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Evaluation of Medicines for Human Use

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FINAL

COMMUNITY HERBAL MONOGRAPH ON *EQUISETUM ARVENSE* L., HERBA

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COMMUNITY HERBAL MONOGRAPH ON *EQUISETUM ARVENSE* 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 *Equisetum arvense* L., herba (horsetail herb) i) Herbal substance Not applicable ii) Herbal preparations a) comminuted herbal substance b) expressed juice (1 : 1.6-2.0) c) liquid extract (1 : 4 - 5) extraction solvent: ethanol 31.5 % (m/m) d) liquid extract (1 : 5) extraction solvent: ethanol 96 % (V/V)/water/sweet wine (16.5/13.5/70) (m/m) e) liquid extract (1 : 5.5) extraction solvent: sweet wine/ethanol 96 % (V/V) (91/9) (m/m) f) dry extract (4 - 7 : 1) extraction solvent: water g) dry extract (7.5 - 10.5 : 1) extraction solvent: ethanol 70 % (V/V)

3. PHARMACEUTICAL FORM

Well-established use	Traditional use
	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 dried material complies with the Ph. Eur. monograph (ref. 01/2008:1825)

[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 an 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* ii) Herbal preparations Single dose a) - comminuted herbal substance for tea preparation: 2 - 3 g herbal substance into 250 ml boiling water - comminuted herbal substance : 570 mg herb b) expressed juice from fresh herb (1 : 1.6-2.0): 20 ml c) liquid extract (1 : 4 - 5) extraction solvent ethanol 31.5 % (m/m): 20 drops d) liquid extract (1 : 5) extraction solvent: ethanol 96 % (V/V)/water/sweet wine (16.5/13.5/70) (m/m): 30 - 40 drops e) liquid extract (1 : 5.5) extraction solvent: sweet wine/ethanol 96 % (V/V) (91/9) (m/m): 25 drops f) dry extract (4 - 7 : 1) extraction solvent: water : 185 mg g) dry extract (7.5 - 10.5 : 1) extraction solvent: ethanol 70 % (V/V): 200 - 225 mg Daily dose: 3 single doses Maximum daily dose: 4 single doses

	The use is not recommended in children under 12 years of age (see section 4.4. Special warnings and precautions for use) **Duration of use** Herbal preparations are traditionally used over a period of 2 to 4 weeks. See also 4.4. Special warnings and precautions for use If the symptoms persist after one week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. **Method of administration** Oral use. For preparations other than tea preparations ensure appropriate fluid intake.

4.3. Contraindications

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

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 or symptoms such as fever, dysuria, spasm or blood in urine occur during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. For liquid 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
	None reported.

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 ability to drive and use machines have been performed.

4.8. Undesirable effects

Well-established use	Traditional use
	Mild gastrointestinal complaints and allergic reactions (e.g. rash) have been reported. 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. 5.2Pharmacokinetic 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

3 July 2008