



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Cynara scolymus* L., folium

Draft

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BG (bălgarski): CS (čeština): artyčokový list DA (dansk): DE (Deutsch): Artischockenblätter EL (elliniká): Φύλλο Κινάρas EN (English): Artichoke leaf ES (español): ET (eesti keel): FI (suomi): FR (français): Feuilles d' artichaut HU (magyar): IT (italiano): Foglie di articiocco	LT (lietuvių kalba): LV (latviešu valoda): artišoka lapas MT (malti): NL (nederlands): artisjok PL (polski): liść karczocha PT (português): alcachofra RO (română): SK (slovenčina): SL (slovenščina): SV (svenska): kronärtskocka <i>IS (islenska):</i> <i>NO (norsk):</i>
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Community herbal monograph on *Cynara scolymus* L., folium

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>Cynara scolymus</i> L., folium (Artichoke leaf)</p> <p>i) Herbal substance</p> <p>Not applicable.</p> <p>ii) Herbal preparations</p> <p>a) Comminuted or powdered dried leaves for herbal tea</p> <p>b) Powdered leaves</p> <p>c) Dry extract (DER 3.8-7.5:1), extraction solvent water</p> <p>d) Soft extract of fresh leaves (DER 15-30:1), extraction solvent water</p> <p>e) Dry extract of fresh leaves (DER 25-35:1), extraction solvent water</p>

3. Pharmaceutical form

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

¹ When dried, the material complies with the Ph. Eur. monograph (ref.: 01/2010:1866).

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>Traditional herbal medicinal product for the symptomatic relief of digestive disorders such as dyspepsia with a sensation of fullness, bloating and flatulence.</p> <p>The product is a traditional herbal medicinal product for use in specified indication exclusively based upon long-standing use.</p>

4.2. Posology and method of administration

Well-established use	Traditional use
	<p>Posology</p> <p><i>Adolescents, Adults and Elderly</i></p> <p>a) Comminuted or powdered dried leaves for herbal tea</p> <p>Daily dose 6 g (3 g 1-2 times daily corresponding to 600 mg dry aqueous extract, or 1.5 g 4 times daily).</p> <p>b) Powdered dried leaves</p> <p>Daily dose 600-1500 mg (in doses of 150, 175, 300, 500 mg).</p> <p>c) Dry extract (DER 3.8-7.5:1)</p> <p>Daily dose 600-900 mg (in doses of 200, 300, or 600 mg).</p> <p>d) Soft extract of fresh leaves (DER 15-30:1)</p> <p>Daily dose of 600-1200 mg (in doses of 200 mg) or in liquid form 9 ml daily (20 g of extract /100 ml).</p> <p>e) Dry extract of fresh leaves (DER 25-35:1)</p> <p>Daily dose 900 mg (single dose up to 450 mg daily).</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>Duration of use</p> <p>If the symptoms persist longer than 2 weeks</p>

Well-established use	Traditional use
	<p>during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Method of administration</p> <p>Oral use.</p>

4.3. Contraindications

Well-established use	Traditional use
	<p>Hypersensitivity to the active substance or to plants of the <i>Asteraceae</i> family (<i>Compositae</i>).</p> <p>Obstructions of bile ducts, cholangitis, gallstones and any other biliary diseases and hepatitis.</p>

4.4. Special warnings and precautions for use

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

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

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

4.6. Pregnancy and lactation

Well-established use	Traditional use
	<p>Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</p>

4.7. Effects on ability to drive and use machines

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

4.8. Undesirable effects

Well-established use	Traditional use
	<p>Slight diarrhoea with abdominal spasm, epigastric complaints like nausea, and heartburn have been reported. The frequency is not known.</p> <p>Allergic reactions may occur. 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
	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 as amended.

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
	<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>Adequate tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.</p>

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

25 November 2010