL (slovenščina): korenina zdravilne špajke
FR (français): valériane (racine de)	SV (svenska): vänderot, rot
HR (hrvatski): odoljenov korijen	IS (íslenska):
HU (magyar): macskagyökér	NO (norsk): valerianarot
IT (italiano): Valeriana radice	



Introduction

This is a summary of the scientific conclusions reached by the Committee on Herbal Medicinal Products (HMPC) on the medicinal uses of Valerian root. It summarises the Committee's recommendations on the use 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. When a Member State authorises a medicine containing Valerian root, detailed instructions on how to take it will be available in the package leaflet that comes with medicine.

The information in this summary report concerns Herbal medicinal products containing Valerian root which are only authorised when they comply with the strict pharmaceutical quality and other requirements for herbal medicinal products. They are approved by the competent authorities to be placed on the market as medicinal products. Other products, like food, food supplements, cosmetic products or medical devices do not follow the same criteria and regulatory requirements as medicinal products and are excluded from this summary.

What is Valerian root and what do Valerian herbal medicines contain?

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

Medicinal products with Valerian contain the comminuted (reducing into tiny pieces) or powdered dried root, the juice of the fresh root, and the dry or liquid extracts of the root. Extracts are obtained by putting the plant material in a solvent (such as ethanol or methanol) to dissolve compounds and form a liquid extract. The solvent is then completely evaporated to obtain a dry extract.

Herbal medicines containing comminuted Valerian root are usually available as herbal tea to be drunk, as solid or liquid form to be taken by mouth, or as bath additive.

What are the medicinal uses of Valerian root?

A Valerian root ethanolic dry extract is used for the treatment of the relief of **mild nervous tension and sleep disorders**. This is based on clinical studies which showed efficacy when used this way.

Valerian root preparations have traditional medicinal use for the **relief of mild symptoms of mental stress and to aid to sleep**. Traditional medicinal use means that the use in the specified indication is exclusively based upon long-standing medicinal use and not based on results from clinical studies.

When is it not recommended to use Valerian root?

You can find detailed instructions on how to take Valerian root medicines and who can use them in the package leaflet that comes with the medicine.

Do not use Valerian root medicines:

- for children under **12 years** of age.
- when you are **pregnant** or if you **breast feed** your child.

Do not bathe with Valerian root medicines if you have **open wounds, skin problems, high fever, severe infections and severe heart and circulation problems.**

Do not **drive or operate machinery** when using Valerian root medicine as it may have an influence on your ability to drive and use machinery.

Consult a doctor or a pharmacist if your mild nervous tension and sleep disorders persist or worsen after **2 weeks** during the continuous use of the medicinal product.

What you need to know before taking Valerian root with other medicines?

No interactions with other medicines have been described in the literature at the time of assessment when using valerian root with other medicines.

What are the risks associated with Valerian root medicines?

You may experience some side effects with Valerian root medicines:

You may get **nausea and abdominal cramps.**

The frequency of these undesirable effects is not known.

How does Valerian root work as a medicine?

The efficacy of a specific preparation of Valerian root in **treating mild nervous tension and sleep disorders** is based on its '**well-established use**'.

This means that there is documented evidence of their medicinal use covering at least 10 years in the EU with published clinical studies to support the efficacy and safety when used for the relief of mild nervous tension and to improve the quality of sleep and the time to fall asleep.

Several publications with clinical studies with dry ethanolic extracts support its use for the treatment of mild nervous tension and sleep disorders. Results showed notably improvements in the time it takes to fall asleep and the quality of the sleep when using the recommended dosage.

In its assessment, the HMPC considered clinical studies where Valerian root ethanolic dry extract has been compared with other treatments. The results showed that valerian root was as effective as other medicines in treating the relief of mild anxiety.

Some studies have shown that Valerian root is clearly better tolerated than other treatments. The efficacy has been shown to be better after at **2 weeks** of treatment, but no comparative long term treatment studies are available.

The HMPC conclusions on the use of valerian root preparations medicines as juice, water extracts, methanolic extracts and tinctures are also based on their '**traditional use**' for **relief of mild symptoms of mental stress and to aid sleep**. 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).

How are herbal medicines containing Valerian root 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. Before approval, the national authorities assess the quality, safety and efficacy of the herbal medicine. The HMPC conclusions are taken into account when evaluating applications for the licensing of herbal medicines.

Information on approved valerian root medicines in EU Member States may be obtained from the relevant national authorities.

Further information

Further information on the HMPC scientific assessment of Valerian root medicines, including details of the Committee's conclusions, can be found under the tab 'Documents' on the Agency's website: [Valerianae radix - herbal medicinal product | European Medicines Agency \(EMA\)](#).