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31 January 2017
EMA/HMPC/745353/2016
Committee on Herbal Medicinal Products (HMPC)

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

Draft

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
Start of public consultation	28 February 2017
End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	31 May 2017

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Ribes nigrum* L., folium; Ribis nigri folium; blackcurrant leaf

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

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[1,2]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC *Ribes nigrum* 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.

[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. Eur. monograph (ref.: 2528).

Well-established use	Traditional use
	Indication 2) Traditional herbal medicinal product to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints. The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology *Adults and elderly* Indication 1) a) Single dose: 2 to 4 g of the comminuted herbal substance in 200 ml of boiling water as a herbal infusion 3 times daily. Daily dose: 6-12 g. b) Single dose: 170 mg of dry extract (7:1, water), 1-3 times daily. Daily dose: 510 mg. c) Single dose: 340 mg of powdered herbal substance, 3-5 times daily. Daily dose: 1020-1700 mg. Indication 2) b) Single dose: 170 mg of dry extract (7:1, water), 1-3 times daily. Daily dose: 510 mg. c) Single dose: 340 mg of powdered herbal substance 3-5 times daily Daily dose: 1020-1700 mg. 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) 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.

Well-established use	Traditional use
	Indication 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. **Method of administration** Indications 1) and 2) Oral use

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance Indication 2) Conditions where reduced fluid intake is recommended (e.g. severe cardiac or renal disease).

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	Indications 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 1) Articular pain accompanied by swelling of joints, redness or fever, should be examined by a doctor. Indication 2) 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. To ensure an increase of the amount of urine, adequate fluid intake is required during

Well-established use	Traditional use
	treatment.

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

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

31 January 2017