28 January 2014
EMA/HMPC/44211/2012
Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Rubus idaeus* L., folium

Final

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Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Rubus idaeus* L., folium; Rubi idaei folium; raspberry leaf

BG (bulgarski): Малина, лист	LT (lietuvių kalba): Paprastųjų aviečių lapai
CS (čeština): maliníkový list	LV (latviešu valoda): Avenes lapas
DA (dansk): Hindbærblad	MT (Malti): Werqa tal-għollieq
DE (Deutsch): Himbeerblätter	NL (Nederlands): Frambozenblad
EL (elliniká): Βάτου ιδαίας φύλλο	PL (polski): Liść maliny
EN (English): Raspberry Leaf	PT (português): Framboeseiro, folha
ES (español): Frambueso, hoja de	RO (română): Frunză de zmeur
ET (eesti keel): vaarikaleht	SK (slovenčina): List maliny
FI (suomi): vadelma, lehti	SL (slovenščina): list malinjaka
FR (français): Ronce (feuille de)	SV (svenska): Hallonblad
HR (hrvatski): malinin list	IS (íslenska):
HU (magyar): málnalevél	NO (norsk): Bringebærblad
IT (italiano): Lampone foglia	

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Community herbal monograph on *Rubus idaeus* L., folium

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
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *Rubus idaeus* L., folium (raspberry leaf) i) Herbal substance Not applicable. ii) Herbal preparations a) Comminuted herbal substance b) Dry extract (DER 4:1): extraction solvent water

3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea for oral use and for infusion preparation for oromucosal use. Herbal preparations in solid dosage form 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 for the symptomatic relief of minor spasm associated with

[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 Ph. Fr. monograph 'Ronce - Rubus' (Ph. Fr. XI edition).

Well-established use	Traditional use
	menstrual periods. Indication 2) Traditional herbal medicinal product for the symptomatic treatment of mild inflammation in the mouth or throat. Indication 3) Traditional herbal medicinal product for the symptomatic treatment of mild diarrhoea. 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[3]

Well-established use	Traditional use
	Posology Indication 1) *Adults* Single dose Dry extract: 113-226 mg, up to 3 to 4 times daily. To be taken after meals. Indication 2) *Adults and elderly* Single dose Comminuted herbal substance for infusion preparation for oromucosal use: 1.5-8 g of the comminuted herbal substance in 150 ml of boiling water, 3 times daily. Use as a gargle. Indication 3) *Adults and elderly* Single dose Herbal tea: 1.5-8 g of the comminuted herbal substance in 150 ml of boiling water as a herbal infusion, 3 times daily.

[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
	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** Indications 1) and 2) If the symptoms persist longer than 1 week 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 3 days during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted **Method of administration** Indication 1) Oral use. Indication 2) Oromucosal use. Indication 3) Oral use.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance(s).

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	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.

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 reproductive toxicity and tests on genotoxicity and carcinogenicity have not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation / last revision

28 January 2014