29 September 2015
EMA/HMPC/375808/2014
Committee on Herbal Medicinal Products (HMPC)

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

Final

Discussion in Working Party on European Union monographs and list (MLWP)	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; *Vaccinium myrtillus* L., fructus recens; Myrtilli fructus recens; Bilberry fruit, fresh

[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'.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

BG (bulgarski): 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): Bilberry fruit, fresh	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): Borovničin plod, osušen	IS (íslenska):
HU (magyar): friss fekete áfonya termés	NO (norsk): Blåbær, friske
IT (italiano): Mirtillo nero frutto fresco	

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[2, 3]

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 (Bilberry fruit, fresh) i) Herbal substance Not applicable. ii) Herbal preparations 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.

[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.: 1602)

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

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 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** Indication 1) and 2) The recommended duration of use is 4 weeks. If the symptoms persist longer 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.

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

29 September 2015