



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

20 November 2018  
EMA/HMPC/432278/2015  
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 Final

Discussion in Working Party on European Union monographs and list (MLWP)	July 2015 September 2015 November 2015 May/June 2016 September 2016 November 2016 January 2017 March 2017 May 2017 September 2017 November 2017 January 2018
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End of consultation (deadline for comments)	July 2018
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Adoption by HMPC Monograph (EMA/HMPC/432278/2015) AR (EMA/HMPC/432276/2015) List of references (EMA/HMPC/432277/2015) Overview of comments received during the public consultation (EMA/638127/2018) HMPC Opinion (EMA/HMPC/811721/2018)	20 November 2018

<b>Keywords</b>	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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**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

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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 (ελληνικά): 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. Name of the medicinal product

To be specified for the individual finished product.

## 2. Qualitative and quantitative composition<sup>1,2</sup>

Well-established use	Traditional use
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC</p> <p><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)</p> <p>(i) Herbal substance</p> <p>Not applicable</p> <p>ii) Herbal preparations</p> <p>Comminuted herbal substance.</p>

## 3. Pharmaceutical form

Well-established use	Traditional use
	<p>Comminuted herbal substance as herbal tea 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
	<p>Indication 1)</p> <p>Traditional herbal medicinal product to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints.</p> <p>Indication 2)</p> <p>Traditional herbal medicinal product for symptomatic</p>

<sup>1</sup> The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

<sup>2</sup> The material complies with the Austrian Pharmacopoeia monograph (ÖAB 2013:076)

Well-established use	Traditional use
	<p>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 administration<sup>3</sup>

Well-established use	Traditional use
	<p><b>Posology</b></p> <p><i>Adolescents, adults and elderly</i></p> <p><b>Indication 1)</b></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><b>Indication 2)</b></p> <p>Herbal tea: 1 g of comminuted herbal substance in 200 ml of boiling water as a herbal infusion 2-3 times daily. The use in children under 12 years of age is not recommended (see section 4.4 ‘Special warnings and precautions for use’).</p> <p><b>Duration of use</b></p> <p><b>Indication 1)</b></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><b>Indication 2)</b></p> <p>If the symptoms persist longer than 3 days during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p><b>Method of administration</b></p> <p>Oral use</p>

#### 4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance.

<sup>3</sup> 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><b>Indication 1)</b></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 under 12 years of age has not been established due to lack of adequate data.</p> <p><b>Indication 1)</b></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><b>Indication 2)</b></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
	<p>Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</p> <p>No fertility data available.</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
	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

20 November 2018