

COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

PASSIFLORA INCARNATA L., HERBA

PASSION FLOWER

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 Committee's 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 passion flower medicines made of?



Passion flower medicines contain the aerial parts (stems, leaves, flowers and fruit) of the passion flower plant. The botanical Latin name of the plant is *Passiflora incarnata* L. Passion flower is a perennial, herbaceous climbing plant native to North, Central and South America. The plant is cultivated and harvested to obtain the dried aerial parts for medicinal use (herbal substance).

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

Passion flower 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.

Preparations made from passion flower 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 passion flower medicines used for?

Passion flower medicines are traditionally used for the relief of mild symptoms of mental stress and to aid sleep, in adults and adolescents over 12 years of age.

The use in these indications is exclusively based on traditional use.

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 passion flower medicines used?

Passion flower medicines can be used from the age of 12 years. Passion flower 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 passion flower 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.

They are generally taken three to four times a day. For further information, see section 4.2 'Posology and method of administration' of the Community herbal monograph on passion flower.

How do passion flower medicines work?

The way that passion flower medicines work in the relief of mild symptoms of mental stress and to aid sleep is not understood.

What studies were conducted with passion flower medicines?

To support the effectiveness of passion flower medicines, the HMPC has reviewed data from the scientific literature, as well as the results from four clinical studies conducted between 1998 and 2005. To look into how passion flower medicines work, studies of different types of passion flower extract have been carried out in experimental models. These studies have supported the known effects of the medicines in inducing sleep and reducing anxiety effects, but it is not yet clear which constituents of the plant are responsible for these effects. Other studies in experimental models have looked into the way that one of the constituents of passion flower may bring about a reduction in anxiety, at doses higher than those used in humans, but these studies did not clarify how passion flower medicines work in anxiety.

The results of the clinical studies were of limited value since they involved too few patients, did not compare passion flower medicines to other treatments, or looked at the treatment of other conditions. However, one of the studies did support the use of passion flower medicines in relieving the symptoms of stress.

The HMPC noted that the traditional use of passion flower in the EU is well documented in well-respected handbooks spanning at least 30 years. The earliest evidence dates back to 1938. On the basis of this long experience, the HMPC concluded that the effectiveness of passion flower medicines is plausible, although additional studies would be needed to fully prove efficacy according to modern standards.

What are the risks associated with passion flower medicines?

Passion flower medicines are generally well tolerated. One case of hypersensitivity (allergy) and one case of nausea (feeling an urge to vomit) and tachycardia (abnormally rapid heart beat) have been reported in the literature. There have been no signs that passion flower medicines may be harmful when they are used under normal conditions.

The full list of all side effects reported for a given passion flower medicine is found in its package leaflet.

Passion flower medicines should not be used in people who may be hypersensitive (allergic) to passion flower.

Because there have been no tests looking at the effects of passion flower 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 traditional use of passion flower 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 passion flower medicines

The medicinal use of passion flower is part of traditional European Phytotherapy.

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 of *Passiflora incarnata* L., herba 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.