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SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

## Community herbal monograph on *Sisymbrium officinale* (L.) Scop., herba

Draft

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Rediscussion in Working Party on Community monographs and Community list (MLWP)	
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<b>Keywords</b>	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Sisymbrium officinale</i> (L.) Scop., herba; <i>Sisymbrium officinalis</i> herba; hedge mustard
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BG (bългарски): мъдрица лечебна, цвят CS (čeština): květ hulevníku lékařského DA (dansk): rank vejsennep DE (Deutsch): Wegraukenkraut EL (elliniká): Σισυμβρίου φαρμακευτικού άνθος EN (English): hedge mustard ES (español): Erísimo, partes aéreas floridas de ET (eesti keel): uniloogaürt FI (suomi): rohtopernaruoho, verso FR (français): Erysimum (parties aériennes fleuries d') HU (magyar): szapora zsombor HR (hrvatska): zelen divlje gorušice IT (italiano): erisimo, parti aeree	LT (lietuvių kalba): vaistinių pikulių žiedai LV (latviešu valoda): ārstniecības žodzenes ziedi MT (malti): mustarda NL (nederlands): heeskruud PL (polski): kwiat stulisza lekarskiego PT (português): rinchão flor RO (română): SK (slovenčina): vnať horčičníka SL (slovenščina): cved navadnega šebenika SV (svenska): vägsenap IS (íslenska): NO (norsk): veisenep
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# Community herbal monograph on *Sisymbrium officinale* (L.) Scop., herba

## 1. Name of the medicinal product

To be specified for the individual finished product.

## 2. Qualitative and quantitative composition<sup>1, 2</sup>

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>Sisymbrium officinale</i> (L.) Scop., herba (hedge mustard)</p> <p>i) Herbal substance Not applicable.</p> <p>ii) Herbal preparations</p> <p>a) Dry extract (DER 3.5-5.5:1), extraction solvent water</p> <p>b) Dry extract (DER 6-8:1), extraction solvent water</p>

## 3. Pharmaceutical form

Well-established use	Traditional use
	<p>Herbal preparations for oromucosal use (in a solid dosage form).</p> <p>Herbal preparation for oral use (in a liquid dosage form).</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

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<sup>1</sup> The material complies with the French Pharmacopoeia monograph (Pharmacopée française 1998 Érysimum, *Sisymbrium officinale*)

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

## 4. Clinical particulars

### 4.1. Therapeutic indications

Well-established use	Traditional use
	<p>Traditional herbal medicinal product for the relief of throat irritation such as hoarseness and dry cough.</p> <p>The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.</p>

### 4.2. Posology and method of administration

Well-established use	Traditional use
	<p><b>Posology</b></p> <p><b>Single dose</b></p> <p><b>Oromucosal use</b></p> <p><i>Adolescents, adults and elderly</i></p> <p>a) Dry extract (DER 3.5-5.5:1), extraction solvent water: 10 mg, 10 – 12 times daily</p> <p>b) Dry extract (DER 6-8:1), extraction solvent water: 7.5 – 10 mg, 10 – 12 times daily</p> <p><i>Children 6 - 11 years of age</i></p> <p>a) Dry extract (DER 3.5-5.5:1), extraction solvent water: 10 mg, 5 - 6 times daily</p> <p>b) Dry extract (DER 6-8:1), extraction solvent water: 7.5 - 10 mg, 5 - 6 times daily</p> <p>The oromucosal use in children under 6 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p>Tablet/lozenge to dissolve in the mouth without chewing.</p> <p><b>Oral use</b></p> <p><i>Adolescents, adults and elderly</i></p> <p>b) Dry extract (DER 6-8:1), extraction solvent water: 82.5 mg, 3 - 4 times daily</p> <p><i>Children 3 - 11 years of age</i></p> <p>b) Dry extract (DER 6-8:1), extraction solvent water: 27.5 mg, 3 - 4 times daily</p> <p>The oral use in children under 3 years of age is not</p>

Well-established use	Traditional use
	<p>recommended (see section 4.4 'Special warnings and precautions for use').</p> <p><b>Duration of use</b></p> <p>If the symptoms persist longer than 1 week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p><b>Method of administration</b></p> <p>Oral use.</p> <p>Oromucosal use.</p>

### 4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance.

### 4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>If dyspnoea, fever or purulent sputum occurs, a doctor or a qualified health care practitioner should be consulted immediately.</p> <p><b>Herbal preparations a) and b)</b></p> <p>The oromucosal use in children under 6 years of age is not recommended because of the pharmaceutical form (solid dosage form) and due to lack of adequate data.</p> <p><b>Herbal preparation b)</b></p> <p>The oral use in children under 3 years of age is not recommended due to lack of adequate data and because medical advice should be sought.</p>

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

Well-established use	Traditional use
	Not known.

#### **4.6. Fertility, pregnancy and lactation**

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

#### **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.  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 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

15 January 2014