



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Mullein flower

Verbascum thapsus L., *V. densiflorum* Bertol. (*V. thapsiforme* Schrad) and *V. phlomoides* L., flos

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

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

What is mullein flower?

Mullein flower is the common name for the flowers of the plants *Verbascum thapsus* L., *V. densiflorum* Bertol. (*V. thapsiforme* Schrad) and *V. phlomoides* L.

The HMPC conclusions only cover dried mullein flowers and preparations that are obtained by drying and comminuting (reducing into tiny pieces) the flowers.

These mullein flower medicines are usually available as herbal tea to be drunk.

These mullein flower medicines 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 their long-standing use, these mullein flower medicines can be used for relief of sore throat associated with dry cough and cold.

Mullein flower medicines should only be used in adults and adolescents over the age of 12 years. If symptoms worsen or last longer than 1 week whilst taking the medicine, a doctor or a qualified healthcare practitioner should be consulted. Detailed instructions on how to take mullein 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 mullein flower medicines?

The HMPC conclusions on the use of these mullein flower medicines for relief of sore throat 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 the lack of clinical studies with mullein flower medicines.

For detailed information, see the HMPC assessment report.

What are the risks associated with mullein 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 mullein 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 mullein flower medicines approved in the EU?

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

Other information about mullein flower medicines

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