



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Cnicus benedictus* L., herba

Draft

Initial assessment	
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BG (bulgarski):	LT (lietuvių kalba): Karčiujų šventadagių žolė
CS (čeština): benediktová nať	LV (latviešu valoda):
DA (dansk): Benediktinertidse	MT (Malti):
DE (Deutsch): Benediktenkraut	NL (Nederlands): gezegende distel
EL (elliniká): κνίκου ιεράκανθα (βενέδικτου) πόα	PL (polski):
EN (English): Holy thistle (St. Benedict's thistle)	PT (português): cardo-santo
ES (español):	RO (română):
ET (eesti keel):	SK (slovenčina): vňať benediktu lekárskeho
FI (suomi): karvaskaunokki, verso	SL (slovenščina): zel benediktinke
FR (français): Charbon-bénit (partie aérienne de)	SV (svenska): kardbenedikt, ört
HR (hrvatski): zelen blaženog čkalja	IS (íslenska):
HU (magyar): benedekfű virágos leveles hajtás	NO (norsk):
IT (italiano):	

European Union herbal monograph on *Cnicus benedictus* L., herba

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</p> <p><i>Cnicus benedictus</i> L., herba</p> <p>i) Herbal substance</p> <p>Not applicable.</p> <p>ii) Herbal preparations</p> <p>a) Powdered herbal substance</p> <p>b) Comminuted herbal substance</p> <p>c) Liquid extract (DER 1:1), extraction solvent Ethanol 25% V/V</p> <p>d) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent Ethanol 25% V/V</p>

3. Pharmaceutical form

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

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 Austrian Pharmacopoeia (ÖAB) monograph (ref.: 2009/007)

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	<p>Indication 1)</p> <p>Traditional herbal medicinal product for the temporary loss of appetite.</p> <p>Indication 2)</p> <p>Traditional herbal medicinal product for symptomatic relief of dyspepsia and mild spasmodic disorders of the gastrointestinal tract.</p> <p>The product is a traditional herbal medicinal product for use in the specified indications exclusively based upon long-standing use.</p>

4.2. Posology and method of administration³

Well-established use	Traditional use
	<p>Posology</p> <p>Indication 1) and 2)</p> <p><i>Adults and Elderly</i></p> <p>a) Single dose: 1 - 2 g, 3 times daily Daily dose: 3 - 6 g</p> <p>b) Single dose: 1.5 - 3 g of the comminuted herbal substance in 150 ml of boiling water as an infusion, 3 times daily Daily dose: 4.5 - 9 g</p> <p>c) Single dose: 1.5 - 2 ml, 3 times daily Daily dose: 4.5 - 6 ml liquid extract</p> <p>d) Single dose: 3 - 6 ml, 3 times daily Daily dose: 9 - 18 ml tincture</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>Duration of use</p>

³For 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
	<p>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.</p> <p>Method of administration</p> <p>Indication 1)</p> <p>Oral use, before meals.</p> <p>Indication 2)</p> <p>Oral use.</p>

4.3. Contraindications

Well-established use	Traditional use
	<p>Hypersensitivity to the active substance(s) and to other to other plants of the Asteraceae (Compositae) family.</p>

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.</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>For tinctures and liquid extracts containing ethanol, the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included.</p>

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

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

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
	None known. If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.

4.9. Overdose

Well-established use	Traditional use
	When taken at doses of more than 5 g per cup of tea, it may cause gastric irritation and vomiting. 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

Well-established use	Traditional use
	Directive 2001/83/EC.

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, unless necessary for the safe use of the product.</p> <p>Adequate tests on genotoxicity have not been performed.</p> <p>Tests on reproductive toxicity and carcinogenicity have not been performed.</p>

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

25 January 2023