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FINAL

COMMUNITY HERBAL MONOGRAPH ON *BETULA PENDULA* ROTH; *BETULA PUBESCENS* EHRH., FOLIUM

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	January 2007 March 2007 May 2007
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COMMUNITY HERBAL MONOGRAPH ON *BETULA PENDULA* ROTH; *BETULA PUBESCENS* EHRH., FOLIUM

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 marketing authorisation application of Article 10(a) of Directive 2001/83/EC as amended	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *Betula pendula* Roth and/or *Betula pubescens* Ehrh. as well as hybrids of both species, folium (birch leaf) i) Herbal substance Whole or fragmented dried leaves ii) Herbal preparations A) powdered herbal substance B) dry extract (DER 3-8:1, extraction solvent water) C) liquid extract prepared from fresh leaves (DER 1:2-2.4, extraction solvent water) D) Liquid extract from fresh leaves stabilised by 96% ethanol vapours (1:1, 50- 60% (V/V) ethanol)

3. PHARMACEUTICAL FORM

Well-established use	Traditional use
	Herbal substance or herbal preparations in solid or liquid dosage forms 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. 01/2005:1174)

[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 *Adults, elderly* Single dose Herbal substance as infusion: 2 - 3 g A) Powdered herbal substance: 650 mg B) Dry extract: 0.25 - 1 g C) Liquid extract prepared from fresh leaves: 15 ml 2 to 3 times daily D) Liquid extract from fresh leaves stabilised by 96% ethanol vapours: 2.5 ml Maximum daily dose The maximum daily dose is 12 g of herbal substance in 4 divided doses or 1.3 g of powdered herbal substance in 2 divided doses or 4 g of dry extract in 4 divided doses or 7.5 ml of liquid extract from fresh leaves stabilised by 96% ethanol vapours in 3 divided doses. The use of birch preparations is not recommended in children under 12 years of age (see section 4.4 Special warnings and precautions for use). **Duration of use** The herbal substance is traditionally used over a period of 2 - 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. To ensure an increase of the amount of urine, adequate fluid intake is required during treatment.

4.3. Contraindications

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

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	The use in children under 12 years of age is not recommended because of the lack of available experience. If complaints or symptoms such as fever, dysuria, spasms, or blood in urine occur during the use of the medicinal product, 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. Pregnancy and lactation

Well-established use	Traditional use
	Safety during pregnancy and lactation has not been established. In the absence of sufficient data, 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
	Gastrointestinal complaints (nausea, vomiting, diarrhoea) and allergic reactions (itching, rash, urticaria, allergic rhinitis) 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 required for the safe use of the product. Adequate tests on genotoxicity have not been performed. Tests on reproductive toxicity and carcinogenicity have not been performed.

6. PHARMACEUTICAL PARTICULARS

Well-established use	Traditional use
	Not applicable.

7. DATE OF COMPILATION/LAST REVISION

8 May 2008