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

Draft

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BG (bălgarski):	LT (lietuvių kalba): Meškauogių lapai
CS (čeština): list medvědice	LV (latviešu valoda): Miltenes lapas
DA (dansk): Melbærrisblad	MT (malti): Weraq tal-Uva ursina
DE (Deutsch): Bärentraubenblätter	NL (nederlands): beredruifblad
EL (elliniká):	PL (polski): liść mącznicy
EN (English): bearberry leaf	PT (português): Uva-ursina, folha
ES (espanol): Uva ursi	RO (română): Frunză de strugurii ursului
ET (eesti keel):	SK (slovenčina): Medvedicový list
FI (suomi):	SL (slovenščina):
FR (français): Busserole	SV (svenska):
HU (magyar): Orvosi medveszőlő levél	*IS (íslenska)*:
IT (italiano): Uva ursina	*NO (norsk):* melbærblad

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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[1,2]

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 Whole or fragmented, dried leaf 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) quantified to 23.5-29.3% of hydroquinone derivatives calculated as anhydrous arbutin determined by spectrophotometry or corresponding amount of arbutin determined by HPLC d) Dry extract (DER 2.5-4.5:1), extraction solvent water quantified to 20-28% of hydroquinone derivatives calculated as anhydrous arbutin determined by spectrophotometry or corresponding amount of arbutin determined by HPLC

3. Pharmaceutical form

Well-established use	**Traditional use**
	Herbal substance or herbal preparations in solid dosage forms or as herbal tea/macerate for oral

1 The material complies with the Ph. Eur. monograph (ref.: 04/2008:1054).
2 The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

Well-established use	Traditional use
	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**
	Traditional herbal medicinal product used for treatment of early symptoms of mild urinary tract infections such as burning sensation during urination and/or frequent urination. 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* a) Herbal tea: 1.5 – 4.0 g of the comminuted herbal substance To make an herbal tea, pour 150 ml of boiling water over 1 g of comminuted herbal substance, steep for 15 minutes. To make a macerate, pour 150 ml of cold water over 1.5 to 4 g of the comminuted herbal substance and steep for minimum 30 minutes stirring frequently. The macerate should be used immediately after preparation. Herbal preparations b), c), d) The amount corresponding to 100 – 210 mg of hydroquinone derivatives calculated as anhydrous arbutin (photometric) or corresponding amount of arbutin (HPLC) 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').

	Duration of use The duration of use should not exceed one week. If the symptoms persist for more than 2 days 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 data are not sufficient and medical advice should be sought. 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. Use of Uvae ursi folium may cause a greenish-brown coloration of the urine that darkens on exposure to air.

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. The use should be avoided during pregnancy (see

	section 5.3 'Preclinical safety data'). In absence o 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. Risk 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

15 July 2010