



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

10 July 2015  
EMA/HMPC/331455/2015  
Committee on Herbal Medicinal Products (HMPC)

## **Herbal medicine: summary for the public**

---

### **Mouse-ear hawkweed**

*Hieracium pilosella* L., herba cum radice

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

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

#### **What is mouse-ear hawkweed?**

Mouse-ear hawkweed is the common name for the above-ground parts (which may include flowers) and parts of the root of the plant *Hieracium pilosella* L. The plant is cultivated or gathered to obtain the plant parts for medicinal use.

Mouse-ear hawkweed preparations are obtained by comminuting (reducing into tiny pieces) or powdering the dried plant parts.

Herbal medicines containing mouse-ear hawkweed are usually available as a herbal tea to be drunk and in solid forms to be taken by mouth.

#### **What are the HMPC conclusions on its medicinal uses?**

The HMPC concluded that, on the basis of its long-standing use, mouse-ear hawkweed can be used as a mild diuretic (a medicine to increase production of urine) for the relief of minor problems of the urinary tract (the structures that carry urine).

Mouse-ear hawkweed should only be used in adults. If symptoms last longer than two weeks during treatment, a doctor or a qualified healthcare practitioner should be consulted. Detailed instructions on how to take mouse-ear hawkweed medicines and who can use them can be found in the package leaflet that comes with the medicine.



## **What evidence supports the use of mouse-ear hawkweed medicines?**

The HMPC conclusions on the use of mouse-ear hawkweed medicines for the relief of minor urinary problems 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.

The HMPC noted the lack of clinical studies with mouse-ear hawkweed, but took into account the well documented use of this herbal medicine for the above uses. For further information, see the HMPC assessment report.

## **What are the risks associated with mouse-ear hawkweed medicines?**

Mouse-ear hawkweed medicines are generally well tolerated. At the time of the HMPC assessment, no side effects had been reported with these medicines.

Mouse-ear hawkweed medicines must not be used in patients with conditions in which a reduced fluid intake is recommended (such as severe heart or kidney disease).

Further information on the risks associated with mouse-ear hawkweed 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%20medicine/Herbal%20medicines%20for%20human%20use).

## **How are mouse-ear hawkweed medicines approved in the EU?**

Any applications for the licensing of medicines containing mouse-ear hawkweed 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 mouse-ear hawkweed medicines in EU Member States should be obtained from the relevant national authorities.

## **Other information about mouse-ear hawkweed medicines**

Further information on the HMPC assessment of mouse-ear hawkweed 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%20medicine/Herbal%20medicines%20for%20human%20use). For more information about treatment with mouse-ear hawkweed medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.