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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 *JUNIPERUS COMMUNIS* L.,  
PSEUDO-FRUCTUS**

<b>DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)</b>	September 2008 November 2008 January 2009
<b>ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION</b>	14 January 2009
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<b>REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)</b>	
<b>ADOPTION BY HMPC</b>	

Comments should be provided using this [template](#) to [hmpc.secretariat@emea.europa.eu](mailto:hmpc.secretariat@emea.europa.eu)  
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<b>KEYWORDS</b>	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Juniperus communis</i> L.; Juniperi pseudo-fructus; juniper berry
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<b>COMMUNITY HERBAL MONOGRAPH ON <i>JUNIPERUS COMMUNIS</i> L., PSEUDO-FRUCTUS</b>
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**1. NAME OF THE MEDICINAL PRODUCT**

To be specified for the individual finished product.

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION<sup>1,2</sup>**

<u>Well-established use</u>	<u>Traditional use</u>
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended  <i>Juniperus communis</i> L., pseudo-fructus (juniper berry)  i) Herbal substance  Cone berries  ii) Herbal preparations  Comminuted cone berries  Liquid extract with 25% ethanol (1:1 V/V)  Tincture with 45% ethanol (1:5 V/V)

**3. PHARMACEUTICAL FORM**

<u>Well-established use</u>	<u>Traditional use</u>
.	Herbal substance or herbal preparations in solid or liquid dosage forms or as herbal tea for oral use.  The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

<sup>1</sup> The material complies with the Eur. Ph. monograph (ref. 01/2008:1532)

<sup>2</sup> 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

<u>Well-established use</u>	<u>Traditional use</u>
	<p>a) 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.</p> <p>b) Traditional herbal medicinal product for symptomatic relief of digestive disorders such as dyspepsia and flatulence</p> <p>The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.</p>

### 4.2. Posology and method of administration

<u>Well-established use</u>	<u>Traditional use</u>
	<p><b>Posology</b></p> <p>i) Herbal substance</p> <p><b>Indication a)</b></p> <p>Cone berries: To start on day 1 with 5 cone berries, increasing the number every day by 1 coneberry (well chewed) up to 15 cone berries, then decrease the number (1 per day less) until 5 coneberries. So the duration of the therapy is 21 days, the maximum daily dose 15 cone berries.</p> <p>ii) Herbal preparations</p> <p><b>Indications a) and b)</b></p> <p>Infusion: 2 g crushed or comminuted herbal substance for tea preparation with boiling water, infusion time 10 minutes: 2-3 times a day</p> <p>Liquid extract (1:1 in 25% ethanol): 2-4 ml 3 times daily</p> <p>Tincture (1:5 in ethanol 45%): 1-2 ml 3 times daily</p> <p>Not to be used in children and adolescents under 18 years of age (see section 4.4 'Special warnings and precautions for use').</p>

	<p><b>Duration of use</b></p> <p>Not to be used for more than 3 weeks without consulting a doctor or a qualified health care practitioner.</p> <p><b>Method of administration</b></p> <p>Oral use.</p> <p><b>Indication a)</b></p> <p>For preparations other than tea preparations, ensure appropriate fluid intake.</p>
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#### 4.3. Contraindications

<u>Well-established use</u>	<p><u>Traditional use</u></p> <p>Hypersensitivity to the active substance.</p> <p>Severe renal disease including infectious interstitial nephritis, pyelitis and pyelonephritis.</p> <p><b>Indication a)</b></p> <p>Conditions where reduced fluid intake is recommended (e.g. severe cardiac diseases).</p>
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#### 4.4. Special warnings and precautions for use

<u>Well-established use</u>	<p><u>Traditional use</u></p> <p>Not to be used in children and adolescents under 18 years of age since no data on the safe use in children and adolescents are available.</p> <p>Appropriate fluid intake is recommended.</p> <p>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.</p> <p>Concomitant treatment with synthetic diuretics is not recommended.</p> <p>For 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.</p>
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#### 4.5. Interactions with other medicinal products and other forms of interaction

<u>Well-established use</u>	<u>Traditional use</u>  None reported.
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#### 4.6. Pregnancy and lactation

<u>Well-established use</u>	<u>Traditional use</u>  Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.
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#### 4.7. Effects on ability to drive and use machines

<u>Well-established use</u>	<u>Traditional use</u>  No studies on the effect on the ability to drive and use machines have been performed.
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#### 4.8. Undesirable effects

<u>Well-established use</u>	<u>Traditional use</u>  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.
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#### 4.9. Overdose

<u>Well-established use</u>	<u>Traditional use</u>  Seizures and kidney damage have been reported in individuals who took more than 10 g of Juniper per day or who took high doses of Juniper for longer than 4 weeks.  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.
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## 5. PHARMACOLOGICAL PROPERTIES

### 5.1. Pharmacodynamic properties

<u>Well-established use</u>	<u>Traditional use</u>
	<p>Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.</p> <p>There is limited evidence from preclinical studies that Juniper may influence glucose levels in diabetes.</p>

### 5.2. Pharmacokinetic properties

<u>Well-established use</u>	<u>Traditional use</u>
	<p>Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.</p>

### 5.3. Preclinical safety data

<u>Well-established use</u>	<u>Traditional use</u>
	<p>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.</p> <p>Based on the results of preclinical investigations it can be concluded that <i>Juniperus communis</i> extract has anti-fertility and abortifacient effects in rats.</p> <p>As no specific investigations were done on the foetuses, there are no data on genotoxicity, reproductive toxicity or carcinogenicity available for <i>Juniperus communis</i> or its preparations.</p>

## 6. PHARMACEUTICAL PARTICULARS

<u>Well-established use</u>	<u>Traditional use</u>
	<p>Not applicable.</p>

## 7. DATE OF COMPILATION/LAST REVISION

14 January 2009