

20 October 2015 EMA/490629/2015

Herbal medicine: summary for the public

Matricaria flower

Matricaria recutita L., flos

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

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

What is matricaria flower?

Matricaria flower is the common name for the flower heads of the plant *Matricaria recutita* L. (also known as chamomile). The flowers for medicinal use are obtained either from plants that have been cultivated or found in the wild.

Matricaria flower preparations are obtained by comminuting (reducing into tiny pieces) the flower, or as dry or liquid extracts. Extracts are prepared using a technique to extract compounds from plant material by dissolving them in a solvent (such as ethanol). For dry extracts the solvent is then evaporated to obtain the extract.

Herbal medicines containing matricaria flower preparations are available as herbal teas to be drunk or their steam inhaled; as infusions to be applied onto the skin or lining of the mouth; as liquid forms to be taken by mouth, used for steam inhalation, for rinsing the mouth or applied on the skin, or used as bath additives; and as semi-solid forms (such as ointments) to be applied onto the skin.

Matricaria flower can 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, matricaria flower medicines can be used for the following:



- treating the symptoms of minor gastro-intestinal (stomach and gut) complaints such as bloating and minor spasms;
- relieving the symptoms of common cold;
- treating minor ulcers (open sores) and inflammations of the mouth and throat;
- as add-on treatment of irritation of the skin and areas around the anus and genitals, once serious conditions have been excluded by a doctor;
- treating minor inflammation of the skin (sunburn) and superficial wounds and small boils (furuncles).

A doctor or a qualified healthcare practitioner should be consulted if symptoms persist for more than one week during treatment. Matricaria flower medicines are usually for use in adults and adolescents (above 12 years of age). Only some matricaria flower preparations are recommended for use in children below 12 years. Detailed instructions on how to take matricaria 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 matricaria flower medicines?

The HMPC conclusions on the use of matricaria flower medicines for the above-mentioned indications are based on their 'traditional use' in these conditions. 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 several clinical studies with matricaria flower used for different conditions. Although possible beneficial effects were observed, the data were insufficient to be used as evidence, particularly because in these studies matricaria flower was not compared with any other treatment. Therefore, the HMPC conclusions on the use of matricaria flower medicines are 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 matricaria flower medicines?

Allergic reactions, sometimes severe, have been reported following contact of liquid chamomile preparations with internal moist surfaces such as the lining of the mouth. Their frequency has not been established.

Matricaria flower medicines must not be used in patients allergic to matricaria flowers or other plants of the *Asteraceae (Compositae)* family. Patients with severe heart and circulation problems should not have full baths with matricaria flowers. Patients with open wounds, extensive skin damage or acute (short-term) skin disease, high fever and severe infections should not have full or partial baths with matricaria flowers.

Further information on the risks associated with matricaria 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 matricaria flower medicines approved in the EU?

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

Other information about matricaria flower medicines

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