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FINAL

COMMUNITY HERBAL MONOGRAPH ON *THYMUS VULGARIS* L. AND  
*THYMUS ZYGIS* L., HERBA

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	October 2006 March 2007 May 2007
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**COMMUNITY HERBAL MONOGRAPH ON *THYMUS VULGARIS* L. AND  
*THYMUS ZYGIS* L., HERBA**

**1. NAME OF THE MEDICINAL PRODUCT**

To be specified for the individual finished product.

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION<sup>1,2</sup>**

<u>Well-established use</u>	<u>Traditional use</u>
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended</p> <p><i>Thymus vulgaris</i> L. or <i>Thymus zygis</i> L. or a mixture of both species, herba (thyme herb)</p> <p>i) Herbal substance Whole leaves and flowers separated from the previously dried stems.</p> <p>ii) Herbal preparations</p> <p>A) Liquid extract (1:1), extraction solvent ethanol 24% (v/v)</p> <p>B) Liquid extract (1:1.16), extraction solvent glycerol 85% (m/m): ethanol 25% (m/m) (0.1:2)</p> <p>C) Liquid extract (1:2-2.5), extraction solvent ammonia solution 10% (m/m) : glycerol 85% (m/m) : ethanol 90% (v/v) : water (1:20:70:109)</p> <p>D) Tincture (1:5 or 1:10), extraction solvent ethanol 70% (v/v)</p> <p>E) Soft extract (5-8:1), extraction solvent ethanol 25% (v/v) or methanol 25%</p> <p>F) Liquid extract from fresh herb (1:1.5-2.5), extraction solvent water</p> <p>G) Dry extract (6-10:1), extraction solvent ethanol 70% (v/v)</p> <p>H) Comminuted herbal substance for tea preparation</p>

<sup>1</sup> The dried material complies with the Ph. Eur. monograph (ref. 01/2005:0865).

<sup>2</sup> The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

### 3. PHARMACEUTICAL FORM

<u>Well-established use</u>	<u>Traditional use</u>  Herbal substance or comminuted herbal substance for tea preparation or other herbal preparations in liquid or solid dosage forms for oral use.  The pharmaceutical form should be described by the European Pharmacopoeia full standard term.
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### 4. CLINICAL PARTICULARS

#### 4.1. Therapeutic indications

<u>Well-established use</u>	<u>Traditional use</u>  Traditional herbal medicinal product used as an expectorant in cough associated with cold.  The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.
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#### 4.2 Posology and method of administration

<u>Well-established use</u>	<u>Traditional use</u>  <b>Posology</b> <i>Adolescents over 12 years of age, adults and elderly</i>  <u>Single dose</u> Herbal substance: 1 - 2 g A) Liquid extract: 1 - 2 ml B) Liquid extract: 1.2 - 2.4 ml C) Liquid extract: 1.0 - 4 g D) Tincture: 40 drops E) Soft extract: 50 mg F) Liquid extract from fresh herb: 10 ml G) Dry extract: 75 - 200 mg H) Comminuted herbal substance for tea preparation: 1 - 2 g  <u>Daily dose</u> Herbal substance: 3 - 8 g A) Liquid extract: 3 - 8 ml B) Liquid extract: 3.5 - 9.3 ml C) Liquid extract: 1 - 14 g D) Tincture: 120 drops E) Soft extract: 300 mg F) Liquid extract from fresh herb: 30 - 40 ml G) Dry extract: 225 - 600 mg
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	<p>H) Comminuted herbal substance for tea preparation: 3 - 8 g</p> <p><i>Children between 4 and 12 years of age</i></p> <p>C) Liquid extract:  Single dose: 0.5 - 0.9 ml  Daily dose: 2.5 - 4 ml, divided into 3-5 single doses.</p> <p>F) Liquid extract from fresh herb:  Single dose: 7 - 10 ml  Daily dose: 14 - 30 ml, divided into 2 - 3 single doses</p> <p>The use in children under 4 years of age is not recommended (see 4.4 Special warnings and precaution for use).</p> <p>Herbal substance and herbal preparations type A, B, D, E, G and H: The use in children under 12 years of age is not recommended (see 4.4 Special warnings and precaution for use).</p> <p><b>Duration of use</b></p> <p>If the symptoms persist longer than 1 week, a doctor or a qualified health care practitioner should be consulted.</p> <p><b>Method of administration</b></p> <p>Oral use.</p> <p>Tea preparation: 1-2 g of herbal substance or comminuted herbal substance for infusion. As an expectorant 3-4 cups of tea per day.</p>
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#### 4.3. Contraindications

<u>Well-established use</u>	<u>Traditional use</u>
	Hypersensitivity to the active substance or to other members of the Lamiaceae family.

#### 4.4. Special warnings and precautions for use

<u>Well-established use</u>	<u>Traditional use</u>
	Herbal preparations C and F: The use in children under 4 years of age is not recommended because medical advice should be sought.
	Herbal substance and all other types of herbal preparations:

	<p>The use in children under 12 years of age is not recommended because of lack of data.</p> <p>When dyspnoea, fever or purulent sputum occurs, a doctor or a qualified health care practitioner should be consulted.</p> <p>For tinctures and extracts 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.</p>
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#### 4.5. Interactions with other medicinal products and other forms of interaction

<u>Well-established use</u>	<u>Traditional use</u>
	None reported

#### 4.6. Pregnancy and lactation

<u>Well-established use</u>	<u>Traditional use</u>
	<p>Safety during pregnancy and lactation has not been established.</p> <p>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

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

#### 4.8. Undesirable effects

<u>Well-established use</u>	<u>Traditional use</u>
	Hypersensitivity reactions (including one case of anaphylactic shock and one case of Quincke edema) and stomach disorders have been observed. The frequency is not known.

#### 4.9. Overdose

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

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

<u>Well-established use</u>	<u>Traditional use</u>
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

### 5.2 Pharmacokinetic properties

<u>Well-established use</u>	<u>Traditional use</u>
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

### 5.3 Preclinical safety data

<u>Well-established use</u>	<u>Traditional use</u>
	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 with extracts have not been performed.

## 6. PHARMACEUTICAL PARTICULARS

<u>Well-established use</u>	<u>Traditional use</u>
	Not applicable.

## 7. DATE OF COMPILATION/LAST REVISION

31 October 2007