EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Cynara cardunculus* L. (syn. *Cynara scolymus* L.), folium

Final

Initial assessment	
Discussion in Working Party on European Union monographs and 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)	15 April 2011
Rediscussion in MLWP	May 2011 July 2011
Adoption by HMPC	13 September 2011
First systematic review	
Discussion in MLWP	January 2017 March 2017 July 2017 September 2017 November 2017 January 2018
Adoption by HMPC	27 March 2018

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Cynara cardunculus* L. (syn. *Cynara scolymus* L.); Cynarae folium; artichoke leaf

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BG (bulgarski): Артишок CS (čeština): artyčokový list DA (dansk): Artiskokblad DE (Deutsch): Artischockenblätter EL (elliniká): κινάρας φύλλο EN (English): artichoke leaf ES (español): alcachofera, hoja de ET (eesti keel): artišokileht FI (suomi): latva-artisokka, lehti FR (français): artichaut (feuille d') HR (hrvatski): artičokin list HU (magyar): articsókalevél IT (italiano): Carciofo foglia	LT (lietuvių kalba): Artišokų lapai 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): list artičoky SL (slovenščina): list artičoke SV (svenska): kronärtskocka, blad IS (íslenska): NO (norsk): artisjokkblad

European Union herbal monograph on *Cynara cardunculus* L. (syn. *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. *Cynara cardunculus* L., folium (artichoke leaf) i) Herbal substance Not applicable ii) Herbal preparations a) Comminuted dried leaves for herbal tea b) Powdered dried leaves c) Dry extract of dried leaves (DER 2-7.5:1), 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 of dried leaves (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] The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance

[2] The material complies with the Ph. Eur. monograph (ref.: 1866)

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: 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 Daily dose 3-6 g b) Powdered dried leaves Daily dose 600-1500 mg (in divided doses, 2-4 times a day) c) Dry extract of dried leaves (DER 2-7.5:1), extraction solvent water Single dose 200-640 mg Daily dose 400-1320 mg d) Dry extract of fresh leaves (DER 15-35:1), extraction solvent water Single dose 200-900 mg Daily dose 600-2700 mg e) Soft extract of fresh leaves (DER 15-30:1), extraction solvent water

[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
	Single dose 600 mg Daily dose 1800 mg f) Soft extract of dried leaves (DER 2.5-3.5:1), extraction solvent ethanol 20% (V/V) Single dose 0.7 g 3 times daily Daily dose 2.1 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). Obstruction of bile duct, cholangitis, liver disease, gallstones and any other biliary disorders that require medical supervision and advice.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	The use in children under 12 years of age has not been established 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.

5.2. Pharmacokinetic properties

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

5.3. Preclinical safety data

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC, 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 September 2018