



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Herbal medicine: summary for the public

Hawthorn leaf and flower

Crataegus spp., folium cum flore

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

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

What are Hawthorn leaf and flower?

Hawthorn leaf and flower is the common name for the leaves and flowers of the several *Crataegus* species.

The HMPC conclusions only cover hawthorn leaf and flower preparations which are obtained by drying and comminuting (reducing into tiny pieces) or powdering the leaves and flowers, by expressing the juice of the fresh leaves and flowers or as dry and liquid extracts. Extracts are prepared using a technique to extract compounds by putting the plant material in a solvent (such as ethanol, water or methanol) to dissolve compounds and form a liquid extract. The solvent is then evaporated to obtain a dry extract.

Herbal medicines containing these hawthorn leaf and flower preparations are usually available as herbal tea to be drunk and in solid or liquid forms to be taken by mouth.

Hawthorn leaf and 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 hawthorn leaf and flower preparations can be used to relieve symptoms of temporary heart complaints related to nervousness,



such as palpitations, after serious conditions have been excluded by a medical doctor. They can also be used to relieve mild symptoms of mental stress and to aid sleep.

Hawthorn leaf and flower medicines should only be used in adults for heart complaints related to nervousness, and in adults and adolescents over the age of 12 years for mild symptoms of mental stress and to aid sleep. If symptoms last longer than two weeks or worsen during the use of the medicine, a doctor or a qualified healthcare practitioner should be consulted. Detailed instructions on how to take hawthorn leaf and 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 Hawthorn leaf and flower medicines?

The HMPC conclusions on the use of hawthorn leaf and flower medicines for heart complaints related to nervousness, mild symptoms of mental stress and to 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.

The HMPC noted a lack of clinical studies with hawthorn leaf and flower medicines. In its assessment, the HMPC also considered data from text books which supported a use for heart complaints related to nervousness, mental stress and to aid sleep.

For detailed information on the studies assessed by the HMPC, see the HMPC assessment report.

What are the risks associated with Hawthorn leaf and 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 hawthorn leaf and 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.

How are Hawthorn leaf and flower medicines approved in the EU?

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

Other information about Hawthorn leaf and flower medicines

Further information on the HMPC assessment of hawthorn leaf and 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. For more information about treatment with hawthorn leaf and flower medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.