



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Herbal tea combinations for use as sedatives

Species sedativae

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

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

What are herbal tea combinations for use as sedatives?

Herbal tea combinations for use as sedatives refer in this evaluation to combinations of up to a maximum of 4 of the following herbal substances:

- *Humulus lupulus* L., flos ([hop strobile](#))
- *Lavandula angustifolia* Mill., flos ([lavender](#))
- *Melissa officinalis* L., folium ([melissa leaf](#))
- *Passiflora incarnata* L., herba ([passion flower](#))
- *Valeriana officinalis* L., radix ([valerian root](#)).

The HMPC conclusions only cover preparations that are obtained by drying and comminuting (reducing into tiny pieces) the relevant plant part.

Herbal medicines containing these preparations are usually available as herbal tea to be drunk 3-4 times a day, the last dose taken just before going to bed.

What are the HMPC conclusions on their medicinal uses?

The HMPC concluded that, on the basis of their long-standing use, these preparations can be used to relieve mild symptoms of mental stress and aid sleep.

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Herbal tea combinations for use as sedatives should only be used in adults and adolescents aged 12 years and over. If symptoms last longer than 2 weeks or worsen while taking the medicine, a doctor or a qualified health care practitioner should be consulted.

Detailed instructions on how to take these medicines and who can use them can be found in the package leaflet that comes with the medicine.

What evidence supports the use of herbal tea combinations for use as sedatives?

The HMPC conclusions on the use of these herbal tea combinations for use as sedatives to relieve mild symptoms of mental stress and 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.

For information on the studies with the individual herbal substances which have been assessed by the HMPC, see the HMPC assessment report and other information published on the Agency's webpages related to each individual substance.

What are the risks associated with herbal tea combinations for use as sedatives?

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

Herbal tea combinations for use as sedatives must not be used in people who are hypersensitive to the active substances.

Further information on the risks associated with these herbal tea combinations for use as sedatives, 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':

<https://www.ema.europa.eu/en/medicines/herbal/combination-species-sedativae>.

How are herbal tea combinations for use as sedatives approved in the EU?

Any applications for the licensing of medicines containing herbal tea combinations for use as sedatives 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 herbal tea combinations for use as sedatives in EU Member States should be obtained from the relevant national authorities.

Other information about herbal tea combinations for use as sedatives

Further information on the HMPC assessment of herbal tea combinations for use as sedatives, including details of the Committee's conclusions, can be found in the section 'Documents' on the Agency's website: <https://www.ema.europa.eu/en/medicines/herbal/combination-species-sedativae>. For more information about treatment with herbal tea combinations for use as sedatives, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.