EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Juniperus communis* L., pseudo-fructus

Final

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Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Juniperus communis* L., pseudo-fructus; Juniperi pseudo-fructus; juniper berry

BG (bălgarski):	LT (lietuvių kalba):
CS (čeština):	LV (latviešu valoda):
DA (dansk):	MT (malti):
DE (Deutsch):	NL (nederlands):
EL (elliniká):	PL (polski):
EN (English): juniper berry	PT (português):
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Community herbal monograph on *Juniperus communis* L., 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 as amended *Juniperus communis* L., pseudo-fructus (juniper berry) i) Herbal substance As defined in the Ph. Eur. monograph. ii) Herbal preparations a) Comminuted herbal substance b) Liquid extract (DER 1:1) with 25% ethanol 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
	Herbal substance or comminuted herbal substance as herbal tea for oral use. Herbal substance or herbal preparations in solid or liquid dosage forms for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

1 The material complies with the Ph. Eur. monograph (ref. 01/2008:1532).
2 The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Indication 1) Traditional herbal medicinal product 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 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

Well-established use	Traditional use
	Posology *Adults and elderly* i) Herbal substance Indication 1) Cone berries: To start on day 1 with 5 cone berries, increasing the number every day by 1 cone berry (well chewed) up to 15 cone berries, then decrease the number (1 per day less) to 5 cone berries. So the duration of the therapy is 21 days, the maximum daily dose being 15 cone berries. ii) Herbal preparations Indications 1) and 2) Herbal tea: 2 g of the crushed or comminuted herbal substance in boiling water as a herbal infusion, 2-3 times daily Liquid extract: 2-4 ml 3 times daily Tincture : 1-2 ml 3 times daily

Well-established use	Traditional use
	Indication 1) Soft extract: 0.57 g once 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** 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. Indication 1) For preparations other than tea preparations, ensure appropriate fluid intake.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance(s). Severe renal disease including infectious interstitial nephritis, pyelitis and pyelonephritis. Indication 1) Conditions where reduced fluid intake is recommended (e.g. severe cardiac diseases).

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. For preparations containing ethanol, the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package

Well-established use	Traditional use
	leaflet of medicinal products for human use', must be included. Indication 1) Appropriate fluid intake is recommended. 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. 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
	Allergic skin reactions have been reported. The frequency is not known. If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.

4.9. Overdose

Well-established use	Traditional use
	In case of prolonged use and overdose, urine will smell of violets. There may be renal irritation and pain in and near the kidney, strong diuresis, albuminuria, haematuria, purplish urine, gastrointestinal upsets, accelerated heartbeat and blood pressure. Rarely symptoms of central stimulation like convulsions occur as well as metrorrhagia and abortion.

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. There is limited evidence from preclinical studies that juniper may influence glucose levels in diabetes.

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. Adequate 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

12 November 2009