



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

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

Final

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BG (bălgarski): хвойна CS (čeština): jalovec DA (dansk): enebær DE (Deutsch): Wachholder EL (elliniká): EN (English): juniper (essential oil) ES (español): enebro ET (eesti keel): kadakas FI (suomi): kataja FR (français): genièvre (huile essentielle de) HU (magyar): boróka IT (italiano): ginepro	LT (lietuvių kalba): kadagys LV (latviešu valoda): kadiķis MT (malti): NL (nederlands): jeneverbes (vluchtige olie) PL (polski): jałowiec PT (português): junípero RO (română): ienupăr SK (slovenčina): brinje SL (slovenščina): borievka SV (svenska): en IS (íslenska): einir NO (norsk): einer
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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^{1, 2}

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

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

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
	<p>Oral use</p> <p>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.</p> <p>Indication 2) Traditional herbal medicinal product for symptomatic relief of digestive disorders such as dyspepsia and flatulence.</p> <p>Cutaneous use</p> <p>Indication 3) Traditional herbal medicinal product as adjuvant in the relief of minor muscular 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>Posology</p> <p>Oral use</p> <p><i>Adults and elderly</i></p> <p>Average daily dose</p> <p>60-100 mg juniper oil 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>Cutaneous use</p> <p><i>Adolescents, adults and elderly</i></p> <p>Bath additive 3-4 times weekly 1-1.5 g juniper oil in full bath for 10-20 minutes 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>

Well-established use	Traditional use
	<p data-bbox="810 255 1018 282">Duration of use</p> <p data-bbox="810 311 1398 450">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 data-bbox="810 479 1145 506">Method of administration</p> <p data-bbox="810 535 922 562">Oral use.</p> <p data-bbox="810 591 1002 618">Cutaneous use.</p>

4.3. Contraindications

Well-established use	Traditional use
	<p data-bbox="810 804 1305 831">Hypersensitivity to the active substance.</p> <p data-bbox="810 860 1070 887">Indications 1) and 2)</p> <p data-bbox="810 896 1390 963">Severe renal disease including infectious interstitial nephritis, pyelitis and pyelonephritis.</p> <p data-bbox="810 978 970 1005">Indication 1)</p> <p data-bbox="810 1014 1366 1081">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 data-bbox="810 1267 1398 1370">If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p data-bbox="810 1400 922 1426">Oral use</p> <p data-bbox="810 1456 1398 1559">The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.</p> <p data-bbox="810 1574 970 1601">Indication 1)</p> <p data-bbox="810 1610 1318 1637">Appropriate fluid intake is recommended.</p> <p data-bbox="810 1666 1422 1805">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 data-bbox="810 1834 1398 1937">The use of this product is not recommended in case of oedema due to limited heart and kidney function.</p> <p data-bbox="810 1966 1007 1993">Cutaneous use</p>

Well-established use	Traditional use
	<p>The use in children under 12 years of age has not been established due to lack of adequate data.</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

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
	<p>Allergic skin reactions have been reported. The frequency is not known.</p> <p>If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.</p>

4.9. Overdose

Well-established use	Traditional use
	<p>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</p>

Well-established use	Traditional use
	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

25 November 2010