



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

28 January 2014  
EMA/HMPC/200429/2012 *Corr.*  
Committee on Herbal Medicinal Products (HMPC)

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

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	March 2012 May 2012 September 2012
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	20 November 2012
End of consultation (deadline for comments <sup>1</sup> )	15 April 2013
Rediscussion in Working Party on Community monographs and Community list (MLWP)	May 2013
Adoption by Committee on Herbal Medicinal Products (HMPC)	9 July 2013
Corrigendum <sup>2</sup>	28 January 2014

<b>Keywords</b>	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Origanum dictamnus</i> L., herba; Origanum dictamnus herba; Dittany of Crete herb
-----------------	---

<sup>1</sup> No comments were received during the period of public consultation. Therefore the final monograph is published together with the final assessment report and list of references, without an 'Overview of comments received during the public consultation'.

<sup>2</sup> Corrigendum: correction in section 4.2 concerning the posology of the herbal tea for oral use (comminuted herbal substance, as a herbal infusion)



<p>BG (bulgarski): Критски риган, стрък  CS (čeština): nař krétského oregana  DA (dansk): Diktammerianurt  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)  HR (hrvatski): zelen kretskog mravinca  HU (magyar): Krétai majoranna virágos hajtás  IT (italiano): Origano di Creta, parti aeree</p>	<p>LT (lietuvių kalba): Raudonėlių žolė  LV (latviešu valoda): Krētas raudenes laksti  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 (íslenska):  NO (norsk): <i>Oregano</i></p>
---	--

# 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>3, 4</sup>

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>Origanum dictamnus</i> L., herba (Dittany of Crete herb)</p> <p>i) Herbal substance</p> <p>Not applicable.</p> <p>ii) Herbal preparations</p> <p>Comminuted herbal substance.</p>

## 3. Pharmaceutical form

Well-established use	Traditional use
	<p>Comminuted herbal substance as herbal tea for oral use.</p> <p>Comminuted herbal substance for infusion or decoction preparation for cutaneous use.</p> <p>The pharmaceutical form should be described by full standard term.</p>

## 4. Clinical particulars

### 4.1. Therapeutic indications

Well-established use	Traditional use
	<p>Indication 1)</p> <p>Traditional herbal medicinal product used for the</p>

<sup>3</sup> Detailed specifications for the herbal substance shall be given by references to bibliographic sources in absence of a monograph in the European Pharmacopoeia, a national pharmacopoeia or national codex currently used officially in a Member State.

<sup>4</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>relief of cough associated with cold.</p> <p><b>Indication 2)</b></p> <p>Traditional herbal medicinal product used for the relief of mild gastrointestinal disorders.</p> <p><b>Indication 3)</b></p> <p>Traditional herbal medicinal product used for the relief of minor skin inflammations and bruises.</p> <p>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 administration<sup>5</sup>

Well-established use	Traditional use
	<p><b>Posology</b></p> <p><b>Indications 1) and 2)</b></p> <p><i>Adults and elderly</i></p> <p>Single dose</p> <p>Herbal tea: 1.5 – 7 g of the comminuted herbal substance in 150 ml of boiling water (<del>allow</del>-steep for 2 – 4 minutes) as a herbal infusion, 3 times daily.</p> <p>Daily dose: 4.5 – 21 g</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><b>Indication 3)</b></p> <p><i>Adolescents, adults and elderly</i></p> <p>Comminuted herbal substance for infusion or decoction preparation for cutaneous use: 30 – 75 g of comminuted herbal substance in 1 l of water.</p> <p>Apply on the affected area, 2 to 5 times daily, in the form of a wet, impregnated dressing.</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>

<sup>5</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 data-bbox="810 255 1018 282"><b>Duration of use</b></p> <p data-bbox="810 309 960 336">Indication 1)</p> <p data-bbox="810 367 1410 506">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 data-bbox="810 533 1066 560">Indications 2) and 3)</p> <p data-bbox="810 591 1410 730">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 data-bbox="810 757 1145 784"><b>Method of administration</b></p> <p data-bbox="810 815 922 842">Oral use.</p> <p data-bbox="810 869 1002 896">Cutaneous use.</p>

### 4.3. Contraindications

Well-established use	Traditional use
	<p data-bbox="810 1088 1394 1155">Hypersensitivity to the active substance or to other plants of the Lamiaceae (Labiatae) family.</p>

### 4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p data-bbox="810 1344 1066 1370">Indications 1) and 2)</p> <p data-bbox="810 1402 1401 1505">The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.</p> <p data-bbox="810 1532 960 1559">Indication 1)</p> <p data-bbox="810 1590 1385 1729">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.</p> <p data-bbox="810 1756 960 1783">Indication 3)</p> <p data-bbox="810 1814 1420 1877">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**

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

#### **4.6. Fertility, pregnancy and lactation**

<b>Well-established use</b>	<b>Traditional use</b>
	No fertility data available.  Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

#### **4.7. Effects on ability to drive and use machines**

<b>Well-established use</b>	<b>Traditional use</b>
	No studies on the effect on the ability to drive and use machines have been performed.

#### **4.8. Undesirable effects**

<b>Well-established use</b>	<b>Traditional use</b>
	None known.  If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.

#### **4.9. Overdose**

<b>Well-established use</b>	<b>Traditional use</b>
	No case of overdose has been reported.

### **5. Pharmacological properties**

#### **5.1. Pharmacodynamic properties**

<b>Well-established use</b>	<b>Traditional use</b>
	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

28 January 2014