

COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

VALERIANA OFFICINALIS L., RADIX

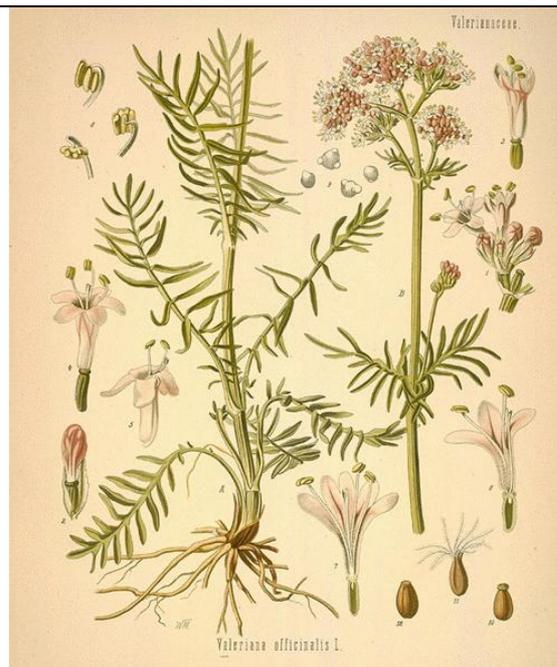
VALERIAN ROOT

HMPC Assessment Report Summary for the Public

*This document is a summary of the **assessment report** adopted by the Committee on Herbal Medicinal Products (HMPC) that describes the data available on the medicinal use of a herbal substance and the conclusions after evaluating these data.*

*If you want more information on the HMPC conclusions, read the **Community herbal monograph** on this herbal medicine. Monographs describe the scientific opinion of the HMPC on herbal medicines, including their content, how they are used, what they are used for, how they work and how they can be used safely.*

What are valerian root medicines made of?



Valerian root medicines contain the root of the valerian plant. The botanical Latin name of the plant is *Valeriana officinalis* L. Valerian is a perennial plant that is found throughout Europe and Northern Asia. The plant is cultivated and harvested to obtain the dried root for medicinal use (herbal substance).

IMPORTANT NOTE: The image is provided to give additional information on the source of the herbal substance/preparation. This image is not intended to encourage collection from the wild.

Valerian root medicines are available in various forms to be taken by mouth, such as herbal tea tablets, capsules and drops. They are made from various herbal preparations such as extracts prepared with ethanol which are prepared by putting the root of the plant in contact with ethanol (alcohol) as an extraction solvent.

Preparations made from valerian root can also be found in combination with other herbal substances that have the same effects. These combination medicines will be assessed separately by the HMPC.

What are valerian root medicines used for?

Extracts prepared with ethanol are used for the relief of mild nervous tension and sleep disorders.

Other valerian root preparations are traditionally used for the relief of mild symptoms of mental stress and to aid sleep. The use in these indications is exclusively based on traditional use only.

The HMPC came to these conclusions after assessment of the bibliographic data available on valerian root preparations. Clinical and non-clinical studies had been performed mainly using the extracts prepared with ethanol whereas the justification for the use of the other preparations is found in their traditional use as herbal medicines.

Many traditional herbal medicines have not been fully investigated with current scientific methods. The EU pharmaceutical legislation provides an opportunity for traditional herbal medicines to be officially registered, based on their traditional use, if they can be used safely without the support from a medical doctor for diagnosis, treatment and follow-up. This traditional use must cover a period of at least 30 years with 15 years of this use within the Community.

How are valerian root medicines used?

Valerian root medicines can be used from the age of 12 years. Valerian root medicines are not recommended for use in children under 12 years of age because there is not enough information on their safe use in this group.

The dose of valerian root medicines and how often they are used depend on what they are being used for and the formulation of the medicine being used. Detailed instructions can be found in the package leaflet that comes with each medicinal product.

When valerian preparations are taken to relieve mild nervous tension or stress, they are generally taken up to three times a day. For sleep disorders, the medicine is normally taken half an hour before bedtime. For further information, see section 4.2 'Posology and method of administration' of the Community herbal monograph on valerian root.

How do valerian root medicines work?

Many components have been identified in preparations containing valerian root and it is not possible to define precisely the action of each component.

The components of medicines containing valerian root preparations are thought to work by acting on various receptors in the brain. However, studies of isolated components of these medicines could not fully explain the activity of the medicines, so it is thought that several components in valerian root preparations work together to bring about their effects.

The studies described above are from experimental models therefore there is no information on how medicines containing valerian root interact with the human body.

What studies were conducted with valerian root medicines?

Because valerian root has been in use for a long time, the data reviewed by the HMPC included the results of studies from the scientific literature including studies using experimental models.

A substantial body of evidence is available on the use of valerian root medicines that contain dried extracts of valerian root prepared with ethanol for the relief of mild nervous tension and sleep

disorders, as well as several studies, some of which measured brain activity using electroencephalograms (EEGs).

There are few studies looking at the safety of valerian root preparations, but the many years of experience of their use in man indicate that they are safe.

The long-standing use over more than 30 years and limited experimental studies make the traditional use in the relief of mild symptoms of mental stress and to aid sleep plausible.

There have been no studies looking at the effects of valerian root on reproduction, effects on the genes or the development of cancer.

What are the risks associated with valerian root medicines?

Valerian root medicines are generally well tolerated. The most common side effects with valerian root medicines affect the stomach and gut, such as nausea (feeling sick) and abdominal (tummy) cramps. The full list of all side effects reported for a given valerian root medicine is found in its package leaflet.

Valerian root medicines should not be used in people who may be hypersensitive (allergic) to valerian root.

The use of valerian root medicines is not recommended in combination with other sedatives because interactions with other medicines cannot be excluded.

No significant cases of abuse or dependence have been reported.

Because there have been no tests looking at the effects of valerian root medicines on reproduction or on the unborn child, they should not be used in women who are pregnant or breast-feeding as a general precaution.

The use of valerian root medicines points to the possibility that they may cause drowsiness and impair the ability to drive and use machinery. Affected patients should not drive or operate machinery.

Other information about valerian root medicines

The medicinal use of Valerian root is part of traditional European Phytotherapy.

For extracts prepared with ethanol the bibliographic data did allow the HMPC to come to scientific conclusions with respect to their rational use.

Important information on the use of a traditional herbal medicine can be found in the package leaflet that comes with each individual product. This information should always be read carefully before using a product.

Further information on the HMPC assessment on *Valeriana officinalis* L., radix is provided in the Community herbal monograph, HMPC Assessment Report, overview of comments received during the public consultation period and other related documents which can be found [here](#).

This summary was last updated in January 2009.