20 July 2022
EMA/HMPC/241320/2021
Committee on Herbal Medicinal Products (HMPC)

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

Draft – Revision 1

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	September 2008 November 2008 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	July 2009 September 2009 November 2009
Adoption by HMPC Monograph (EMEA/HMPC/441929/2008) AR (EMEA/HMPC/441930/2008) List of references (EMEA/HMPC/ 442959/2008) Overview of comments received during the public consultation (EMEA/HMPC/421352/2009) HMPC Opinion (EMEA/HMPC/678925/2009)	12 November 2009
First systematic review	
Discussion in HMPC	May 2021 July 2021 September 2021 November 2021 January 2022 March 2022 May 2022 July 2022
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End of consultation (deadline for comments). <Comments should be provided using this template to hmpc.secretariat@ema.europa.eu>.	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

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

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 *Juniperus communis* L., galbulus (pseudo-fructus) (juniper cone berry) i) Herbal substance Not applicable. ii) Herbal preparations a) Comminuted herbal substance b) Liquid extract (DER 1:1), extraction solvent ethanol 25% V/V c) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 45% V/V 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. 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) Traditional herbal medicinal product used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary tract complaints. Indication 2) Traditional herbal medicinal product used for symptomatic relief of digestive disorders such as dyspepsia and flatulence. 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 *Adults and elderly* Herbal preparations Indication 1) Preparation a) 2.0–2.5 g of the comminuted herbal substance in 150 ml boiling water as a herbal infusion, 1-3 times daily Single dose: 2-2.5 g Daily dose: 2.5-6 g Preparation b) SD: 2-4 ml 3 times daily DD: 6-12 ml Preparation c) SD: 1-2 ml 3 times daily DD: 3-6 ml Preparation d) SD: 0.57 g once daily

[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
	DD: 0.57 g Indication 2) Preparation a) 2.0–2.5 g of the comminuted herbal substance in 150 ml boiling water as a herbal infusion, 1-4 times daily SD: 2-2.5 g DD: 2.5-10 g 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** 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** 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. If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. Additional to Indication 1): Not recommended to be used in case of severe renal disease including infectious interstitial nephritis, pyelitis and pyelonephritis.

Well-established use	Traditional use
	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. Because adequate fluid intake is required during treatment (see section 4.2. 'Method of administration'), *Juniperus communis* L., galbulus (pseudo-fructus) is not recommended for patients with conditions where reduced fluid intake is advised by a medical doctor. 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. 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.

Well-established use	Traditional use
	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. No or no adequate tests on reproductive toxicity, genotoxicity and carcinogenicity have been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

20 July 2022