



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Assessment Report Summary for the Public (ARSP)

Mouse-ear hawkweed

Hieracium pilosella L., herba cum radice

Other names

BG (bulgarski): Рунянка, стрък с корен	LT (lietuvių kalba): Kudlių žolė su šaknimis
CS (čeština): nať jestřábníku chlupáčku s kořenem	LV (latviešu valoda): Mazās mauragas laksts ar sakni
DA (dansk): Håret gøgeurt	MT (Malti): ħaxixa bl-għeruq tal-heraċju
DE (Deutsch): Kleines Habichtskraut mit Wurzeln	NL (Nederlands): Muizenoor, kruid en wortel
EL (elliniká): πιλοσέλλας πόα με ρίζα	PL (polski): ziele jastrzębca kosmaczka z korzeniami
EN (English): Mouse-ear hawkweed	PT (português): pilosela, partes aéreas e raízes
ES (español): vellosilla, partes aéreas con raíz de	RO (română): iarba si radcina de vulturica
EE (eesti keel): karutubakaürt koos juurtega	SK (slovenčina): vňat' chlupánika s koreňom
FI (suomi): huopakeltano, verso juurineen	SL (slovenščina): zel in korenina dolgodlakave škržolice
FR (français): piloselle (plante entière de)	SV (svenska): gråfibbla, ört och rot
HR (hrvatski): zelen s korijenom male runjike	IS (íslenska):
HU (magyar): ezüstös hölgymál virágos hajtás gyökérrel	NO (norsk): hårsveve, urt med rot
IT (italiano): Pilosella parti aeree fiorite con radice	

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Introduction

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, whole plant. It summarises the Committee's recommendations on the use of Mouse-ear hawkweed, whole plant.

The HMPC conclusions are taken into account by EU Member States when evaluating applications for the licensing of herbal medicines containing Mouse-ear hawkweed, whole plant. When a Member State authorises a medicine containing Mouse-ear hawkweed, detailed instructions on how to take it will be available in the package leaflet that comes with medicine.

The information in this summary report concerns herbal medicinal products containing Mouse-ear hawkweed, whole plant which are only authorised when they comply with the strict pharmaceutical quality and other requirements for herbal medicinal products. They are approved by the competent authorities to be placed on the market as medicinal products. Other products, like food, food supplements, cosmetic products or medical devices do not follow the same criteria and regulatory requirements as medicinal products and are excluded from this summary.

What is Mouse-ear hawkweed whole plant and what do Mouse-ear hawkweed herbal medicines contain?

Mouse-ear hawkweed whole plant is the common name for the above and underground part of *Pilosella officinarum* Vall., synonym *Hieracium pilosella* L.

Medicinal products with Mouse-ear hawkweed whole plant contain comminuted (reduced into tiny pieces) or powered, above and under-ground part of the plant.

Herbal medicines containing these Mouse-ear hawkweed preparations are usually available as herbal tea to be drunk, and in solid or liquid forms to be taken by mouth.

What are the medicinal uses of Mouse-ear hawkweed whole plant?

Mouse-ear hawkweed preparations have a traditional use for the **relief of symptoms associated with minor urinary tract complaints** in addition to the general recommendation of a sufficient fluid intake to increase the amount of urine.

Traditional medicinal use means that the use in the specified indication is exclusively based upon long-standing medicinal use and not based on results from clinical studies.

When is it not recommended to use Mouse-ear hawkweed whole plant?

You can find detailed instructions on how to take Mouse-ear hawkweed medicines and who can use them in the package leaflet that comes with the medicine.

Do not use Mouse-ear hawkweed whole plant:

- for children and adolescents **under 18 year** of age.
- if you are **pregnant or breast feed** your child.
- if you are allergic to the Mouse-ear hawkweed plant or to plants of the Asteraceae (Compositae) family.
- when reduced fluid intake is advised by a doctor.

Consult a doctor or a pharmacist:

- if complaints or symptoms occur during the use of Mouse-ear hawkweed medicines such **as fever, painful urination, spasms, or blood in the urine.**
- if your symptoms persist longer than **2 weeks** during the use of the medicinal product.

What you need to know before taking Mouse-ear hawkweed whole plant with other medicines?

No interactions with other medicines have been described in the literature at the time of assessment when using Mouse-ear hawkweed whole plant, with other medicines.

What are the risks associated with Mouse-ear hawkweed medicines?

No side effects have been reported with Mouse-ear hawkweed medicines at the time of assessment.

How does Mouse-ear hawkweed whole plant work as a medicine?

The HMPC conclusions on the use of these Mouse-ear hawkweed medicines for the **relief of symptoms associated with minor urinary tract complaints** in addition to the general recommendation of a sufficient fluid intake to increase the amount of urine 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).

How are herbal medicines containing Mouse-ear hawkweed whole plant 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. Before approval, the national authorities assess the quality, safety and efficacy of the herbal medicine. The HMPC conclusions are taken into account when evaluating applications for the licensing of herbal medicines.

Information on approved Mouse-ear hawkweed medicines in EU Member States may be obtained from the relevant national authorities.

Further information

Further information on the HMPC scientific assessment of Mouse-ear hawkweed medicines, including details of the Committee's conclusions, can be found under the tab 'Documents' on the Agency's website: [Pilosellae herba cum radice - herbal medicinal product | European Medicines Agency \(EMA\)](#).