



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Herbal medicine: summary for the public

Arnica flower

Arnica montana L., flos

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

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

What is arnica flower?

Arnica flower is the common name for the flower heads of the plant *Arnica montana* L.

The HMPC conclusions only cover arnica flower preparations which are obtained using a technique to extract compounds by putting the plant material in a solvent to dissolve compounds and form a liquid extract.

Herbal medicines containing these arnica flower preparations are usually available in semi-solid and liquid forms to be applied to the skin.

Arnica 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 arnica flower preparations can be used for the relief of bruises, sprains and localised muscle pain.

Arnica flower medicines should only be used in adults and adolescents from the age of 12 years. If symptoms last longer than 3 to 4 days or worsen during the use of the medicine a doctor or a qualified healthcare practitioner should be consulted. Detailed instructions on how to take arnica 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 arnica flower medicines?

The HMPC conclusions on the use of these arnica flower medicines for the relief of bruises, sprains and localised muscle pain 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 number of clinical studies involving patients with bruises and soft tissue or joint pain. Although a possible effect in terms of improvement in pain intensity and bruising was observed, firm conclusions could not be drawn due to shortcomings in the studies such as small number of patients and lack of controls. Therefore, the HMPC conclusions on the use of these arnica 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 arnica flower medicines?

Side effects have been reported with arnica flower medicines. These include allergic reactions such as itching, redness of the skin and eczema, but their frequency is unknown.

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

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

Other information about arnica flower medicines

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