European Medicines Agency
Evaluation of Medicines for Human Use

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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

DRAFT

COMMUNITY HERBAL MONOGRAPH ON *SOLIDAGO VIRGAUREA* L., HERBA

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	July 2007 September 2007 October 2007
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REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	
ADOPTION BY HMPC	

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KEYWORDS	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Solidago virgaurea* L.; Solidaginis virgaureae herba; European goldenrod

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COMMUNITY HERBAL MONOGRAPH ON *SOLIDAGO VIRGAUREA* L., 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 i) Herbal substance Dried flowering aerial parts of *Solidago virgaurea* L. ii) Herbal preparations - Liquid extract (1:1) prepared with ethanol/water 25% v/v - Tincture (1:5) prepared with ethanol/water 45% v/v - Dry extract (5-7:1) prepared with ethanol/water 30 - 60% v/v - Comminuted herbal substance

3. PHARMACEUTICAL FORM

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

[1] The material complies with the Ph. Eur. monograph (ref. no 01/2006:1893).
[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 to increase the amount of urine to achieve flushing of the urinary tract as adjuvant in minor urinary complaints The product is a traditional herbal medicinal product for use in specified indication exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology *Adolescents over 12 years of age, adults* Single dose - 3 - 4 g dried herb for preparation of an herbal tea, 2 - 4 times daily - Liquid extract: 0.5 - 2 ml, 3 times daily - Tincture: 0.5 - 2 ml, 3 times daily - Dry extract: 350 - 450 mg, 3 times daily The use in children under 12 years of age is not recommended (see also 4.4. Special warnings and precautions for use). **Duration of use** The herbal substance is traditionally used over a period of 2 up to 4 weeks. If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. **Method of administration** Oral use. For extracts, ensure appropriate fluid intake.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance or to the Asteraceae. Conditions where a reduced fluid intake is recommended (e.g. severe cardiac or renal diseases or obstruction of the urinary tract).

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	The use is not recommended in children under 12 years of age because of the lack of available experience. If complaints of symptoms such as fever, dysuria, spasms or blood in the urine occur during the use of medicinal product, a doctor or a qualified health care professional should be consulted. For tinctures and extracts containing ethanol, the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included.

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

Well-established use	Traditional use
	Concomitant treatment with synthetic diuretics is not recommended.

4.6. 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.

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
	Hypersensitivity reactions and gastrointestinal complaints may occur. The frequency is not known. If other adverse reactions not mentioned above 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

31 October 2007