



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

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

Discussion in Working Party on European Union monographs and European Union list (MLWP) and 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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<p>BG (bulgarski): американска червена боровинка, плод</p> <p>CS (čeština): plod klikvy velkoplodé</p> <p>DA (dansk): storfrugtet tranebær</p> <p>DE (Deutsch): cranberry</p> <p>EL (elliniká): καρπός μυρτίλλου μακροκάρπου</p> <p>EN (English): cranberry</p> <p>ES (español): arándano rojo, fruto de</p> <p>ET (eesti keel): suureviljalise jõhvika vili</p> <p>FI (suomi): amerikankarpalo, marja</p> <p>FR (français): canneberge (fruit de)</p> <p>HR (hrvatski): plod američke brusnice</p> <p>HU (magyar): amerikai nagytermésű áfonya termés</p> <p>IT (italiano): mirtillo rosso americano</p>	<p>LT (lietuvių kalba): stambiauogės spanguolės vaisiai</p> <p>LV (latviešu valoda): lielās dzērvenes augļi</p> <p>MT (Malti): frott tal-cranberry</p> <p>NL (Nederlands): veenbes, vrucht</p> <p>PL (polski): owoc żurawiny wielkoowocowej</p> <p>PT (português): arando americano, fruto</p> <p>RO (română): fruct de merişor american</p> <p>SK (slovenčina): plod brusnice veľkoplodej</p> <p>SL (slovenščina): plod brusnice veľkoplodej</p> <p>SV (svenska): amerikanskt tranbär, bär</p> <p>IS (<i>íslenska</i>):</p> <p>NO (<i>norsk</i>): amerikanske tranebær</p>
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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
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended</p> <p><i>Vaccinium macrocarpon</i> Aiton, fructus (cranberry fruit)</p> <p>i) Herbal substance</p> <p>Not applicable.</p> <p>ii) Herbal preparations</p> <p>expressed juice from the fresh fruit (DER 1:0.6-0.9).</p>

3. Pharmaceutical form

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

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Indication 1)

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 USP 24 The United States Pharmacopoeia, NF 19 The National Formulary

Well-established use	Traditional use
	<p data-bbox="810 255 967 286">Indication 1)</p> <p data-bbox="810 315 1358 528">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 urination in women, after serious conditions have been excluded by a medical doctor.</p> <p data-bbox="810 557 967 589">Indication 2)</p> <p data-bbox="810 618 1385 786">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.</p> <p data-bbox="810 815 1347 920">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 1106 935 1137">Posology</p> <p data-bbox="810 1167 1123 1198"><i>Female adults and elderly</i></p> <p data-bbox="810 1227 967 1258">Indication 1)</p> <p data-bbox="810 1288 1147 1319">50 - 80 ml 2 - 4 times daily</p> <p data-bbox="810 1348 967 1379">Indication 2)</p> <p data-bbox="810 1408 1075 1440">15 - 80 ml twice daily</p> <p data-bbox="810 1469 1390 1547">The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p data-bbox="810 1576 1369 1677">The use in men is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p data-bbox="810 1706 1015 1738">Duration of use</p> <p data-bbox="810 1767 967 1798">Indication 1)</p> <p data-bbox="810 1827 1385 1906">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</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>consulted.</p> <p>Indication 2)</p> <p>No restriction.</p> <p>If the patient experience symptoms of urinary tract infection 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>Oral use.</p>

4.3. Contraindications

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

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>The use in children and adolescents under 18 years of age is not recommended because the data is not sufficient and medical advice should be sought.</p> <p>The use in men and pregnant women is not recommended because lower urinary tract symptoms in these populations require medical supervision.</p> <p>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.</p> <p>If the symptoms worsen or if complaints such as fever, dysuria, spasms, or blood in urine occur</p>

	during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.
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4.5. Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
	<p>Cranberry juice and other cranberry products may potentiate the effect of warfarin and therefore concomitant use is contraindicated (see section 4.3. 'Contraindications').</p> <p>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 is contraindicated (see section 4.3. 'Contraindications')</p>

4.6. Fertility, pregnancy and lactation

Well-established use	Traditional use
	<p>No fertility data available.</p> <p>Safety during pregnancy and lactation has not been established.</p> <p>In absence of sufficient data, the use during pregnancy and lactation is not recommended.</p>

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
	<p>Gastrointestinal disorders: nausea, vomiting, diarrhoea, constipation and dyspepsia. The frequency is not known.</p> <p>Skin and subcutaneous tissue disorders: urticaria and rash. The frequency is not known.</p> <p>If other adverse reactions not mentioned above</p>

Well-established use	Traditional use
	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

05 May 2021