



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 November 2024
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Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Pilosella officinarum* Vall. (syn *Hieracium pilosella* L.), herba cum radice

Final – Revision 1

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	November 2013 January 2014 March 2014 May 2014
Adopted by Committee on Herbal Medicinal Products (HMPC) for release for consultation	1 July 2014
End of consultation (deadline for comments)	31 October 2014
Re-discussion in MLWP	November 2014 January 2015
Adoption by HMPC Monograph (EMA/HMPC/680374/2013) Assessment Report (EMA/HMPC/680373/2013) List of References (EMA/HMPC/35510/2014) HMPC Opinion (EMA/HMPC/165127/2015)	5 May 2015
First revision	
Discussion in HMPC	March 2023 May 2023 July 2023
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¹ No comments were received during the period of public consultation.

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

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BG (bългарski): 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):
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
ET (eesti keel): karutubakaürt koos juurtega	SK (slovenčina): vňať 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	

European Union herbal monograph on *Pilosella officinarum* Vall. (syn *Hieracium pilosella* L.), herba cum radice

1. Name of the medicinal product

To be specified for the individual finished product.

2. Qualitative and quantitative composition^{2, 3}

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC <i>Pilosella officinarum</i> Vall., herba cum radice (Mouse-ear hawkweed) i) Herbal substance Not applicable ii) Herbal preparations a) Comminuted herbal substance b) Powdered herbal substance

3. Pharmaceutical form

Well-established use	Traditional use
	Herbal preparations in solid or liquid dosage forms for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Traditional herbal medicinal product used for the relief of symptoms associated with minor urinary tract complaints in addition to the general

² The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

³ The material complies with the Ph. Fr. monograph (Piloselle)

Well-established use	Traditional use
	<p>recommendation of a sufficient fluid intake to increase the amount of urine.</p> <p>The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.</p>

4.2. Posology and method of administration⁴

Well-established use	Traditional use
	<p>Posology</p> <p><i>Adults and elderly</i></p> <p>a) Herbal tea</p> <p>Single dose: 2-4 g of the comminuted herbal substance in 250 ml of boiling water as an herbal infusion, 3 times daily.</p> <p>b) Powdered herbal substance:</p> <p>Single dose: 200-520 mg, 2-4 times daily. Daily dose: 560 mg up to 1300 mg.</p> <p>The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p>Duration of use</p> <p>If the symptoms persist longer than 2 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Method of administration</p> <p>Oral use.</p>

4.3. Contraindications

Well-established use	Traditional use
	<p>Hypersensitivity to the active substance(s) and to other plants of the Asteraceae (Compositae) family.</p>

⁴ For guidance on herbal substance/herbal preparation administered as herbal tea or as infusion/decoction/macerate preparation, please refer to the HMPC 'Glossary on herbal teas' (EMA/HMPC/5829/2010).

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.</p> <p>If complaints or symptoms such as fever, dysuria, spasms, or blood in urine occur during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Because adequate fluid intake is required during treatment <i>Pilosella officinarum</i> Vall., herba cum radice is not recommended for patients with conditions where reduced fluid intake is advised.</p>

4.5. Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
	None reported.

4.6. Fertility, pregnancy and lactation

Well-established use	Traditional use
	<p>Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</p> <p>No fertility data available.</p>

4.7. Effects on ability to drive and use machines

Well-established use	Traditional use
	No studies on the effect on the ability to drive and use machines have been performed.

4.8. Undesirable effects

Well-established use	Traditional use
	None known.

Well-established use	Traditional use
	If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.

4.9. Overdose

Well-established use	Traditional use
	No case of overdose has been reported.

5. Pharmacological properties

5.1. Pharmacodynamic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC.

5.2. Pharmacokinetic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC.

5.3. Preclinical safety data

Well-established use	Traditional use
	<p>Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC, unless necessary for the safe use of the product.</p> <p>Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.</p>

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

20 November 2024