EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

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

Draft

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	September 2018 January 2019 May 2019 September 2019 January 2020 March 2020 May 2020 July 2020 September 2020
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Re-discussion in MLWP	
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BG (bulgarski): Водна детелина, лист CS (čeština): vachtový list DA (dansk): Bukkeblad DE (Deutsch): Bitterkleeblätter EL (elliniká): Μηνιανθούς τριφύλλου φύλλο EN (English): bogbean leaf ES (español): Trébol de agua, hoja de ET (eesti keel): Ubaleht FI (suomi): raate, lehti FR (français): ményanthe, trèfle d'eau HR (hrvatski): list gorkog trolista HU (magyar): vidrafűlevél IT (italiano): Trifoglio fibrino, foglia	LT (lietuvių kalba): Trilapių pupalaiškių lapai LV (latviešu valoda): trejlapu puplakša lapas MT (Malti): Weraq tax-Xnien tal-Għadajjar NL (Nederlands): Waterdrieblad, blad PL (polski): Liść bobrka PT (português): Menianto, folha RO (română): frunză de trifoi de baltă SK (slovenčina): list vachty trojlistej SL (slovenščina): list navadnega mrzličnika SV (svenska): vattenklöver, blad *IS (íslenska)*: *NO (norsk):* Bukkeblad

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[2, 3]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *Menyanthes trifoliata* L., folium (bogbean) i) Herbal substance Not applicable. ii) Herbal preparations a) Comminuted herbal substance b) Powdered herbal substance c) Liquid extract (DER 1:1), extraction solvent ethanol 25% V/V d) Tincture (DER 1:5), extraction solvent ethanol 45% V/V

3. Pharmaceutical form

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

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

[3] The material complies with the Ph. Eur. (9.0) (ref:1605)

4. Clinical particulars

4.1. Therapeutic indications

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

4.2. Posology and method of administration[4]

Well-established use	Traditional use
Posology	**Posology** Indication 1) and 2) *Adults and Elderly* a) Herbal teas a1) 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 Daily doses: 0.8 - maximum 4.8 g Indication 1) a2) Herbal tea: 0.5-1.5 g of the comminuted herbal substance in 150 ml of water as decoction used 3 times daily Daily doses: 1.5-4.5 g. *Adults*

[4] 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
	b) Powdered herbal substance in single dose 0.5 g, 3-4 times daily. Daily dose 1.5-2.0 g The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). Indication 3) *Adults and Elderly* a) Herbal tea: 1-2 g of the comminuted herbal substance in 150 ml of boiling water as infusion, used 3 times daily b) Powdered herbal substance in single doses 1-2 g, 3 times daily c) Liquid extract (DER 1:1) extraction solvent ethanol 25% V/V Single dose 1.0-2.0 ml, 3 times daily e) Tincture (DER 1:5), extraction solvent 45% ethanol V/V Single dose 1.0-3.0 ml, 3 times 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'). **Duration of use** Indication 1) and 2) 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. Indication 3) 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. **Method of administration** Indications 1), 2), 3)

Well-established use	Traditional use
	Oral use Indication 1) herbal tea infusion/decoction used 30 minutes before meal Indication 2) herbal tea infusion used between meals.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance. Active gastric or duodenal ulcer.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	Indication 1) and 2) The use in children and adolescents under 18 years of age has not been established due to lack of adequate data. If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. Indication 3) The use in children and adolescents under 18 years of age has not been established due to lack of adequate data. If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. Patients with articular pain accompanied by swelling of joints, redness or fever should be examined by a doctor. 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.

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 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

23 September 2020