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## Herbal medicine: summary for the public

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### Rose flower

*Rosa gallica* L., *Rosa centifolia* L., or *Rosa damascena* Mill., flos

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

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

#### **What is rose flower?**

Rose flower is the common name for the petals of the plants *Rosa gallica* L., *Rosa centifolia* L., or *Rosa damascena* Mill.

The HMPC conclusions only cover rose flower preparations which are obtained by drying the petals or comminuting (reducing into tiny pieces) them.

Herbal medicines containing these rose flower preparations are usually available as infusions to be applied to the lining of the mouth or the skin.

Rose 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 rose flower preparations can be used for mild inflammation of the skin or lining of the mouth and throat.

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

The HMPC conclusions on the use of these rose flower medicines for mild mouth, throat and skin inflammation 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 also considered a clinical study involving 50 patients with inflammation of the lining of the mouth, where rose flower mouthwash was compared with placebo (a dummy treatment). Results showed that rose flower mouthwash was more effective than placebo in treating mouth inflammation. However, since the study was small, the HMPC conclusions on the use of these rose flower medicines are mainly 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 rose 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 rose 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_medicine/Herbal_medicines_for_human_use).

## **How are rose flower medicines approved in the EU?**

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

## **Other information about rose flower medicines**

Further information on the HMPC assessment of rose 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_medicine/Herbal_medicines_for_human_use). For more information about treatment with rose flower medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.