



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

## Opinion of the HMPC on a European Union herbal monograph on *Hieracium pilosella* L., herba cum radice

### Opinion

**This document was valid from 5 May 2015 until 20 November 2024.**

The HMPC, in accordance with Article 16h(3) of Directive 2001/83/EC, as amended, and as set out in the appended assessment report, establishes by a majority of 28 out of 29 votes a European Union herbal monograph on *Hieracium pilosella* L., herba cum radice which is set out in Annex I.

The divergent position is appended to this opinion.

The Norwegian HMPC member agrees with the above-mentioned recommendation of the HMPC.

This opinion is forwarded to Member States, to Iceland and Norway, together with its Annex I and appendices.

The European Union herbal monograph and assessment report will be published on the European Medicines Agency website.

London, 5 May 2015



**Annex I: European Union herbal monograph  
(EMA/HMPC/680374/2013)**

Superseded

## Appendix I: Assessment report (EMA/HMPC/680373/2013)

Superseded

## Appendix II: Divergent position

Superseded

The member of the HMPC mentioned below did not agree with the HMPC's opinion for the following reason:

Regarding the EU Herbal monograph for *Pilosella herba cum radice*, from a Dutch point of view the indication "Traditional herbal medicinal product used to achieve flushing of the urinary tract as an adjuvant in minor urinary tract complaints. The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.", is preferable.

Because the increase in amount of urine, is not demonstrated.

Emiel van Galen, HMPC member from the Netherlands

London, 5 May 2015