



5 May 2015
EMA/HMPC/680374/2013
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Hieracium pilosella* L., herba cum radice

Final

Discussion in Working Party on European Union monographs and European Union list (MLWP)	November 2013 January 2014 March 2014 May 2014
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Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; <i>Hieracium pilosella</i> L., herba cum radice; Pilosellae herba cum radice; Mouse-ear hawkweed
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BG (bulgarski): Рунянка, стрък с корен CS (čeština): nař jestřábníku chlupáčku s kořenem DA (dansk): Håret gøgeurt DE (Deutsch): Kleines Habichtskraut mit Wurzeln EL (elliniká): Πόα με ρίζα πιλοσέλλας EN (English): Mouse ear Hawkweed ES (español): Vellozilla, partes aéreas con raíz de ET (eesti keel): karutubakaürt koos juurtega FI (suomi): huopakeltano, verso juurineen FR (français): Piloselle (plante entière de) HR (hrvatski): zelen s korijenom male runjike HU (magyar): Ezüstös hölgymál virágos hajtás gyökérrel IT (italiano): Pilosella parti aeree fiorite con radice	LT (lietuvių kalba): Kudlių žolė su šaknimis LV (latviešu valoda): Mazās mauragas laksts ar sakni MT (Malti): NL (Nederlands): Muizenoor, kruid en wortel PL (polski): ziele jastrzębca kosmaczka z korzeniami PT (português): Pilosela, partes aéreas e raízes RO (română): SK (slovenčina): Vňať chlpaníka s koreňom SL (slovenščina): zel in korenina dolgodlakave škržolice SV (svenska): Gråfibbla, ört och rot <i>IS (islenska):</i> <i>NO (norsk):</i> Hårsveve, urt med rot
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European Union herbal monograph on *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^{1,2}

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

3. Pharmaceutical form

Well-established use	Traditional use
	<p>Herbal preparations in solid dosage forms for oral use.</p> <p>Comminuted herbal substance as herbal tea for oral use.</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	<p>Traditional herbal medicinal product used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor</p>

¹ The dried material complies with the Ph. Fr. monograph (Piloselle)

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

Well-established use	Traditional use
	urinary tract complaints. The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.

4.2. Posology and method of administration³

Well-established use	Traditional use
Posology	Posology <i>Adults and elderly</i> a) Herbal tea Single dose: 2-4 g of the comminuted herbal substance in 250 ml of boiling water as an herbal infusion, 3 times daily. b) Powdered herbal substance: Single dose: 280–520 mg Daily dose: 1300 mg The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). Duration of use 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. Method of administration Oral use.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance(s) and to other plants of the Asteraceae (Compositae) family. Conditions where a reduced fluid intake is recommended (e.g. severe cardiac or renal disease).

³ 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 Rev.1).

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>

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
	<p>None known.</p> <p>If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.</p>

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 as amended.

5.2. Pharmacokinetic properties

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

5.3. Preclinical safety data

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

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

5 May 2015