EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 November 2022
EMA/HMPC/49135/2017
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Vaccinium macrocarpon* Aiton, fructus

Final

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP) and the Committee on Herbal Medicinal Products (HMPC)	January 2017 November 2017 January 2018 March 2018 January 2020 March 2020 May 2020 July 2020 September 2020 November 2020 January 2021 March 2021 May 2021
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BG (bulgarski): Американска червена боровинка, плод CS (čeština): plod klikvy velkoplodé DA (dansk): Storfrugtet tranebær DE (Deutsch): Cranberry EL (elliniká): καρπός μυρτίλλου μακροκάρπου EN (English): Cranberry ES (español): arándano rojo, fruto de ET (eesti keel): suureviljalise jõhvika vili FI (suomi): amerikankarpalo, marja FR (français): canneberge (fruit de) HR (hrvatski): plod američke brusnice HU (magyar): amerikai nagytermésű áfonya termés IT (italiano): mirtillo rosso americano	LT (lietuvių kalba): Stambiauogės spanguolės vaisiai LV (latviešu valoda): Lielās dzērvenes augļi MT (Malti): frott tal-cranberry NL (Nederlands): Veenbes, vrucht PL (polski): owoc żurawiny wielkoowocowej PT (português): arando americano, fruto RO (română): fruct de merișor american SK (slovenčina): plod brusnice veľkoplodej SL (slovenščina): plod brusnice veľkoplodej SV (svenska): amerikanskt tranbär, bär *IS (íslenska)*: *NO (norsk):* amerikanske tranebær

European Union herbal monograph on *Vaccinium macrocarpon* Aiton, fructus

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 *Vaccinium macrocarpon* Aiton, fructus (cranberry fruit) i) Herbal substance Not applicable. ii) Herbal preparations Expressed juice from the fresh fruit (DER 1: 0.6-0.9)

3. Pharmaceutical form

Well-established use	Traditional use
	Herbal preparations in liquid dosage forms for oral 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 used for relief of symptoms of mild recurrent lower urinary tract infections such as burning sensation during urination and/or frequent

[1] The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.
[2] Detailed specifications for the herbal substance shall be given by references to bibliographic sources in absence of a monograph in the European Pharmacopoeia, a national pharmacopoeia or national codex currently used officially in a Member State.

Well-established use	Traditional use
	urination in women, after serious conditions have been excluded by a medical doctor. Indication 2) Traditional herbal medicinal product used for prevention of recurrent uncomplicated lower urinary tract infections in women, after serious conditions have been excluded by a medical doctor. 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 *Female adults and elderly* Indication 1) 50-60 ml expressed juice 2 - 4 times daily Indication 2) 30 ml expressed juice once daily The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). The use in men is not recommended (see section 4.4 'Special warnings and precautions for use'). **Duration of use** Indication 1) 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. Indication 2) No restriction. If the patient experience symptoms of urinary tract infection during the use of the medicinal product, a doctor or a qualified health care

Well-established use	Traditional use
	practitioner should be consulted. **Method of administration** Oral use.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to cranberry (*Vaccinium macrocarpon* Ait.) fruit. Patients with kidney disorders who experienced recurrent urinary tract infections require medical supervision. Concomitant use with tacrolimus and warfarin (see section 4.5 'Interactions with other medicinal products and other forms of interaction').

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	The use in children and adolescents under 18 years of age is not recommended because data is not sufficient and medical advice should be sought. The use in men and pregnant women is not recommended because lower urinary tract symptoms in these populations require medical supervision. Cranberry concentrate has a high content of oxalate, and there may be an increased risk of stone formation in the urinary tract in patients with stone history. 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.

4.5. Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
	Cranberry juice and other cranberry products may potentiate the effect of warfarin and therefore concomitant use should be avoided (see section 4.3. 'Contraindications'). Decreased tacrolimus serum levels have been reported from the concomitant use of cranberry juice and tacrolimus in a renal allografted patient. The concomitant use of cranberry preparations and tacrolimus should be avoided (see section 4.3. 'Contraindications').

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
	Gastrointestinal disorders: nausea, diarrhoea and dyspepsia. The frequency is not known. Skin and subcutaneous tissue disorders: urticaria and rash. 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. 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

23 November 2022