



1 July 2014
EMA/HMPC/680374/2013
Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Hieracium pilosella* L., herba

Draft

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| Keywords | Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Hieracium pilosella</i> L., <i>herba</i> ; Hawkweed |
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| BG (bългарски): Рунянка, стрък с цвят CS (čeština): nař jestřábníku chlupáčku s květem DA (dansk): Håret gøgeurt DE (Deutsch): Kleines Habichtskraut mit Blüten EL (elliniká): Πιλοσέλλας πόα ανθισμένη EN (English): Mouse ear Hawkweed ES (español): Pílosela ET (eesti keel): Karutubakaürt koos õitega FI (suomi): Huopakeltano, verso kukkineen FR (français): Píloselle HU (magyar): Ezüstös hölgymál virágos hajtás HR (hrvatska): Zelen s cvijetom male runjike IT (italiano): Pílosella parti aeree con fiore LT (lietuvių kalba): Vanagių žolė su žiedais | LV (latviešu valoda): Mazās mauragas laksti ar ziediem MT (malti): Widnet il-Far NL (nederlands): Muizenoor PL (polski): Ziele jastrzębca kosmaczka z kwiatem PT (português): Pílosela, partes aéreas floridas RO (română): SK (slovenčina): Jastrabníková vňař s kvetom SL (slovenščina): Zel in cvet dolgodlakave škržolice SV (svenska): Gråfibbla, ovanjordiska delar i blom IS (íslenska): NO (norsk): Hårsveve, urt med blomst |
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Community herbal monograph on

Hieracium pilosella, L., herba

1. Name of the medicinal product

To be specified for the individual finished product.

2. Qualitative and quantitative composition¹

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

3. Pharmaceutical form

| Well-established use | Traditional use |
|----------------------|--|
| | Herbal preparations in solid 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 to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary tract complaints. |

¹ 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 |
|----------------------|--|
| | 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 administration²

| Well-established use | Traditional use |
|------------------------|--|
| <p>Posology</p> | <p>Posology</p> <p><i>Adults and elderly</i></p> <p>a) Herbal tea: 2-4 g of the comminuted herbal substance in water as an herbal infusion, 3 times daily.</p> <p>b) Powdered herbal substance: Single dose: 280–520 mg Daily dose: 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 or to plants of the Asteraceae (Compositae) family.</p> <p>Conditions where a reduced fluid intake is recommended (e.g. severe cardiac or renal disease).</p> |

² 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 reported.</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

1 July 2014