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Evaluation of Medicines for Human Use

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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

DRAFT

COMMUNITY HERBAL MONOGRAPH ON *RIBES NIGRUM* L., FOLIUM

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	March 2009 May 2009 July 2009
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ADOPTION BY HMPC	

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KEYWORDS	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Ribes nigrum* L.; Ribis nigri folium; blackcurrant leaf

BG (bălgarski):
CS (čeština):
DA (dansk):
DE (Deutsch): Joahnnisberen
EL (elliniká):
EN (English): blackcurrant
ES (espanol):
ET (eesti keel):
FI (suomi):
FR (français): cassis
HU (magyar):
IT (italiano):
LT (lietuvių kalba):
LV (latviešu valoda):
MT (malti):
NL (nederlands): zwarte bes
PL (polski):
PT (português):
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COMMUNITY HERBAL MONOGRAPH ON *RIBES NIGRUM* L., FOLIUM

1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual medicinal product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION[1]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended i) Herbal substance *Ribes nigrum* L. dried leaves (blackcurrant) ii) Herbal preparations a) Comminuted herbal substance b) Dry extract (7:1, water)

3. PHARMACEUTICAL FORM

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea for oral use. Herbal preparations in solid dosage forms. 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
	1) Traditional herbal medicinal product for 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) 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 specified indications exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology Comminuted herbal substance as herbal tea: 2 to 4 g per cup 3 times daily. Comminuted herbal substance in hard capsules: • Single dose: 250-500 mg • Daily dose: 750-1700 mg Dry extract (7:1, water) 169 mg 1 to 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** The herbal substance is traditionally used over a period of 2 (indication 1) to 4 weeks (indication 2). If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. **Method of administration** Oral use. To ensure an increase of the amount of urine, adequate fluid intake is required during treatment.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance. Oedema due to limited heart or kidney function.

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. 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. Concomitant treatment with synthetic diuretics is not recommended.

4.5. Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
	None reported.

4.6. 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.

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. 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

16 July 2009