EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 September 2011
EMA/HMPC/150218/2009
Committee on Herbal Medicinal Products (HMPC)

This document was valid from 13 September 2011 until March 2018. It is now superseded by a new version adopted by the HMPC on 27 March 2018 and published on the EMA website.

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	May 2010 July 2010 November 2010
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	25 November 2010
End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	15 April 2011
Rediscussion in Working Party on Community monographs and Community list (MLWP)	May 2011 July 2011
Adoption by Committee on Herbal Medicinal Products (HMPC)	13 September 2011

Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Cynara scolymus* L., folium; Cynarae folium; Artichoke leaf

BG (bălgarski): АртишокCS (čeština): Artyčokový list DA (dansk): Artiskokblad DE (Deutsch): Artischockenblätter EL (elliniká): Κιναρασ φυλλο EN (English): Artichoke leaf ES (espanol): Alcachofera, hoja de ET (eesti keel): Artišokileht FI (suomi): FR (français): Artichaut (feuille d') HU (magyar): Articsókalevél IT (italiano): Carciofo foglia	LT (lietuvių kalba): LV (latviešu valoda): Artišoka lapas MT (malti): Werqa tal-Qaqoċċ NL (nederlands): Artisjok PL (polski): Liść karczocha PT (português): Alcachofra, folha RO (română): Frunză de anghinară SK (slovenčina): Artičokový list SL (slovenščina): List artičoke SV (svenska): Kronärtskocka, blad *IS (íslenska)*: *NO (norsk)*: Artisjokkblad

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7051
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *Cynara scolymus* L., folium (Artichoke leaf) i) Herbal substance Not applicable. ii) Herbal preparations a) Comminuted dried leaves for herbal tea b) Powdered leaves c) Dry extract (DER 2.5-7.5:1), extraction solvent water d) Dry extract of fresh leaves (DER 15-35:1), extraction solvent water e) Soft extract of fresh leaves (DER 15-30:1), extraction solvent water f) Soft extract (DER 2.5-3.5:1), extraction solvent ethanol 20% (v/v)

3. Pharmaceutical form

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

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

4.2. Posology and method of administration[3]

Well-established use	Traditional use
	Posology *Adolescents, adults and elderly* a) Comminuted dried leaves for herbal tea Herbal tea: 1.5 g of the comminuted herbal substance in 150 ml of boiling water as a herbal infusion 4 times daily or 3 g of the comminuted herbal substance in 150 ml of boiling water as a herbal infusion 1-2 times daily b) Powdered leaves Daily dose 600-1500 mg (in divided doses 2-4 times a day of 150, 175, 300 or 500 mg) c) Dry extract (DER 2.5-7.5:1), extraction solvent water Daily dose 600-1320 mg (in divided doses of 200-600 mg) d) Dry extract of fresh leaves (DER 15-35:1), extraction solvent water Daily dose 900-2400 mg (in divided doses of 300-600 mg) e) Soft extract of fresh leaves (DER 15-30:1), extraction solvent water Daily dose 600-1200 mg (in divided doses of 200 mg)

[3] For guidance on herbal substance/herbal preparation administered as herbal tea or as infusion/decoction/macerate preparation, please refer to the HMPC 'Glossary on herbal teas' (EMA/HMPC/5829/2010 Rev.1).

Well-established use	Traditional use
	or in liquid form: 9 ml daily (20 g of extract/100 ml) f) Soft extract (DER 2.5-3.5:1), extraction solvent ethanol 20% (v/v) Daily dose 2.1 g (in divided doses of 0.7 g) The use in children under 12 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.

4.3. Contraindications

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

4.4. Special warnings and precautions for use

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

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

Well-established use	Traditional use
	None reported.

4.6. Fertility 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. No fertility data available.

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
	Slight diarrhoea with abdominal spasm, epigastric complaints like nausea, and heartburn have been reported. The frequency is not known. Allergic reactions may occur. 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
	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
	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

13 September 2011