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SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

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

Draft

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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
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended</p> <p><i>Cetraria islandica</i> (L.) Acharius s.l., thallus, (Iceland moss)</p> <p>i) Herbal substance</p> <p>Not applicable.</p> <p>ii) Herbal preparations</p> <p>a) Comminuted herbal substance</p> <p>b) Soft extract (DER 2-4:1), extraction solvent water</p> <p>c) Soft extract (DER 0.4-0.8:1), extraction solvent water</p> <p>d) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 40% 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 solid and liquid dosage forms for oral or oromucosal 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 Ph. Eur. monograph (ref.: 07/2010:1439)

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	<p data-bbox="810 405 967 432">Indication 1)</p> <p data-bbox="810 461 1414 562">Traditional herbal medicinal product used as a demulcent for the symptomatic treatment of oral or pharyngeal irritation and associated dry cough</p> <p data-bbox="810 591 967 618">Indication 2)</p> <p data-bbox="810 647 1347 696">Traditional herbal medicinal product used in temporary loss of appetite.</p> <p data-bbox="810 725 1422 835">The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.</p>

4.2. Posology and method of administration³

Well-established use	Traditional use
	<p data-bbox="810 1025 935 1052">Posology</p> <p data-bbox="810 1081 916 1108"><u>Oral use</u></p> <p data-bbox="810 1160 1262 1187">a) Comminuted herbal substance</p> <p data-bbox="810 1216 1034 1243"><i>Adults and elderly</i></p> <p data-bbox="810 1294 967 1321">Indication 1)</p> <p data-bbox="810 1328 1398 1541">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 macerate should be used immediately after preparation.</p> <p data-bbox="810 1570 967 1597">Indication 2)</p> <p data-bbox="810 1626 1378 1765">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</p> <p data-bbox="810 1794 1422 1895">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>

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

Well-established use	Traditional use
	Method of administration <i>Preparations a) and d)</i> Oral use <i>Preparations b) and c)</i> Oromucosal use

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) and 2) <i>Preparations a) and d)</i> The use in children and adolescents under 18 years of age has not been established due to lack of adequate data. Indication 1) <i>Preparations b) and c)</i> The use in children under 6 years of age is not recommended because of the pharmaceutical form (solid dosage form). 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. 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. 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

6 May 2014