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SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

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

Draft

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Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Rubus idaeus</i> L., folium; Rubi idaei folium; raspberry leaf
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BG (bългарски): Малина, лист CS (čeština): maliníkový list DA (dansk): Hindbærblad DE (Deutsch): Himbeerblätter EL (elliniká): Βάτου ιδαίας φύλλο EN (English): Raspberry Leaf ES (español): Frambueso, hoja de ET (eesti keel): vaarikaleht FI (suomi): vadelma, lehti FR (français): Ronce (feuille de) HU (magyar): málnalevél IT (italiano):	LT (lietuvių kalba): Paprastųjų aviečių lapai LV (latviešu valoda): Avenes lapas MT (malti): Werqa tal-ġholliq NL (nederlands): Frambozenblad PL (polski): Liść maliny PT (português): Framboeseiro, folha RO (română): SK (slovenčina): List maliny SL (slovenščina): list malinjaka SV (svenska): Hallonblad IS (islenska): NO (norsk): Bringebærblad
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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
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended</p> <p><i>Rubus idaeus</i> L., folium (raspberry leaf)</p> <p>i) Herbal substance Not applicable.</p> <p>ii) Herbal preparations</p> <p>a) Comminuted herbal substance</p> <p>b) Dry extract (DER 4:1): extraction solvent water</p>

3. Pharmaceutical form

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

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
	<p>menstrual periods.</p> <p>Indication 2)</p> <p>Traditional herbal medicinal product for the symptomatic treatment of mild inflammation in the mouth or throat.</p> <p>Indication 3)</p> <p>Traditional herbal medicinal product for the symptomatic treatment of mild diarrhoea.</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 administration³

Well-established use	Traditional use
	<p>Posology</p> <p>Indication 1)</p> <p><i>Adults</i></p> <p>Single dose</p> <p>Dry extract: 113-226 mg up to 3 to 4 times daily.</p> <p>Indication 2)</p> <p><i>Adults and elderly</i></p> <p>Single dose</p> <p>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.</p> <p>Indication 3)</p> <p><i>Adults and elderly</i></p> <p>Single dose</p> <p>Herbal tea: 1.5-8 g of the comminuted herbal substance in 150 ml of boiling water as a herbal infusion, 3 times daily.</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>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>Duration of use</p> <p>Indications 1) and 2)</p> <p>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.</p> <p>Indication 3)</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>Method of administration</p> <p>Indication 1)</p> <p>Oral use. To be taken after meals.</p> <p>Indication 2)</p> <p>Oromucosal use.</p> <p>Indication 3)</p> <p>Oral use.</p>

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
	<p>The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.</p> <p>If the symptoms worsen during the use of the medicinal product, 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 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

12 March 2013