28 January 2015
EMA/HMPC/375808/2014
Committee on Herbal Medicinal Products (HMPC)

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

Draft

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Rediscussion in MLWP	
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Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Vaccinium myrtillus* L., fructus recens; Myrtilli fructus recens; fresh bilberry fruit

BG (bălgarski): Черна боровинка, пресен плод	LT (lietuvių kalba): Šviežios mėlynių uogos
CS (čeština): čerstvý borůvkový plod	LV (latviešu valoda): Mellenes augļi, svaigi
DA (dansk): Blåbær, friske	MT (Malti): Frott tal-Mirtillu
DE (Deutsch): Frische Heidelbeeren	NL (Nederlands): Blauwe Bosbes, verse bessen
EL (elliniká): Καρπός νωπού Μυρτίλλου	PL (polski): Owoc borówki czernicy, świeży
EN (English): fresh bilberry fruit	PT (português): Mirtilo, fruto fresco
ES (español): Arándano, fruto fresco de	RO (română): Afine proaspete
ET (eesti keel): värske mustikas	SK (slovenčina): Plod čučoriedky, čerstvý
FI (suomi): mustikka, marja, tuore	SL (slovenščina): sveži plod borovnice
FR (français): Myrtille (fruit frais de)	SV (svenska): Blåbär, färskt bär
HR (hrvatski): mustikka, marja, tuore	IS (íslenska):
HU (magyar): friss fekete áfonya termés	NO (norsk): Blåbær, friske
IT (italiano): Mirtillo nero frutto fresco	

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

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 *Vaccinium myrtillus* L., fructus recens (fresh bilberry fruit) i) Herbal substance Not applicable ii) Herbal preparations a) Dry extract; DER 153-76:1; extraction solvent methanol 70% v/v containing 36% anthocyanosides, corresponding to 25% anthocyanidins

3. Pharmaceutical form

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

[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.:8.0/1602 for the herbal substance and 8.0/2394 for the herbal preparation)

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Indication 1) Traditional herbal medicinal product to relieve symptoms of discomfort and heaviness of legs related to minor venous circulatory disturbances. Indication 2) Traditional herbal medicinal product to relieve symptoms of cutaneous capillary fragility. 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[3]

Well-established use	Traditional use
	Posology *Adults and elderly* Indication 1) and 2) Single dose: 80 -180 mg Daily dose: up to 160 - 540 mg **Duration of use** Indication 1) and 2) The recommended duration of use is 4 weeks. If the symptoms persist for more than 2 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. **Method of administration** Indication 1) and 2) Oral use.

[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).

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
	The use in children and adolescents under 18 years of age has not been established due to lack of adequate data. If there is inflammation of the skin, thrombophlebitis or subcutaneous induration, severe pain, ulcers, sudden swelling of one or both legs, cardiac or renal insufficiency, a doctor should be consulted. If the symptoms worsen or persist longer than 2 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

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
	Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended. 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. Adequate 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