



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 September 2017
EMA/HMPC/745353/2016
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Ribes nigrum* L., folium

Final

Initial assessment	
Discussion in Working Party on European Union monographs and list (MLWP)	March 2009 May 2009 July 2009
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	16 July 2009
End of consultation (deadline for comments)	15 December 2009
Re-discussion in MLWP	May 2010
Adoption by HMPC Monograph (EMA/HMPC/142986/2009) AR (EMA/HMPC/142989/2009) List of references (EMA/HMPC/143130/2009) Overview of comments received during public consultation (EMA/HMPC/5687/2010) HMPC Opinion (EMA/HMPC/282667/2010)	06 May 2010
First systematic review	
Discussion in Working Party on European Union monographs and list (MLWP)	November 2016
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	31 January 2017
End of consultation (deadline for comments ¹)	31 May 2017
Re-discussion in MLWP	July 2017
Adoption in HMPC	19 September 2017

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; <i>Ribes nigrum</i> L., folium; Ribis nigri folium; blackcurrant leaf
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¹ 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'.

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BG (bulgarski): Лист от черно френско грозде	LT (lietuvių kalba): Juodųjų serbentų lapai
CS (čeština): list rybízu černého	LV (latviešu valoda): Upeņu lapas
DA (dansk): Solbærblad	MT (Malti): werqa tar-ribes
DE (Deutsch): Schwarze Johannisbeerblätter	NL (Nederlands): zwarte aalbes
EL (elliniká): φύλλο ριβησίου του μέλανος	PL (polski): Liść porzeczki czarnej
EN (English): blackcurrant leaf	PT (português): groselheira-negra, folha
ES (español): grosellero negro, hoja de	RO (română): frunza de coacaz negru
ET (eesti keel): musta sõstra leht	SK (slovenčina): list ríbezle čiernej
FI (suomi): mustaherukka, lehti	SL (slovenščina): list črnega ribeza
FR (français): cassis (feuille de)	SV (svenska): svartvinbär, blad
HR (hrvatski): list crnog ribizla	IS (íslenska):
HU (magyar): feketeribizli levél	NO (norsk): solbærblad
IT (italiano): Ribes nero foglia	

Field Code Changed

European Union herbal monograph on *Ribes nigrum* 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 <i>Ribes nigrum</i> L., folium (blackcurrant leaf) i) Herbal substance Not applicable ii) Herbal preparations a) Comminuted herbal substance b) Dry extract (DER 7:1), extraction solvent water c) Powdered herbal substance

3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea for oral use. Herbal preparations in solid dosage forms 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 relief of minor articular pain.

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. monograph (ref.: 2528).

Well-established use	Traditional use
	<p data-bbox="675 405 807 432">Indication 2)</p> <p data-bbox="675 450 1158 568">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 data-bbox="675 591 1123 674">The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.</p>

4.2. Posology and method of administration

Well-established use	Traditional use
	<p data-bbox="675 831 778 857">Posology</p> <p data-bbox="675 869 855 896"><i>Adults and elderly</i></p> <p data-bbox="675 913 807 940">Indication 1)</p> <p data-bbox="675 952 1010 978">a) Comminuted herbal substance</p> <p data-bbox="675 1001 1158 1084">Single dose: 2 to 4 g of the comminuted herbal substance in 200 ml of boiling water as a herbal infusion 3 times daily.</p> <p data-bbox="675 1106 868 1133">Daily dose: 6-12 g.</p> <p data-bbox="675 1155 925 1182">b) Dry extract (DER 7:1)</p> <p data-bbox="675 1205 1158 1256">Single dose: 170 mg of dry extract (7:1, water), 1-3 times daily.</p> <p data-bbox="675 1279 925 1305">Daily dose: 170-510 mg.</p> <p data-bbox="675 1328 978 1355">c) Powdered herbal substance</p> <p data-bbox="675 1377 1085 1429">Single dose: 340 mg of powdered herbal substance, 3-5 times daily.</p> <p data-bbox="675 1451 952 1478">Daily dose: 1020-1700 mg.</p> <p data-bbox="675 1500 807 1527">Indication 2)</p> <p data-bbox="675 1550 925 1576">b) Dry extract (DER 7:1)</p> <p data-bbox="675 1599 1158 1650">Single dose: 170 mg of dry extract (7:1, water), 1-3 times daily.</p> <p data-bbox="675 1673 925 1700">Daily dose: 170-510 mg.</p> <p data-bbox="675 1722 978 1749">c) Powdered herbal substance</p> <p data-bbox="675 1771 1085 1823">Single dose: 340 mg of powdered herbal substance 3-5 times daily</p>

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Well-established use	Traditional use
	<p>Daily dose: 1020-1700 mg.</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>Duration of use</p> <p>Indication 1)</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>Indication 2)</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>Method of administration</p> <p>Indications 1) and 2)</p> <p>Oral use</p>

4.3. Contraindications

Well-established use	Traditional use
	<p>Hypersensitivity to the active substance.</p> <p>Indication 2)</p> <p>Conditions where 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>Indications 1) and 2)</p> <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> <p>Indication 1)</p> <p>Articular pain accompanied by swelling of joints,</p>

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Well-established use	Traditional use
	<p>redness or fever, should be examined by a doctor.</p> <p>Indication 2)</p> <p>If complaints of symptoms such as fever, dysuria, spasms or blood in the urine occur during the use of the medicinal product, a doctor or a qualified health care professional should be consulted.</p> <p>To ensure an increase of the amount of urine, adequate fluid intake is required during treatment.</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
	<p>None known</p> <p>If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.</p>

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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

19 September 2017