30 September 2014
EMA/HMPC/280193/2013
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Sisymbrium officinale* (L.) Scop., herba

Final

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BG (bălgarski): мъдрица лечебна, цвят	IT (italiano): erisimo, parti aeree
CS (čeština): květ hulevníku lékařského	LT (lietuvių kalba): vaistinių pikulių žiedai
DA (dansk): rank vejsennep	LV (latviešu valoda): ārstniecības žodzenes ziedi
DE (Deutsch): Wegraukenkraut	MT (malti): mustarda
EL (elliniká): Σισυμβρίου φαρμακευτικού άνθος	NL (nederlands): heeskruid
EN (English): hedge mustard	PL (polski): kwiat stulisza lekarskiego
ES (espanol): Erísimo, partes aéreas floridas de	PT (português): rinchão flor
ET (eesti keel): uniloogaürt	RO (română): Iarbă de brâncuță
FI (suomi): rohtopernaruoho, kukka	SK (slovenčina): vnať horčičníka
FR (français): Erysimum (parties aériennes fleuries d')	SL (slovenščina): cved navadnega šebenika
HU (magyar): szapora zsombor	SV (svenska): vägsenap
HR (hrvatska): zelen divlje gorušice	*IS (íslenska)*:
	NO (norsk): veisennep

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European Union 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[1, 2]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *Sisymbrium officinale* (L.) Scop., herba (hedge mustard) i) Herbal substance Not applicable. ii) Herbal preparations a) Dry extract (DER 3.5-5.5:1), extraction solvent water b) Dry extract (DER 6-8:1), extraction solvent water

3. Pharmaceutical form

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

[1] The material complies with the French Pharmacopoeia monograph (Pharmacopée française 1998 Érysimum, Sisymbrium officinale)
[2] 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
	Traditional herbal medicinal product for the relief the symptoms of throat irritation such as hoarseness and dry cough. The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.

4.2. Posology and method of administration

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

Well-established use	Traditional use
	recommended (see section 4.4 'Special warnings and precautions for use'). **Duration of use** 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. **Method of administration** Oromucosal use. Oral use.

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
	If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. If dyspnoea, fever or purulent sputum occurs, a doctor or a qualified health care practitioner should be consulted immediately. Herbal preparations a) and b) 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. Herbal preparation b) 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.

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

Well-established use	Traditional use
	Not reported.

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
	The content of cardenolides has to be specified in the herbal preparations and should be ≤1ppm.

7. Date of compilation/last revision

30 September 2014