

20 October 2015
EMA/487922/2015

Herbal medicine: summary for the public

Matricaria oil

Matricaria recutita L., aetheroleum

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

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

What is matricaria oil?

Matricaria oil is the common name for the essential oil of 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 oil is obtained by a current of steam through the fresh or dried flowers or flowering tops of the plant. After cooling, the essential oil separates from the water and can be collected.

Herbal medicines containing matricaria oil are usually available in liquid forms to be used as bath additives.

Matricaria oil 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 oil medicines can be used as add-on treatment of irritation of the skin and areas around the anus and genitals, once serious conditions have been excluded by a medical doctor.

Matricaria oil medicines should only be used in adults and adolescents (above 12 years of age). A doctor or a qualified healthcare practitioner should be consulted if symptoms persist for more than one

week during treatment. Detailed instructions on how to take matricaria oil 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 oil medicines?

The HMPC conclusions on the use of matricaria oil medicines for irritation of the skin and areas around anus and genitals are based on their 'traditional use' in this condition. 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.

Although observational data with matricaria oil medicines as a bath additive for irritation of the skin are available, they were too limited to be used as evidence. Therefore, the HMPC conclusions on the use of matricaria oil 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 oil 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 oil medicines must not be used in patients who are allergic to matricaria oil or other plants of the same family (Asteraceae (Compositae)). Patients with severe heart and circulation problems should not have full baths with matricaria oil. 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 oil.

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

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

Other information about matricaria oil medicines

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