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EMA/HMPC/678995/2013
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Vaccinium myrtillus* L., fructus siccus

Draft

Discussion in Working Party on European Union monographs and European Union list (MLWP)	Sep 2013 Jan 2014 May 2014 Jul 2014 Sep 2014 Nov 2014 Jan 2015
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Rediscussion in MLWP	
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Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; <i>Vaccinium myrtillus</i> L., fructus siccus; Vaccini myrtilli fructus siccus; dried bilberry fruit
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BG (bългарski): Черна боровинка, изсушен плод	LT (lietuvių kalba): Mėlynių vaisiai
CS (čeština): borůvkový plod	LV (latviešu valoda): Mellenes augļi, žāvēti
DA (dansk): Blåbær	MT (Malti): Frott niexef tal-Mirtillu
DE (Deutsch): Getrocknete Heidelbeeren	NL (Nederlands): Blauwe Bosbes, gedroogde bessen
EL (elliniká): Καρπός Μυρτίλλου	PL (polski): Owoc borówki czernicy, suchy
EN (English): dried bilberry fruit	PT (português): Mirtilo, fruto seco
ES (español): Arándano, fruto seco de	RO (română): Afine uscate
ET (eesti keel): kuivatatud mustikas	SK (slovenčina): Plod čučoriedky, suchý
FI (suomi): mustikka, marja, kuivattu	SL (slovenščina): posušeni plod borovnice
FR (français): Myrtille (fruit sec de)	SV (svenska): Blåbär, torkat bär
HR (hrvatski): Borovničin plod, svjež	IS (íslenska):
HU (magyar): szárított fekete áfonya termés	NO (norsk): Blåbær, tørrede
IT (italiano): Mirtillo nero frutto secco	



European Union herbal monograph on *Vaccinium myrtillus* L., fructus siccus

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 <i>Vaccinium myrtillus</i> L., fructus siccus (dried bilberry fruit) i) Herbal substance Ripe, dry fruits ii) Herbal preparations a) Comminuted herbal substance

3. Pharmaceutical form

Well-established use	Traditional use
	Herbal substance or comminuted herbal substance as herbal tea for oral use or for decoction preparation for oromucosal 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
	Indication 1) Traditional herbal medicinal product for symptomatic treatment of mild diarrhoea.

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

²The material complies with the Ph. Eur. monograph (ref.: 01/2008:1588).

Well-established use	Traditional use
	<p data-bbox="810 309 967 340">Indication 2)</p> <p data-bbox="810 369 1422 472">Traditional herbal medicinal product for symptomatic treatment of minor inflammations of the oral mucosa.</p> <p data-bbox="810 501 1350 604">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 data-bbox="810 781 935 813">Posology</p> <p data-bbox="810 824 1203 855"><i>Adolescents, adults, and elderly</i></p> <p data-bbox="810 866 940 898">Daily dose</p> <p data-bbox="810 927 967 958">Indication 1)</p> <p data-bbox="810 969 1390 1133">Herbal tea: 15 – 60 g of herbal substance or comminuted herbal substance as a decoction, in divided doses of 5 – 15 g in 250 ml of water, 3 – 4 times daily.</p> <p data-bbox="810 1207 967 1238">Indication 2)</p> <p data-bbox="810 1258 1430 1400">Herbal substance or comminuted herbal substance for decoction preparation for oromucosal use: 20 g of herbal substance or comminuted herbal substance in 200 ml of water.</p> <p data-bbox="810 1429 1257 1460">Rinse the mouth several times daily.</p> <p data-bbox="810 1480 1394 1583">The use in children under 12 years of age is not recommended (see 4.4 'Special warnings and precautions for use')</p> <p data-bbox="810 1635 1023 1666">Duration of use</p> <p data-bbox="810 1686 967 1718">Indication 1)</p> <p data-bbox="810 1738 1426 1901">If the symptoms persist longer than 3 days during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</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>Indication 2)</p> <p>If the symptoms persist longer than 1 week 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>Indication 1)</p> <p>Oral use.</p> <p>Indication 2)</p> <p>Oromucosal use.</p>

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>The use in children under 12 years of age has not been established due to lack of adequate data.</p> <p>Indication 1)</p> <p>If the symptoms worsen or persist longer than 3 days during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Indication 2)</p> <p>If the symptoms worsen or persist longer than 1 week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p>

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
	Can be used during pregnancy and lactation. No concern has arisen about any malformation in humans, following the consumption of dried bilberry fruit. 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
	None known. If adverse reactions 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. Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

28 January 2015