24 January 2012
EMA/HMPC/573460/2009 Rev.1
Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Arctostaphylos uva-ursi* (L.) Spreng., folium

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	September 2009 May 2010 July 2010
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	14 July 2010
End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	15 December 2010
Rediscussion in Working Party on Community monographs and Community list (MLWP)	January 2011 March 2011
Adoption by Committee on Herbal Medicinal Products (HMPC)	31 March 2011
Discussion in Working Party on Community monographs and Community list (MLWP)	September 2011
Adoption[1] by Committee on Herbal Medicinal Products (HMPC)	24 January 2012

Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Arctostaphylos uva-ursi* (L.) Spreng., folium; Uvae ursi folium; bearberry leaf

BG (bălgarski): Мечо грозде, лист	LT (lietuvių kalba): Meškauogių lapai
CS (čeština): Medvědicový list	LV (latviešu valoda): Miltenes lapas
DA (dansk): Melbærrisblad	MT (malti): Werqa ta' l-Ulva Ursi
DE (Deutsch): Bärentraubenblätter	NL (nederlands): Beredruif
EL (elliniká): Φύλλο αρκτοκομάρου	PL (polski): Liść mącznicy
EN (English): Bearberry leaf	PT (português): Uva-ursina, folha
ES (espanol): Gayuba, hoja de	RO (română): Frunză de strugurii ursului
ET (eesti keel): Leesikaleht	SK (slovenčina): Medvedicový list
FI (suomi): Sianpuolukka, lehti	SL (slovenščina): List vednozelenega gornika
FR (français): Busserole (feuille de)	SV (svenska): Mjölonblad
HU (magyar): Orvosi medveszőlő levél	*IS (íslenska)*:
IT (italiano): Uva ursina foglia	*NO (norsk)*: Melbærblad

[1] Rev. 1: after assessment of comments received in July 2011 regarding the changes in the monograph on Uvae ursi folium concerning the gender-specific indication (see overview of comments EMA/HMPC/46410/2011 Rev.1)

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7051
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Community herbal monograph on *Arctostaphylos uva-ursi* (L.) Spreng., folium

1. Name of the medicinal product

To be specified for the individual finished product.

2. Qualitative and quantitative composition[2, 3]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *Arctostaphylos uva-ursi* (L.) Spreng., folium (bearberry leaf) i) Herbal substance Not applicable. ii) Herbal preparations a) Comminuted herbal substance b) Powdered herbal substance c) Dry extract (DER 3.5 - 5.5:1), extraction solvent ethanol 60% (V/V), containing 23.5 - 29.3% of hydroquinone derivatives calculated as anhydrous arbutin (spectrophotometry) d) Dry extract (DER 2.5 - 4.5:1), extraction solvent water, containing 20 - 28% of hydroquinone derivatives calculated as anhydrous arbutin (spectrophotometry)

3. Pharmaceutical form

Well-established use	**Traditional use**
	Herbal preparations in solid dosage forms or as herbal tea for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

2 The material complies with the Ph. Eur. monograph (ref.: 04/2008:1054).
3 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 used for treatment of symptoms of mild recurrent lower urinary tract infections such as burning sensation during urination and/or frequent urination in women, after serious conditions have been excluded by a medical doctor. 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[4]

Well-established use	Traditional use
	Posology *Female adults and elderly* a) Herbal tea 1.5-4 g of the comminuted herbal substance in 150 ml of boiling water as a herbal infusion, 2 to 4 times daily corresponding to the maximum daily dose of 8 g. 1.5-4 g of the comminuted herbal substance in 150 ml of water as a macerate, 2 to 4 times daily corresponding to the maximum daily dose of 8 g. The macerate should be used immediately after preparation. Herbal preparations b), c), d) Single dose corresponding to 100-210 mg of hydroquinone derivatives calculated as anhydrous arbutin (spectrophotometry), 2 to 4 times daily. The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').

[4] For guidance on herbal preparation administered as herbal tea, please refer to the HMPC 'Glossary on herbal teas' (EMA/HMPC/5829/2010 Rev.1).

	The use in men is not recommended (see section 4.4 'Special warnings and precautions for use'). **Duration of use** Not to be used for more than one week. If the symptoms persist for more than 4 days or worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. **Method of administration** Oral use.

4.3. Contraindications

Well-established use	**Traditional use**
	Hypersensitivity to the active substance. Kidney disorders.

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 concerns requiring medical advice. The use in men is not recommended because of concerns requiring medical supervision. 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. Uvae ursi folium may cause a greenish-brown coloration of the urine.

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
	No fertility data available. Safety during pregnancy and lactation has not been established. The use should be avoided during pregnancy (see section 5.3 'Preclinical safety data'). In absence of sufficient data, the use during 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
	Nausea, vomiting, stomach-ache 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. Available tests on genotoxicity of water and ethanolic extracts of Uvae ursi folium are inadequate. Reproductive toxicity has not been studied. Available carcinogenicity studies have been negative. Arbutin, the principal component of Uvae ursi folium, displayed some maternal and fetal toxicity in rats after subcutaneous administration of 400 mg/kg/day. No effect on reproduction has been observed at doses of 100 mg/kg/day. Toxicity tests with hydroquinone, a hydrolysis product of arbutin, have demonstrated some evidence of genotoxicity and carcinogenicity. Risks posed by the exposure of hydroquinone during the short-term treatment with Uvae ursi folium preparations are considered minimal.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

24 January 2012