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## Mallow leaf

*Malva sylvestris* L. and/or *Malva neglecta* Wallr., folium

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

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

### What is mallow leaf?

Mallow leaf is the common name for the leaf of the plants *Malva sylvestris* L. and/or *Malva neglecta* Wallr.

The HMPC conclusions only cover mallow leaf preparations that are obtained by drying and comminuting the leaves (reducing them into tiny pieces).

Herbal medicines containing this mallow leaf preparation are usually available as herbal tea to be drunk and in liquid forms to be taken by mouth or to be applied to the lining of the mouth.

Mallow leaf 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, this mallow leaf preparation can be used to treat irritation of the mouth or throat and associated dry cough. It can also be used to relieve mild discomfort of the stomach and gut.

Mallow leaf medicines should only be used in adults and adolescents from 12 years of age. A doctor or a qualified healthcare practitioner should be consulted if mouth or throat irritation lasts longer than 1 week or if stomach and gut discomfort lasts longer than 2 weeks during use of the medicine. Detailed instructions on how to take mallow leaf medicines and who can use them can be found in the package leaflet that comes with the medicine.

## **What evidence supports the use of mallow leaf medicines?**

The HMPC conclusions on the use of these mallow leaf medicines for mouth or throat irritation and associated dry cough, and mild stomach and gut discomfort 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.

In its assessment, the HMPC considered studies in laboratory tests showing anti-inflammatory effects of mallow leaf preparations. The HMPC noted the lack of studies with mallow leaf in patients. For detailed information on the studies assessed by the HMPC, see the HMPC assessment report under the section 'Documents' on the Agency's website: [ema.europa.eu/medicines/herbal/malvae-folium](http://ema.europa.eu/medicines/herbal/malvae-folium).

## **What are the risks associated with mallow leaf 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 mallow leaf medicines, including the appropriate precautions for their safe use, can be found in the monograph under the section 'Documents' on the Agency's website: [ema.europa.eu/medicines/herbal/malvae-folium](http://ema.europa.eu/medicines/herbal/malvae-folium).

## **How are mallow leaf medicines approved in the EU?**

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

## **Other information about mallow leaf medicines**

Further information on the HMPC assessment of mallow leaf medicines, including details of the Committee's conclusions, can be found under the section 'Documents' on the Agency's website: [ema.europa.eu/medicines/herbal/malvae-folium](http://ema.europa.eu/medicines/herbal/malvae-folium). For more information about treatment with mallow leaf medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.