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EMA/HMPC/637833/2018  
Committee on Herbal Medicinal Products (HMPC)

## European Union herbal monograph on *Menyanthes trifoliata* L., folium

Final

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP) and Committee on Herbal Medicinal Products (HMPC)	September 2018
	January 2019
	May 2019
	September 2019
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	May 2020
	July 2020
September 2020	
Adopted by HMPC for release for consultation	23 September 2020
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	May 2021
Adoption by HMPC	05 May 2021

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; <i>Menyanthes trifoliata</i> L., folium; Menyanthidis trifoliatae folium; bogbean leaf
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<sup>1</sup> 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'.



BG (bulgarski): Водна детелина, лист	LT (lietuvių kalba): Trilapių pupalaiškių lapai
CS (čeština): vachtový list	LV (latviešu valoda): trejlapu puplakša lapas
DA (dansk): Bukkeblad	MT (Malti): Weraq tax-Xnien tal-Ghadajjar
DE (Deutsch): Bitterkleeblätter	NL (Nederlands): Waterdrieblad, blad
EL (elliniká): Μηνιανθούς τριφύλλου φύλλο	PL (polski): Liść bobrka
EN (English): bogbean leaf	PT (português): Menianto, folha
ES (español): Trébol de agua, hoja de	RO (română): frunză de trifoi de baltă
ET (eesti keel): Ubaleht	SK (slovenčina): list vachty trojlistej
FI (suomi): raate, lehti	SL (slovenščina): list navadnega mrzličnika
FR (français): ményanthe, trèfle d'eau	SV (svenska): vattenklöver, blad
HR (hrvatski): list gorkog trolista	<i>IS (íslenska):</i>
HU (magyar): vidrafűlevél	<i>NO (norsk): Bukkeblad</i>
IT (italiano): Trifoglio fibrino, foglia	

# European Union herbal monograph on *Menyanthes trifoliata* L., folium

## 1. Name of the medicinal product

To be specified for the individual finished product.

## 2. Qualitative and quantitative composition<sup>2, 3</sup>

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>Menyanthes trifoliata</i> L., folium (bogbean leaf)</p> <p>i) Herbal substance</p> <p>Not applicable.</p> <p>ii) Herbal preparations</p> <p>a) Comminuted herbal substance</p> <p>b) Powdered herbal substance</p> <p>c) Liquid extract (DER 1:1) extraction solvent ethanol 25% (V/V)</p> <p>d) Tincture (1:5), extraction solvent 45% ethanol (V/V)</p>

## 3. Pharmaceutical form

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

<sup>2</sup> The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

<sup>3</sup> The material complies with the Ph. Eur. (9.0) (ref: 1605)

## 4. Clinical particulars

### 4.1. Therapeutic indications

Well-established use	Traditional use
	<p><b>Indication 1)</b></p> <p>Traditional herbal medicinal product used in temporary loss of appetite.</p> <p><b>Indication 2)</b></p> <p>Traditional herbal medicinal product used for the relief of mild digestive disorders such as bloating and flatulence.</p> <p><b>Indication 3)</b></p> <p>Traditional herbal medicinal product used for relief of minor articular and muscular pain.</p> <p>The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.</p>

### 4.2. Posology and method of administration <sup>4</sup>

Well-established use	Traditional use
<p><b>Posology</b></p>	<p><b>Posology</b></p> <p><b>Indication 1) and 2)</b></p> <p><i>Adults and Elderly</i></p> <p>a) Herbal teas</p> <p>a. Herbal tea: 0.4-1.6 g of the comminuted herbal substance in 150 ml of boiling water as herbal tea infusion used 2-4 times daily</p> <p>Daily doses: 0.8-4.8 g</p> <p><b>Indication 1)</b></p> <p>b. Herbal tea: 0.5-1.5 g of the comminuted herbal substance in 150 ml of water as decoction used 3 times daily</p> <p>Daily doses: 1.5-4.5 g</p>

<sup>4</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) Powdered herbal substance in single dose 0.5 g, 3-4 times daily</p> <p>Daily dose 1.5-2.0 g</p> <p>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><b>Indication 3)</b></p> <p><i>Adults and Elderly</i></p> <p>a) Herbal tea: 1.0-2.0 g of the comminuted herbal substance in 150 ml of boiling water as infusion, used 3 times daily</p> <p>b) Powdered herbal substance in single doses 1.0-2.0 g, 3 times daily</p> <p>c) Liquid extract (DER 1:1) extraction solvent ethanol 25% (V/V)</p> <p>Single dose 1-2 ml, 3 times daily</p> <p>d) Tincture (DER 1:5), extraction solvent ethanol 45% (V/V)</p> <p>Single dose 1-3 ml, 3 times daily</p> <p>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><b>Duration of use</b></p> <p><b>Indication 1) and 2)</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 3)</b></p> <p>If the symptoms persist longer than 4 weeks 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><b>Indications 1), 2), 3)</b></p> <p>Oral use.</p>

Well-established use	Traditional use
	<p data-bbox="805 255 963 286"><b>Indication 1)</b></p> <p data-bbox="805 313 1374 378">Herbal tea infusion/decoction used 30 minutes before meal.</p> <p data-bbox="805 405 963 436"><b>Indication 2)</b></p> <p data-bbox="805 463 1302 495">Herbal tea infusion used between meals.</p>

**4.3. Contraindications**

Well-established use	Traditional use
	<p data-bbox="805 676 1302 707">Hypersensitivity to the active substance.</p> <p data-bbox="805 734 1198 766">Active gastric or duodenal ulcer.</p>

**4.4. Special warnings and precautions for use**

Well-established use	Traditional use
	<p data-bbox="805 952 1051 983"><b>Indication 1) and 2)</b></p> <p data-bbox="805 1010 1358 1117">The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.</p> <p data-bbox="805 1144 1394 1252">If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p data-bbox="805 1279 963 1310"><b>Indication 3)</b></p> <p data-bbox="805 1337 1358 1444">The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.</p> <p data-bbox="805 1471 1394 1579">If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p data-bbox="805 1606 1355 1713">Patients with articular pain accompanied by swelling of joints, redness or fever should be examined by a doctor.</p> <p data-bbox="805 1740 1394 1892">For tinctures and extracts containing ethanol, the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included.</p>

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

<b>Well-established use</b>	<b>Traditional use</b>
	None reported.

#### **4.6. Fertility, pregnancy and lactation**

<b>Well-established use</b>	<b>Traditional use</b>
	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**

<b>Well-established use</b>	<b>Traditional use</b>
	No studies on the effect on the ability to drive and use machines have been performed.

#### **4.8. Undesirable effects**

<b>Well-established use</b>	<b>Traditional use</b>
	None known.  If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.

#### **4.9. Overdose**

<b>Well-established use</b>	<b>Traditional use</b>
	No case of overdose have been reported.

### **5. Pharmacological properties**

#### **5.1. Pharmacodynamic properties**

<b>Well-established use</b>	<b>Traditional use</b>
	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 genotoxicity have not been performed.  Tests on reproductive toxicity 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