15 March 2023
EMA/HMPC/241320/2021
Committee on Herbal Medicinal Products (HMPC)

# European Union herbal monograph on *Juniperus communis* L., galbulus (pseudo-fructus)

Final - Revision 1

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| **Initial assessment** | |
| Discussion in Working Party on European Union monographs and European Union list (MLWP) | September 2008<br>November 2008<br>January 2009 |
| Adopted by Committee on Herbal Medicinal Products (HMPC) for release for consultation | 14 January 2009 |
| End of consultation (deadline for comments) | 15 May 2009 |
| Re-discussion in MLWP/HMPC | July 2009<br>September 2009<br>November 2009 |
| Adoption by HMPC<br>Monograph (EMA/HMPC/441929/2008)<br>AR (EMA/HMPC/441930/2008)<br>List of references (EMA/HMPC/442959/2008)<br>Overview of comments received during the public consultation (EMA/HMPC/421352/2009)<br>HMPC Opinion (EMA/HMPC/678925/2009) | 12 November 2009 |
| **First revision** | |
| Discussion in HMPC | May 2021<br>July 2021<br>September 2021<br>November 2021<br>January 2022<br>March 2022<br>May 2022<br>July 2022 |
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**Official address** Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
**Address for visits and deliveries** Refer to www.ema.europa.eu/how-to-find-us
**Send us a question** Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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| End of consultation (deadline for comments) | 30 November 2022 |
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| Keywords | Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Juniperus communis* L., galbulus (pseudo-fructus); juniper cone berry |

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|---|---|
| BG (bălgarski): Хвойна, псевдоплод | LT (lietuvių kalba): Kadagių vaisiai |
| CS (čeština): jalovcový plod | LV (latviešu valoda): Paegļa augļi |
| DA (dansk): Enebær | MT (malti): frotta tal-ġnibru / ġnipru |
| DE (Deutsch): Wacholderbeeren | NL (nederlands): Jeneverbes |
| EL (elliniká): αρκεύθου καρπός | PL (polski): Owoc jałowca |
| EN (English): Juniper cone berry | PT (português): zimbro |
| ES (espanol): enebro, baya de | RO (română): fruct de ienupăr |
| ET (eesti keel): kadakavili | SK (slovenčina): nepravý plod borievky |
| FI (suomi): kataja, marja | SL (slovenščina): plod navadnega brina |
| FR (français): genièvre (baie de) | SV (slovenščina): en, bär |
| HR (hrvatski): borovičin plod | IS (íslenska): |
| HU (magyar): borókabogyó | NO (norsk): einebær |
| IT (italiano): Ginepro pseudofrutto | |

# European Union herbal monograph on *Juniperus communis* L., galbulus (pseudo-fructus)

## 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><br>*Juniperus communis* L., galbulus (pseudo-fructus) (juniper cone berry)<br><br>i) Herbal substance<br><br>Not applicable.<br><br>ii) Herbal preparations<br><br>a) Comminuted herbal substance<br><br>b) Liquid extract (DER 1:1), extraction solvent ethanol 25% (V/V)<br><br>c) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 45% (V/V)<br><br>d) Soft extract (DER 1.7-1.8:1), extraction solvent water |

## 3. Pharmaceutical form

| Well-established use | Traditional use |
|---|---|
| | Comminuted herbal substance as herbal tea for oral use.<br><br>Herbal preparations in liquid dosage forms for oral use. |

[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.: 07/2019:1532).

# 4. Clinical particulars

## *4.1. Therapeutic indications*

| Well-established use | Traditional use |
|---|---|
| | Indication 1)<br><br>Traditional herbal medicinal product used to increase the amount of urine to achieve flushing of the urinary tract in minor urinary tract complaints.<br><br>Indication 2)<br><br>Traditional herbal medicinal product used for symptomatic relief of digestive disorders such as dyspepsia and flatulence.<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>Herbal preparations<br><br>Indication 1)<br><br>Preparation a)<br>2.0–2.5 g of the comminuted herbal substance in 150 ml boiling water as a herbal infusion, 1-3 times daily<br><br>Single dose: 2-2.5 g<br><br>Daily dose: 2.5-6 g<br><br>Preparation b)<br><br>SD: 2-4 ml 3 times daily<br><br>DD: 6-12 ml<br><br>Preparation c)<br><br>SD: 1-2 ml 3 times daily<br><br>DD: 3-6 ml |

[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 |
|---|---|
| | Preparation d)<br>SD: 0.57 g once daily<br>DD: 0.57 g<br>Indication 2)<br>Preparation a)<br>2.0–2.5 g of the comminuted herbal substance in 150 ml boiling water as a herbal infusion, 1-4 times daily<br>SD: 2-2.5 g<br>DD: 2.5-10 g<br>The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').<br>**Duration of use**<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>**Method of administration**<br>Oral use. To ensure an increase of the amount of urine, adequate fluid intake is required during treatment (see section 4.4.). |

## *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 |
|---|---|
| | The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.<br>If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.<br>Additional to Indication 1): |

| Well-established use | Traditional use |
|---|---|
| | Not recommended to be used in case of severe renal disease including infectious interstitial nephritis, pyelitis and pyelonephritis.<br><br>If complaints or 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.<br><br>Because adequate fluid intake is required during treatment (see section 4.2. 'Method of administration'), *Juniperus communis* L., galbulus is not recommended for patients with conditions where reduced fluid intake is advised by a medical doctor.<br><br>For liquid preparations containing ethanol, the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included. |

## *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.<br><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><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 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.<br><br>No adequate tests on reproductive toxicity and no tests on genotoxicity and carcinogenicity have been performed. |

## 6. Pharmaceutical particulars

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

# 7. Date of compilation/last revision

15 March 2023