



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 September 2016
EMA/275240/2014

Herbal medicine: summary for the public

Passion flower

Passiflora incarnata L., herba

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

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

What is passion flower?

Passion flower is the common name for the above-ground parts of the plant *Passiflora incarnata* L.

The HMPC conclusions only cover passion flower preparations which are obtained by comminuting (reducing into tiny pieces) or powdering the dried above-ground parts or as dry and liquid extracts. Extracts are obtained by putting the plant material in a solvent (such as ethanol) to dissolve compounds and form a liquid extract. To obtain a dry extract the solvent is then evaporated.

Herbal medicines containing these passion flower preparations are usually available as herbal teas to be drunk or as solid or liquid forms to be taken by mouth.

Passion flower 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, on the basis of its long-standing use, these passion flower preparations can be used for the relief of mild symptoms of mental stress and to aid sleep.

Passion flower medicines should only be used in adults and adolescents over the age of 12 years. A doctor or a qualified healthcare practitioner should be consulted if the symptoms last for more than 2 weeks or worsen during the use of the medicine. Detailed instructions on how to take passion flower medicines and who can use them can be found in the package leaflet that comes with the medicine.



What evidence supports the use of passion flower medicines?

The HMPC conclusions on the use of these passion flower medicines for mild symptoms of mental stress and to aid sleep are based on their 'traditional use' in these conditions. 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 published clinical studies of passion flower medicines. However, the low number of patients involved and other serious shortcomings in the design of the studies prevented any firm conclusions being drawn. Therefore, the HMPC conclusions on the use of passion flower 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 passion flower medicines?

At the time of the HMPC assessment, no side effects had been reported with these medicines.

Further information on the risks associated with these passion flower 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 passion flower medicines approved in the EU?

Any applications for the licensing of medicines containing passion flower 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 passion flower medicines in EU Member States should be obtained from the relevant national authorities.

Other information about passion flower medicines

Further information on the HMPC assessment of passion flower 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 passion flower medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.