



22 May 2012
EMA/HMPC/121816/2010
Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Cichorium intybus* L., radix

Draft

Discussion in Working Party on Community monographs and Community list (MLWP)	July 2010 September 2010 November 2011 March 2012
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	22 May 2012
End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	15 October 2012
Rediscussion in Working Party on Community monographs and Community list (MLWP)	
Adoption by Committee on Herbal Medicinal Products (HMPC)	

Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Cichorium intybus</i> L., radix; Cichorii intybi radix; Chicory root
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BG (bългарski): Синя жлъчка, корен CS (čeština): Čekankový kořen DA (dansk): Cikorierod DE (Deutsch): Wegwartenwurzel EL (elliniká): EN (English): Chicory root ES (español): Achicoria, raíz de ET (eesti keel): Sigurijuur FI (suomi): Sikuri, juur FR (français): Chicorée (racine de) HU (magyar): Mezei katáng gyökér IT (italiano): Cicoria radice	LT (lietuvių kalba): LV (latviešu valoda): Cigoriņa saknes MT (malti): NL (nederlands): Cichoreiwortel PL (polski): Korzeń cykorii podróżnika PT (português): Chicória, raiz RO (română): Rădăcină de cicoare SK (slovenčina): Čakankový koreň SL (slovenščina): Korenina navadnega potrošnika SV (svenska): Cikoriarot IS (íslenska): NO (norsk): Sikorirot
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Community herbal monograph on *Cichorium intybus* L., radix

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 <i>Cichorium intybus</i> L., radix (Chicory root) i) Herbal substance Not applicable. ii) Herbal preparations Comminuted herbal substance.

3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Traditional herbal medicinal product for the relief of symptoms related to mild digestive disorders (such as feeling of abdominal fullness, flatulence and slow digestion) and temporary loss of appetite. The product is a traditional herbal medicinal product for use in the specified indication

¹ The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

Well-established use	Traditional use
	exclusively based upon long-standing use.

4.2. Posology and method of administration³

Well-established use	Traditional use
	<p>Posology</p> <p><i>Adolescents, adults and elderly</i></p> <p>Herbal tea: 2-4 g of the comminuted herbal substance in 250 ml of boiling water as a herbal infusion once daily.</p> <p>Herbal tea: 2-4 g of the comminuted herbal substance in 250 ml of water as a decoction once 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 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
	Hypersensitivity to the active substance and to other plants of the Asteraceae (Compositae) family.

4.4. Special warnings and precautions for use

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>If the symptoms worsen during the use of the</p>

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
	medicinal product, a doctor or a qualified health care practitioner should be consulted.

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
	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
	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. 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

22 May 2012