



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Fragaria vesca* L., *Fragaria moschata* Weston, *Fragaria viridis* Weston and *Fragaria x ananassa* (Weston) Duchesne ex Rozier, folium Draft

Discussion in Working Party on European Union monographs and list (MLWP)	Jul 2015 Sep 2015 Nov 2015 May/Jun 2016 Sep 2016 Nov 2016 Jan 2017 Mar 2017 May 2017 Sep 2017 Nov 2017 Jan 2018
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Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; <i>Fragaria vesca</i> L.; <i>Fragaria moschata</i> Weston; <i>Fragaria viridis</i> Weston; <i>Fragaria x ananassa</i> (Weston) Duchesne ex Rozier folium; wild strawberry leaf
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BG (bългарски): Горска ягода, лист	LT (lietuvių kalba): Žemuogių lapai
CS (čeština): jahodníkový list	LV (latviešu valoda): Meža zemenes lapas
DA (dansk): Jordbærblad	MT (Malti): werqa tal-Frawli
DE (Deutsch): Erdbeerblätter	NL (Nederlands): Bosaardbei
EL (elliniká): χαμαικεράσου εδωδιμου φύλλο	PL (polski): Liść poziomki
EN (English): wild strawberry leaf	PT (português): morangueiro-bravo, folha
ES (español): fresa, hoja de	RO (română): frunză de frag
ET (eesti keel): maasikaleht	SK (slovenčina): list jahody
FI (suomi): ahomansikka, lehti	SL (slovenščina): list navadnega jagodnjaka
FR (français): fraisier (feuille de)	SV (svenska): smultron, blad
HR (hrvatski): list šumske jagode	IS (íslenska):
HU (magyar): erdei szamóca levél	NO (norsk): markjordbærblad
IT (italiano): Fragola foglia	

1. European Union herbal monograph on *Fragaria vesca* L., *Fragaria moschata* West., *Fragaria viridis* West. and *Fragaria x ananassa* (West.) Duchesne ex Rozier, foliumName 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 <i>Fragaria vesca</i> L.; <i>Fragaria moschata</i> West.; <i>Fragaria viridis</i> West.; <i>Fragaria x ananassa</i> (West.) Duchesne ex Rozier, folium (wild strawberry leaf) (i) Herbal substance Not applicable ii) Herbal preparations Comminuted herbal substance.

3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea 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 to increase the amount of urine to achieve flushing of the urinary tract

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 ÖAB(ref.:2013:076)

Well-established use	Traditional use
	<p>as an adjuvant in minor urinary complaints.</p> <p>Indication 2)</p> <p>Traditional herbal medicinal product for symptomatic treatment of mild diarrhoea.</p> <p>The product is a traditional herbal medicinal product for use in the specified indications exclusively based upon long-standing use.</p>

4.2. Posology and method of administration³

Well-established use	Traditional use
	<p>Posology</p> <p><i>Adolescents, adults and elderly</i></p> <p>Indication 1)</p> <p>Herbal tea: 4-8 g of comminuted herbal substance in 200 ml of water as a decoction, divided in 2 – 4 single doses</p> <p>Indication 2)</p> <p>Herbal tea: 1 g of comminuted herbal substance in 200 ml of boiling water as a herbal infusion 2 - 3 times daily.</p> <p>The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p>Duration of use</p> <p>Indication 1)</p> <p>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.</p> <p>Indication 2)</p> <p>If the symptoms persist longer than 3 days during the use of the medicinal product, a doctor or a qualified</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>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 the active substance.</p> <p>Indication 1)</p> <p>Conditions where a reduced fluid intake is recommended (e.g. severe cardiac or renal disease).</p>

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>The use in children and adolescents under 12 years of age has not been established due to lack of adequate data.</p> <p>Indication 1)</p> <p>To ensure an increase of the amount of urine, adequate fluid intake is required during treatment.</p> <p>If complaints or symptoms 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.</p> <p>Indication 2)</p> <p>If recurrent diarrhoea or bloody stools occur, 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
	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.

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

27 March 2018