EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Cetraria islandica* (L.) Acharius s.l., thallus

Final

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Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Cetraria islandica* (L.) Acharius s.l., thallus; Lichen islandicus; Iceland moss

BG (bălgarski): Исландски лишей
CS (čeština): Islandský lišejník
DA (dansk): Islandsk mos
DE (Deutsch): Isländisches Moos
EL (elliniká): Λειχήν Ισλανδίας
EN (English): Iceland moss
ES (español): Liquen de Islandia, talo de
ET (eesti keel): Islandi käokõrva maapealne osa
FI (suomi): Islanninjäkälä
FR (français): Lichen d'Islande
HR (hrvatska): Islandski lišaj
HU (magyar): Izlandi zuzmó
IT (italiano): Lichene islandico
LT (lietuvių kalba): Islandinių kerpenų gniužulai
LV (latviešu valoda): Islandes ķērpja lapoņi
MT (malti): Likeni tal-Islanda
NL (nederlands): IJslands Mos
PL (polski): Porost islandzki
PT (português): Líquene-da-islândia
RO (română): Lichen de Islanda
SK (slovenčina): Lišajník islandský
SL (slovenščina): Islandski lišaj
SV (svenska): Islandslav
IS (íslenska):
NO (norsk): Islandsk lav

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Community herbal monograph on *Cetraria islandica* (L.) Acharius s.l., thallus

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 *Cetraria islandica* (L.) Acharius s.l., thallus, (Iceland moss) i) Herbal substance Not applicable. ii) Herbal preparations a) Comminuted herbal substance b) Soft extract (DER 2-4:1), extraction solvent water c) Soft extract (DER 0.4-0.8:1), extraction solvent water d) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 40% 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 forms for oral or oromucosal 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.: 07/2010:1439)

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Indication 1) Traditional herbal medicinal product used as a demulcent for the symptomatic treatment of oral or pharyngeal irritation and associated dry cough. Indication 2) Traditional herbal medicinal product used in temporary loss of appetite. The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.

4.2. Posology and method of administration[3]

Well-established use	Traditional use
	Posology **<u>Oral use</u>** ***a) Comminuted herbal substance*** Indication 1) *Adolescents, adults and elderly* Herbal tea: 1.5 g of the comminuted herbal substance in 150 ml of boiling water as a herbal infusion or as a macerate 3 to 4 times daily Daily dose: 4–6 g The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). Indication 2) *Adults and elderly* Herbal tea: 1–2 g of the comminuted herbal substance in 150 ml of water as an infusion or decoction 3 times daily Daily dose: 4-6 g The use in children and adolescents under 18 years of age is not recommended (see section 4.4

[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
	'Special warnings and precautions for use'). ***d) Tincture*** Indication 1) and 2) *Adults and elderly* Single dose: 1-1.5 ml 3 times daily Daily dose: 3-4.5 ml The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **<u>Oromucosal use</u>** ***b) Soft extract (DER 2-4:1)*** Indication 1) *Adolescents, adults and elderly* Single dose: 100-200 mg several times daily Daily dose: 2 g *Children 6-12 years of age* Single dose: 100 mg 4 to 6 times daily Daily dose: 400 to 600 mg The use in children under 6 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). ***c) Soft extract (DER 0.4-0.8:1)*** Indication 1) *Adolescents, adults and elderly* Single dose: 80-160 mg several times daily Daily dose: 0.8-1.6 g *Children 6-12 years of age* Single dose: 80 mg 4 to 6 times daily Daily dose: 320 to 480 mg The use in children under 6 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **Duration of use** Indication 1) and 2) If the symptoms persist longer than one week

Well-established use	Traditional use
	during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. **Method of administration** ***Preparations a) and d)*** Oral use ***Preparations b) and c)*** Oromucosal use The macerate should be used immediately after preparation.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	Indication 1) If dyspnoea, fever or purulent sputum occurs during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. ***Preparation a)*** The use in children under 12 years of age has not been established due to lack of adequate data. ***Preparations b) and c)*** The use in children under 6 years of age is not recommended because of the pharmaceutical form (solid dosage form). ***Preparation d)*** The use in children and adolescents under 18 years of age has not been established due to lack of adequate data. Indication 2)

Well-established use	Traditional use
	Preparations a) and d) The use in children and adolescents under 18 years of age has not been established due to lack of adequate data. Indications 1) and 2) Absorption of concomitantly administered medicines may be delayed. As a precautionary measure, the product should not be taken ½ to 1 hour before or after intake of other medicinal products. For tinctures 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.

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.

Well-established use	Traditional use
	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

24 November 2014