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Calendula flower

Calendula officinalis L., flos

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

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

What is calendula flower?

Calendula flower (or marigold) is the common name for the flowers of the plant *Calendula officinalis* L.

The HMPC conclusions only cover calendula flower preparations that are obtained by drying and comminuting (reducing into tiny pieces) the flowers or by putting the plant material in a solvent (such as ethanol or olive oil) to dissolve compounds and form a liquid extract.

Herbal medicines containing calendula flower preparations are usually available as infusions to be applied to the lining of the mouth or the skin, and in liquid and semi-solid forms to be applied to the skin.

Calendula 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 their long-standing use, these calendula flower preparations can be used for treating minor inflammation of the skin (such as sunburn) and as an aid in healing of minor wounds. They can also be used to treat minor mouth or throat inflammation.

Calendula flower medicines should only be used in patients over the age of 6 years for skin inflammation and minor wounds and patients over the age of 12 years for mouth or throat inflammation. 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 calendula



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 calendula flower medicines?

The HMPC conclusions on the use of these calendula flower medicines for skin inflammations, minor wounds and mouth or throat 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 clinical studies for treatment of skin conditions, such as ulcers in the leg veins, skin burns and skin inflammation. However, firm conclusions could not be drawn as there were problems with the design of the studies. Therefore, the HMPC conclusions on the use of these calendula 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 calendula flower medicines?

Skin sensitisation has been reported with calendula flower medicines but the frequency is not known.

Calendula flower medicines must not be used in patients who are hypersensitive (allergic) to plants of the Asteraceae family.

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

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

Other information about calendula flower medicines

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