



29 September 2015
EMA/HMPC/678995/2013
Committee on Herbal Medicinal Products (HMPC)

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

Final

Discussion in Working Party on European Union monographs and list (MLWP)	September 2013 January 2014 May 2014 July 2014 September 2014 November 2014
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	28 January 2015
End of consultation (deadline for comments ¹)	15 May 2015
Re-discussion in MLWP	July 2015
Adoption by HMPC	29 September 2015
Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; <i>Vaccinium myrtillus</i> L., fructus siccus; Myrtilli fructus siccus; Billberry fruit, dried

¹ No comments were received during the period of public consultation. Therefore the final monograph is published together with the final assessment report and list of references, without an 'Overview of comments received during the public consultation'.



BG (bulgarski): Черна боровинка, изсушен плод	LT (lietuvių kalba): Džiovinτος mėlynių uogos
CS (čeština): borůvkový plod	LV (latviešu valoda): Mellenes augļi, žāvēti
DA (dansk): Blåbær, tørrede	MT (Malti): Frott niexef tal-Mirtillu
DE (Deutsch): Getrocknete Heidelbeeren	NL (Nederlands): Blauwe Bosbes, gedroogde bessen
EL (elliniká): Καρπό ξηρού Μυρτίλλου	PL (polski): Owoc borówki czernicy, suchy
EN (English): Bilberry fruit, dried	PT (português): Mirtilo, fruto seco
ES (español): Arándano, fruto seco de	RO (română): Afine uscate
ET (eesti keel): kuivatatud mustikas	SK (slovenčina): Plod čučoriedky, usušený
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^{2, 3}

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 (Bilberry fruit, dried) i) Herbal substance Ripe, dry fruits ii) Herbal preparations 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.

² The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

³ The material complies with the Ph. Eur. monograph (ref.: 1588)

Well-established use	Traditional use
	<p data-bbox="810 259 970 291">Indication 2)</p> <p data-bbox="810 313 1391 421">Traditional herbal medicinal product for symptomatic treatment of minor inflammations of the oral mucosa.</p> <p data-bbox="810 443 1350 551">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 administration⁴

Well-established use	Traditional use
	<p data-bbox="810 745 938 777">Posology</p> <p data-bbox="810 786 1193 817"><i>Adolescents, adults and elderly</i></p> <p data-bbox="810 831 970 862">Indication 1)</p> <p data-bbox="810 884 1401 1028">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 1041 970 1072">Indication 2)</p> <p data-bbox="810 1095 1295 1202">Herbal substance or comminuted herbal substance for decoction preparation for oromucosal use:</p> <p data-bbox="810 1211 1391 1274">20 g of herbal substance or comminuted herbal substance in 200 ml of water.</p> <p data-bbox="810 1301 1257 1332">Rinse the mouth several times daily.</p> <p data-bbox="810 1355 1398 1462">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 1507 1024 1538">Duration of use</p> <p data-bbox="810 1561 970 1592">Indication 1)</p> <p data-bbox="810 1615 1414 1758">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> <p data-bbox="810 1780 970 1812">Indication 2)</p> <p data-bbox="810 1834 1414 1942">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</p>

⁴ 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>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
	<p>Can be used during pregnancy and lactation.</p> <p>No concern has arisen about any malformation in</p>

Well-established use	Traditional use
	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

Well-established use	Traditional use
	<p>necessary for the safe use of the product.</p> <p>Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.</p>

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

29 September 2015