EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Equisetum arvense* L., herba

Draft

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Discussion in Working Party on European Union monographs and European Union list (MLWP)	September 2007 October 2007
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	31 October 2007
End of consultation (deadline for comments).	15 February 2008
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Adoption by HMPC Monograph (EMEA/HMPC/394894/2007) AR (EMEA/HMPC/394895/2007) List of references (EMEA/HMPC/394897/2007) Overview of comments received during the public consultation (EMEA/HMPC/230479/2008) HMPC Opinion (EMEA/HMPC/305044/2008)	3 July 2008
First systematic review	
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Rediscussion in MLWP	
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Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Equisetum arvense* L., herba; Equiseti herba; horsetail herb

BG (bulgarski): Полски хвощ, стрък CS (čeština): přesličková nať DA (dansk): Padderok DE (Deutsch): Schachtelhalmkraut EL (elliniká): πόα Ιππουρίδος EN (English): Horsetail herb ES (español): Cola de caballo, partes aéreas de ET (eesti keel): osjaürt FI (suomi): peltokorte FR (français): Prêle (tige de) HR (hrvatski): zelen poljske preslice HU (magyar): Mezei zsurló meddő hajtás IT (italiano): Equiseto (Coda cavallina) parti aeree	LT (lietuvių kalba): Asiūklių žolė LV (latviešu valoda): Kosas laksti MT (Malti): Denb iż-żiemel NL (Nederlands): Heermoes PL (polski): Ziele skrzypu PT (português): Cavalinha RO (română): iarbă de coada calului SK (slovenčina): Vňať prasličky SL (slovenščina): zel njivske preslice SV (svenska): Åkerfräken, ört *IS (íslenska)*: *NO (norsk):* Kjerringrokk

European Union 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 from fresh herbal substance (DER 1:1.6-2.0) c) Liquid extract from fresh herbal substance (DER 1:9), extraction solvent: water d) Dry extract (DER 4-7:1) extraction solvent: water e) Liquid extract (DER 1:5), extraction solvent: ethanol 96% (V/V) : water : sweet wine 16.5% (V/V) (16.5:13.5:70) (m/m) f) Liquid extract (DER 1:4.5-5.0) extraction solvent: sweet wine 16% (V/V):ethanol 96% (V/V) (91:9) (m/m) g) Liquid extract (DER 1:1) extraction solvent: 25% ethanol h) Liquid extract (DER 1:4-5), extraction solvent: ethanol 31.5% (V/V) i) Dry extract (DER 7.5-10.5:1) extraction solvent: ethanol 70% (V/V)

[1]The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

[2] The material complies with the Ph. Eur. monograph (ref.: 1825)

3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea or in solid dosage forms for oral use. Herbal preparations in liquid or solid dosage forms for oral use. Comminuted herbal substance for infusion or decoction preparation for cutaneous use. Herbal preparations in liquid dosage forms for cutaneous 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
	Indication 1 Traditional herbal medicinal product used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints. Indication 2 Traditional herbal medicinal product used for supportive treatment of superficial wounds. 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 administration[3]

Well-established use	**Traditional use**
	Posology Indication 1 *Adolescents, adults and elderly* a) Herbal tea: single dose: 1-4 g of the comminuted herbal substance in 150 ml of boiling water as an infusion or as a decoction (5-15 minutes), 3-4 times daily daily dose: 3-12 g Comminuted herbal substances in solid form: single dose: 570 mg 3 times daily daily dose: 1.7 g b) single dose: 10-20 ml, 3 times daily daily dose: 30-60 ml c) single dose: 10 ml, 3-4 times daily daily dose: 30-40 ml d) single dose: 370 mg 3 times daily or 540 mg 2 times daily daily dose: 1080-1110 mg e) single dose: 0.96-1.23 ml, 3-4 times daily daily dose: 2.88-4.92 ml f) single dose: 1.1 ml, 3 times daily daily dose: 3.3 ml g) single dose: 1-4 ml, 3 times daily daily dose: 3-12 l h) single dose: 0.7 ml, 3 times daily daily dose: 2.1 ml i) single dose: 200-225 mg, 3 times daily daily dose: 600-675 mg The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').

[3] 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).

Well-established use	**Traditional use**
	Indication 2 *Adolescents, adults and elderly* a) single dose: 10 g of the comminuted herbal substance in 1l of water as decoction for impregnated dressing and irrigation daily dose: one to several times b) single dose: 40 ml of the expressed juice in 500 ml water for impregnated dressing and irrigation daily dose: one to several times The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **Duration of use** Indication 1 Herbal preparations are traditionally used over a period of 2 to 4 weeks. Indication 1 and 2 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** Indication 1 Oral use. Indication 2 Cutaneous use.

4.3. Contraindications

Well-established use	**Traditional use**
	Hypersensitivity to the active substance. Indication 1 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 in children under 12 years of age has not been established due to lack of adequate data. Indication 1 If complaints or symptoms such as fever, dysuria, spasm or blood in urine occur or if the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. For preparations other than tea preparations ensure appropriate fluid intake. For 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. Indication 2 If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. If signs of skin infection are observed, a doctor or a qualified health care practitioner should be consulted.

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
	Indication 1 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.

Well-established use	Traditional use
	Indication 2 There are no data on use during pregnancy or lactation. In the absence of sufficient data, the use during pregnancy is not recommended. Products containing Equiseti herba should not be applied to the breast of breastfeeding women. 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
	Indication 1 Mild gastrointestinal complaints have been reported. The frequency is not known. Indication 1 and 2 Allergic reactions (e.g. rash, swelling of the face) 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. 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

7 July 2015