European Medicines Agency
Evaluation of Medicines for Human Use

London, 8 May 2007
Doc. Ref. EMEA/HMPC/260019/2006

COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

DRAFT

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
ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION	8 May 2007
END OF CONSULTATION (DEADLINE FOR COMMENTS)	15 August 2007
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; *Betula pendula* Roth; *Betula pubescens* Ehrh.; Betulae folium; birch leaf

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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 - powdered herbal substance - dry extract with water (3-8:1)

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 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. 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 Dry extract: 0.25 - 1 g Maximum daily dose The maximum daily dose is 12 g of herbal substance in 4 divided doses or 4 g of dry extract in 4 divided doses. The use of birch preparations is not recommended in children and adolescents under 18 years of age (see also 4.4 Special warnings and precautions for use). **Duration of use** The herbal substance is traditionally used over a period of 2 - 3 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 and adolescents under 18 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. A water extract of birch leaf showed a very weak mutagenic response in the Ames test, however additional genotoxicity studies are necessary to assess genotoxicity. 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 2007