21 January 2026
EMA/HMPC/296855/2025
Committee on Herbal Medicinal Products (HMPC)

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

Draft – Revision 2

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| **Initial assessment** | |
| Discussion in Working Party on European Union monographs and European Union list (MLWP) | March 2009<br>May 2009<br>July 2009 |
| Adopted by Committee on Herbal Medicinal Products (HMPC) for release for consultation | 16 July 2009 |
| End of consultation | 15 December 2009 |
| Re-discussion in MLWP | May 2010 |
| Adoption by HMPC<br>Monograph (EMA/HMPC/142986/2009)<br>Assessment Report (EMA/HMPC/142989/2009)<br>List of References (EMA/HMPC/143130/2009)<br>Overview of Comments received during the public consultation (EMA/HMPC/5687/2010)<br>HMPC Opinion (EMA/HMPC/282667/2010) | 06 May 2010 |
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| End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu. | 15 May 2026 |

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

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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 | |

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

## 3. Pharmaceutical form

To be specified for the individual finished product.

## 4. Clinical particulars

### *4.1. Therapeutic indications*

| Well-established use | Traditional use |
|---|---|
| | Indication 1)<br>Traditional herbal medicinal product for the relief of minor articular pain.<br>Indication 2)<br>Traditional herbal medicinal product for the relief of symptoms associated with mild urinary tract complaints in addition to the general |

[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 |
|---|---|
| | recommendation of a sufficient fluid intake to increase the amount of urine.<br><br>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**<br><br>*Adults and Elderly*<br><br>Indication 1)<br><br>a) Comminuted herbal substance<br><br>Single dose: 2 to 4 g of the comminuted herbal substance in 200 ml of boiling water as a herbal infusion 3 times daily.<br><br>Daily dose: 6-12 g<br><br>b) Powdered herbal substance<br><br>Single dose: 340 mg of powdered herbal substance, 3-5 times daily.<br><br>Daily dose: 1020-1700 mg.<br><br>c) Dry extract (DER 7:1)<br><br>Single dose: 170 mg of dry extract (7:1, water), 1-3 times daily.<br><br>Daily dose: 170-510 mg.<br><br>Indication 2)<br><br>b) Powdered herbal substance<br><br>Single dose: 340 mg of powdered herbal substance 3-5 times daily<br><br>Daily dose: 1020-1700 mg.<br><br>c) Dry extract (DER 7:1)<br><br>Single dose: 170 mg of dry extract (7:1, water), 1-3 times daily.<br><br>Daily dose: 170-510 mg. |

[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).

| Well-established use | Traditional use |
|---|---|
| | Paediatric population<br><br>*Children and adolescents*<br><br>The use in children and adolescents under 18 years of age is not recommended. No data available.<br><br>**Duration of use**<br><br>Indication 1)<br><br>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.<br><br>Indication 2)<br><br>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.<br><br>**Method of administration**<br><br>Indications 1) and 2)<br><br>Oral use. |

## *4.3. Contraindications*

| Well-established use | Traditional use |
|---|---|
| | Hypersensitivity to the active substance. |

## *4.4. Special warnings and precautions for use*

| Well-established use | Traditional use |
|---|---|
| | Indication 1)<br><br>Articular pain accompanied by swelling of joints, redness or fever, should be examined by a doctor.<br><br>Indication 2)<br><br>If complaints or symptoms such as fever, dysuria, spasms, or blood in urine occur during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. |

| Well-established use | Traditional use |
|---|---|
| | Because adequate fluid intake is required during treatment *Ribes nigrum* L., folium is not recommended for patients with conditions where reduced fluid intake is advised. |

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

| Well-established use | Traditional use |
|---|---|
| | No interaction studies have been performed. |

## *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.<br>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.<br>If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted. |

## *4.9. Overdose*

| Well-established use | Traditional use |
|---|---|
| | No information available. |

# 5. Pharmacological properties

## *5.1. Pharmacodynamic properties*

| Well-established use | Traditional use |
|---|---|
| | No information required. |

## *5.2. Pharmacokinetic properties*

| Well-established use | Traditional use |
|---|---|
| | No information required. |

## *5.3. Preclinical safety data*

| Well-established use | Traditional use |
|---|---|
| | Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed. |

# Additional information

| Well-established use | Traditional use |
|---|---|
| | Not applicable. |