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Committee on Herbal Medicinal Products (HMPC)

## Community herbal monograph on *Origanum dictamnus* L., herba

Draft

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BG (bългарски): Критски риган, стрък CS (čeština): nař krétského oregana DA (dansk): DE (Deutsch): Kretisches Dostenkraut EL (elliniká): Δικτάμνου πόα EN (English): Dittany of Crete herb ES (español): Orégano de Creta, partes aéreas de ET (eesti keel): kreeta pune ürt FI (suomi): kreetanmeirami FR (français): Dictame de Crête (parties aériennes) HU (magyar): Krétai majoranna virágos hajtás IT (italiano):	LT (lietuvių kalba): Raudonėlių žolė LV (latviešu valoda): MT (malti): Merdqux NL (nederlands): Kandische majoraan PL (polski): Ziele lebiodki kreteńskie PT (português): Orégão RO (română): SK (slovenčina): Vňař pamajoránu gréckeho SL (slovenščina): zel kretske dobre misli SV (svenska): Kretadiptam IS (islenska): NO (norsk): Oregano
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# Community herbal monograph on *Origanum dictamnus* L., herba

## 1. Name of the medicinal product

To be specified for the individual finished product.

## 2. Qualitative and quantitative composition<sup>1</sup>

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended <i>Origanum dictamnus</i> L., herba (Dittany of Crete herb) 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. Comminuted herbal substance for infusion or decoction preparation for cutaneous use. The pharmaceutical form should be described by full standard term.

## 4. Clinical particulars

### 4.1. Therapeutic indications

Well-established use	Traditional use
	<b>Indication 1)</b> Traditional herbal medicinal product used for the relief of cough associated with cold.

<sup>1</sup> 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
	<p data-bbox="810 255 967 286"><b>Indication 2)</b></p> <p data-bbox="810 315 1406 378">Traditional herbal medicinal product used for the relief of mild gastrointestinal disorders.</p> <p data-bbox="810 405 967 436"><b>Indication 3)</b></p> <p data-bbox="810 465 1406 528">Traditional herbal medicinal product used for the relief of minor skin inflammations and bruises.</p> <p data-bbox="810 557 1350 658">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 administration<sup>2</sup>

Well-established use	Traditional use
	<p data-bbox="810 846 935 878"><b>Posology</b></p> <p data-bbox="810 902 1067 934"><b>Indications 1) and 2)</b></p> <p data-bbox="810 958 1034 990"><i>Adults and elderly</i></p> <p data-bbox="810 1014 1398 1151">Single dose Herbal tea: 3 – 7 g of the comminuted herbal substance in 150 ml of boiling water as a herbal infusion, 3 times daily. Daily dose 9-21 g</p> <p data-bbox="810 1220 842 1252">Or</p> <p data-bbox="810 1276 1390 1413">Single dose Herbal tea: 1.5 – 5 g of the comminuted herbal substance in 150 ml of boiling water as a decoction, 3 times daily. Daily dose 4.5-15 g</p> <p data-bbox="810 1482 1422 1583">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 data-bbox="810 1608 967 1639"><b>Indication 3)</b></p> <p data-bbox="810 1664 1193 1695"><i>Adolescents, adults and elderly</i></p> <p data-bbox="810 1720 1422 1856">Comminuted herbal substance for infusion or decoction preparation for cutaneous use: 30-75 g of comminuted herbal substance in 1 l of water, 2 to 5 times daily.</p> <p data-bbox="810 1881 1398 1953">The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings</p>

<sup>2</sup> 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>and precautions for use').</p> <p><b>Duration of use</b></p> <p>Indication 1)</p> <p>If the symptoms persist longer than 1 week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Indications 2) and 3)</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><b>Method of administration</b></p> <p>Oral use</p> <p>Cutaneous use.</p> <p>Apply as a wet dressing to the affected areas of the skin 2-5 times daily. The infusion/decoction is applied cutaneously.</p>

### 4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance or to other plants of the Lamiaceae family.

### 4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>Indications 1) and 2)</p> <p>The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.</p> <p>Indication 1)</p> <p>If the symptoms worsen during the use of the medicinal product or if dyspnoea, high fever or purulent sputum occurs, a doctor or a qualified health care practitioner should be consulted immediately.</p>

Well-established use	Traditional use
	<p>Indication 3)</p> <p>The use in children under 12 years of age has not been established due to lack of adequate data.</p>

#### **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
	<p>No fertility data available.</p> <p>Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</p>

#### **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
	<p>None known.</p> <p>If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.</p>

#### **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 genotoxicity, reproductive toxicity and carcinogenicity have not been performed.

## 6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

## 7. Date of compilation/last revision

20 November 2012