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Committee on Herbal Medicinal Products (HMPC)

## Community herbal monograph on *Juniperus communis* L., aetheroleum

Draft

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BG (bългарски): CS (čeština): DA (dansk): DE (Deutsch): EL (ελληνικά): EN (English): Juniper oil ES (español): ET (eesti keel): FI (suomi): FR (français): Genièvre (huile essentielle de) HU (magyar): IT (italiano):	LT (lietuvių kalba): LV (latviešu valoda): MT (malti): NL (nederlands): Jeneverbes PL (polski): PT (português): RO (română): SK (slovenčina): SL (slovenščina): SV (svenska): <i>IS (íslenska):</i> <i>NO (norsk):</i>
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# Community herbal monograph on *Juniperus communis* L., aetheroleum

## 1. Name of the medicinal product

To be specified for the individual finished product.

## 2. Qualitative and quantitative composition<sup>1, 2</sup>

Well-established use	Traditional use
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended</p> <p><i>Juniperus communis</i> L., aetheroleum (juniper oil)</p> <p>i) Herbal substance Not applicable.</p> <p>ii) Herbal preparations Essential oil obtained by steam distillation from the ripe, non-fermented berry cones.</p>

## 3. Pharmaceutical form

Well-established use	Traditional use
	<p><b>Herbal preparation in liquid dosage forms for oral and cutaneous use.</b></p> <p><b>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</b></p>

## 4. Clinical particulars

### 4.1. Therapeutic indications

Well-established use	Traditional use
	<p><b>Oral use</b></p> <p>Indication 1)</p> <p>Traditional herbal medicinal product to increase the amount of urine to achieve flushing of the</p>

<sup>1</sup> The material complies with the Ph. Eur. monograph (ref.: 1/2008:1832).

<sup>2</sup> The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

Well-established use	Traditional use
	<p>urinary tract as an adjuvant in minor urinary tract complaints.</p> <p><b>Indication 2)</b></p> <p>Traditional herbal medicinal product for symptomatic relief of digestive disorders such as dyspepsia and flatulence.</p> <p><b>Cutaneous use</b></p> <p><b>Indication 3)</b></p> <p>Traditional herbal medicinal product as adjuvant in the relief of minor muscle and articular pain.</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

Well-established use	Traditional use
	<p><b>Posology</b></p> <p><b>Oral use</b></p> <p><i>Adults</i></p> <p><b>Average daily dose</b></p> <p>60-100 mg to be taken in 1-3 doses.</p> <p>The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p><b>Cutaneous use</b></p> <p><i>Adolescents, adults</i></p> <p>Bath additive 3-4 times weekly 1-1.5 g juniper oil full bath for 10-20 min at 35-38°C</p> <p>The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p><b>Duration of use</b></p> <p>If symptoms persist longer than 2 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p><b>Method of administration</b></p>

Well-established use	Traditional use
	<p>Oral use.</p> <p>Cutaneous use.</p>

### 4.3. Contraindications

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

### 4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p><b>Oral use</b></p> <p>The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.</p> <p><b>Cutaneous use</b></p> <p>The use in children under 12 years of age has not been established due to lack of adequate data.</p> <p><b>Indications 1) and 2)</b></p> <p>If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p><b>Indication 1)</b></p> <p>Appropriate fluid intake is recommended.</p> <p>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.</p> <p>The use of this product is not recommended in case of oedema due to limited heart and kidney function.</p> <p><b>Indication 3)</b></p> <p>In cases of hypertension, a full bath should be used with caution.</p>

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

<b>Well-established use</b>	<b>Traditional use</b>
	None reported.

#### **4.6. Pregnancy and lactation**

<b>Well-established use</b>	<b>Traditional use</b>
	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**

<b>Well-established use</b>	<b>Traditional use</b>
	No studies on the effect on the ability to drive and use machines have been performed.

#### **4.8. Undesirable effects**

<b>Well-established use</b>	<b>Traditional use</b>
	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**

<b>Well-established use</b>	<b>Traditional use</b>
	In case of prolonged oral use and overdose, urine will smell of violets. There may be renal irritation and kidney pain, strong diuresis, albuminuria, haematuria, purplish urine, gastrointestinal upsets, increased 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 non-clinical 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

15 March 2010