



30 January 2018
EMA/HMPC/750269/2016
Committee on Herbal Medicinal Products (HMPC)

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

Final

Initial assessment	
Discussion in Working Party on European Union monographs and 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)	15 December 2010
Re-discussion in MLWP	January 2011 March 2011
Adoption by HMPC	31 March 2011
First revision	
Discussion in Working Party on European Union monographs and list (MLWP)	September 2011
Adoption by HMPC <ul style="list-style-type: none">• Monograph (EMA/HMPC/573460/2009 Rev. 1)• AR (EMA/HMPC/573462/2009 Rev. 1)• List of references (EMA/HMPC/573461/2009 Rev. 1)• Overview of comments received during public consultation (EMA/HMPC/46410/2011 Rev. 1)• HMPC Opinion (EMA/HMPC/888910/2011)	24 January 2012
Second revision	
Discussion in Working Party on European Union monographs and list (MLWP)	November 2016 January 2017
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	28 March 2017
End of consultation (deadline for comments)	15 July 2017
Rediscussion in MLWP	September 2017 November 2017
Adoption by HMPC	30 January 2018



Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; <i>Arctostaphylos uva-ursi</i> (L.) Spreng., folium; Uvae ursi folium; bearberry leaf
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<p>BG (bulgarski): Мечо грозде, лист</p> <p>CS (čeština): medvědicový list</p> <p>DA (dansk): Melbærrisblad</p> <p>DE (Deutsch): Bärentraubenblätter</p> <p>EL (elliniká): φύλλο αρκτοκομάρου</p> <p>EN (English): bearberry leaf</p> <p>ES (español): gayuba, hoja de</p> <p>ET (eesti keel): leesikaleht</p> <p>FI (suomi): sianpuolukka, lehti</p> <p>FR (français): busserole (feuille de)</p> <p>HR (hrvatski): medvjekin list</p> <p>HU (magyar): orvosi medveszőlő levél</p> <p>IT (italiano): uva ursina foglia</p>	<p>LT (lietuvių kalba): Meškauogių lapai</p> <p>LV (latviešu valoda): Miltenes lapas</p> <p>MT (Malti): werqa ta' l-ulva ursi</p> <p>NL (Nederlands): Beredruif</p> <p>PL (polski): Liść mącznicy</p> <p>PT (português): uva-ursina, folha</p> <p>RO (română): frunză de strugurii ursului</p> <p>SK (slovenčina): list medvedice</p> <p>SL (slovenščina): list vednozelenega gornika</p> <p>SV (svenska): mjölon, blad</p> <p>IS (íslenska):</p> <p>NO (norsk): melbærblad</p>
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European Union 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
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC</p> <p><i>Arctostaphylos uva-ursi</i> (L.) Spreng., folium (bearberry leaf)</p> <p>i) Herbal substance</p> <p>Not applicable</p> <p>ii) Herbal preparations</p> <p>a) Comminuted herbal substance</p> <p>b) Powdered herbal substance</p> <p>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)</p> <p>d) Dry extract (DER 2.5-4.5:1), extraction solvent water, containing 20-28% of hydroquinone derivatives calculated as anhydrous arbutin (spectrophotometry)</p> <p>e) Liquid extract (DER 1:1), extraction solvent ethanol 25% V/V</p>

3. Pharmaceutical form

Well-established use	Traditional use
	<p>Comminuted herbal substance as herbal tea for oral use.</p> <p>Herbal preparations in liquid or solid dosage forms for</p>

¹ The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

² The material complies with the Ph. Eur. monograph (ref.: 1054)

Well-established use	Traditional use
	<p>oral use.</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	<p>Traditional herbal medicinal product used for relief 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.</p> <p>The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.</p>

4.2. Posology and method of administration³

Well-established use	Traditional use
	<p>Posology</p> <p><i>Female adults and elderly</i></p> <p>a) Comminuted herbal substance</p> <p>Herbal tea: 1.5-4 g of the comminuted herbal substance in 150 ml of boiling water as a herbal infusion or in 150 ml of water as a macerate 2 to 4 times daily</p> <p>Maximum daily dose: 8 g</p> <p>b) Powdered herbal substance</p> <p>Single dose: 700 – 1050 mg twice daily</p> <p>Maximum daily dose: 1.75 g</p> <p>c) and d) Dry extracts</p> <p>Single dose: the dose corresponding to 100–210 mg of hydroquinone derivatives calculated as anhydrous arbutin 2–4 times daily</p> <p>Daily dose: the dose corresponding to 200–840 mg of hydroquinone derivatives calculated as anhydrous</p>

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
	<p>arbutin</p> <p>e) Liquid extract</p> <p>Single dose: 1.5–4 ml up to three times daily Maximum daily dose: 8 ml</p> <p>The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p>The use in men is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p>Duration of use</p> <p>Not to be used for more than one week.</p> <p>If the symptoms persist for more than 4 days during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Method of administration</p> <p>Oral use</p> <p>The macerate should be used immediately after preparation.</p>

4.3. Contraindications

Well-established use	Traditional use
	<p>Hypersensitivity to the active substance. Kidney disorders</p>

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>The use in children and adolescents under 18 years of age is not recommended because of concerns requiring medical advice.</p> <p>The use in men is not recommended because of concerns requiring medical supervision.</p> <p>If the symptoms worsen or if complaints 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.</p> <p>Uvae ursi folium may cause a greenish-brown coloration of the urine.</p>

Well-established use	Traditional use
	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
	No fertility data available. Safety during pregnancy and lactation has not been established. In absence of sufficient data, the 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
	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.

5.2. Pharmacokinetic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC.

5.3. Preclinical safety data

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC, 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

30 January 2018