EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 November 2014
EMA/HMPC/573241/2014
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Betula pendula* Roth and/or *Betula pubescens* Ehrh. as well as hybrids of both species, folium

Final

Initial assessment	
Discussion in Working Party on European Union monographs and list (MLWP)	January 2007 March 2007 May 2007
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	8 May 2007
End of consultation (deadline for comments)	15 August 2007
Rediscussion in MLWP	January 2008 May 2008
Adoption by HMPC Monograph (EMEA/HMPC/260019/2006) AR (EMEA/HMPC/260018/2006) List of references (EMEA/HMPC/207742/2007) Overview of comments received during the public consultation (EMEA/HMPC/488559/2007) HMPC Opinion (EMEA/HMPC/453698/2007)	8 May 2008
First systematic review	
Discussion in MLWP	September 2014
Adoption by HMPC	24 November 2014

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Betula pendula* Roth; *Betula pubescens* Ehrh.; Betulae folium; birch leaf

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BG (bulgarski): Бреза, лист CS (čeština): březový list DA (dansk): Birkeblad DE (Deutsch): Birkenblätter EL (elliniká): Φύλλο βετούλης- φύλλο σημύδας EN (English): Birch leaf ES (español): Abedul, hoja de ET (eesti keel): Kaseleht FI (suomi): Koivu, lehti FR (français): Bouleau (feuille de) HR (hrvatski): Brezov list HU (magyar): Nyírfalevél IT (italiano): Betulla foglia	LT (lietuvių kalba): Beržų lapai LV (latviešu valoda): Bērzu lapas MT (Malti): Werqa tal-Betulla NL (Nederlands): Berkeblad PL (polski): Liść brzozy PT (português): Bétula, folha RO (română): Frunză de mesteacăn SK (slovenčina): Brezový list SL (slovenščina): List breze SV (svenska): Björkblad *IS (íslenska)*: *NO (norsk):* Bjørkeblad

European Union herbal monograph on *Betula pendula* Roth and/or *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 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 Not applicable. ii) Herbal preparations a) Comminuted herbal substance b) Powdered herbal substance c) Dry extract (DER 3-8:1), extraction solvent water d) Liquid extract prepared from fresh leaves (DER 1:2-2.4), extraction solvent water e) Liquid extract prepared from fresh leaves stabilised by 96% ethanol vapours (DER 1:1), extraction solvent ethanol 50-60% (V/V)

3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea for oral use. Herbal preparations in solid or liquid dosage forms for oral use. The pharmaceutical form should be described by

[1] The declaration of the active substance for an individual finished product should be in accordance with relevant herbal quality guidance.
[2] The dried material complies with the Ph. Eur. monograph (ref. 04/2013:1174)

Well-established use	Traditional use
	the European Pharmacopoeia full standard term.

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 the specified indication exclusively based upon long-standing use.

4.2. Posology and method of administration[3]

Well-established use	Traditional use
	Posology *Adolescents, adults and elderly* *a) Comminuted herbal substance* Herbal tea: 2-3 g of the comminuted herbal substance in 150 ml of boiling water as a herbal infusion up to 4 times daily b) *Powdered herbal substance* Single dose: 650 mg, 2 times daily c) *Dry extract:* Single dose: 0.25–1 g, 4 times daily d) *Liquid extract:* Single dose: 15 ml, 2-3 times daily e) *Liquid extract stabilized:* Single dose: 2.5 ml, 3 times daily 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** The herbal preparations are traditionally used

[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
	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 the active substance or to birch pollen. 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 has not been established due to lack of adequate data. 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. 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.

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
	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.

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

Well-established use	Traditional use
	Directive 2001/83/EC as amended.

5.3. Preclinical safety data[4]

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. 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

24 November 2014