



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

25 September 2019  
EMA/HMPC/59032/2017  
Committee on Herbal Medicinal Products (HMPC)

## European Union herbal monograph on *Thymus vulgaris* L., *Thymus zygis* L., aetheroleum

Draft – Revision 1

<b>Initial assessment</b>	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	March 2009 May 2009
Adopted by Committee on Herbal Medicinal Products (HMPC) for release for consultation	14 May 2009
End of consultation (deadline for comments)	15 September 2009
Re-discussion in MLWP	November 2009 January 2010
Adoption by HMPC Monograph (EMA/HMPC/131901/2009) List Entry (EMA/HMPC/255527/2009) Assessment Report (EMA/HMPC/131903/2009) List of references (EMA/HMPC/131905/2009) Overview of comments (monograph) received during the public consultation (EMA/638578/2009) Overview of comments (list entry) received during the public consultation (EMA/404999/2010) HMPC Monograph Opinion (EMA/HMPC/25419/2010) HMPC List Entry Opinion (EMA/HMPC/573557/2010)	16 September 2010
<b>First systematic review</b>	
Discussion in HMPC/MLWP	January 2017 July 2017 November 2017 January 2019 July 2019 September 2019
Adopted by HMPC for release for consultation	25 September 2019
Start of public consultation	15 October 2019
End of consultation (deadline for comments). Comments should be provided using this <a href="#">template</a> to <a href="mailto:hmpc.secretariat@ema.europa.eu">hmpc.secretariat@ema.europa.eu</a> .	15 January 2020

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Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; <i>Thymus vulgaris</i> L., <i>Thymus zygis</i> L.; Thymi aetheroleum; thyme essential oil, thyme oil
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BG (bългарski): Мащерка, масло CS (čeština): tymiánová silice DA (dansk): Timianolie DE (Deutsch): Thymianöl EL (elliniká): αιθέριο έλαιο θύμου EN (English): thyme oil ES (español): tomillo, aceite esencial de ET (eesti keel): liivateeõli FI (suomi): timjamiöljy FR (français): thym (huile essentielle de) HR (hrvatski): timijanovo eterično ulje HU (magyar): kakukkfűolaj IT (italiano): Timo essenza	LT (lietuvių kalba): Čiobrelių eterinis aliejus LV (latviešu valoda): Timiānu ēteriskā eļļa MT (malti): żejt tat-timu NL (nederlands): Tijmolie PL (polski): Olejek eteryczny tymiankowy PT (português): óleo essencial de tomilho RO (română): ulei volatil de cimbru SK (slovenčina): silica tymianu SL (slovenščina): eterično olje vrtna materine dušice SV (svenska): timjanolja IS (íslenska): NO (norsk): timianolja
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# European Union herbal monograph on *Thymus vulgaris* L., *Thymus zygis* L., aetheroleum

## 1. Name of the medicinal product

To be specified for the individual finished product.

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

Well-established use	Traditional use
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC.</p> <p><i>Thymus vulgaris</i> L. or <i>Thymus zygis</i> L. or a mixture of both species, aetheroleum (thyme oil)</p> <p>i) Herbal substance</p> <p>Not applicable</p> <p>ii) Herbal preparations</p> <p>Essential oil</p>

## 3. Pharmaceutical form

Well-established use	Traditional use
	<p>Herbal preparations in liquid dosage forms for oral use (Indication 1) and in liquid or semi-solid dosage forms for cutaneous use and use as a bath additive (Indication 2).</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia 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 as an expectorant in cough associated with cold.</p> <p>Indication 2)</p>

<sup>1</sup> The material complies with the Ph. Eur. monograph (ref. 1374).

<sup>2</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>Traditional herbal medicinal product for the relief of symptoms in coughs and colds.</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

Well-established use	Traditional use
	<p><b>Posology</b></p> <p><b>Indication 1)</b></p> <p><i>Adults and elderly</i></p> <p>Oral use:</p> <p>Single dose: 0.2–0.25 ml</p> <p>Dosage frequency: 3–5 times daily</p> <p>Daily dose: 0.6–1.25 ml</p> <p>The oral use in children and adolescents under 18 years of age is not recommended (see 4.4 Special warnings and precaution for use).</p> <p><b>Indication 2)</b></p> <p><i>Adults and elderly</i></p> <p>Cutaneous use: in liquid and semi-solid dosage forms in concentrations up to 10%; apply up to 3 times daily.</p> <p>Use as bath additive: 0.007–0.025 g per litre.</p> <p><i>Adolescents</i></p> <p>Use as bath additive: 0.007–0.025 g per litre.</p> <p><i>Children 6–12 years</i></p> <p>Use as bath additive: 0.0035–0.017 g per litre.</p> <p><i>Children 3–6 years</i></p> <p>Use as bath additive: 0.0017–0.0082 g per litre.</p> <p>One bath every day or every second day.</p> <p>The <b>cutaneous use</b> in children and adolescents under 18 years of age is not recommended (see 4.4 Special warnings and precaution for use).</p> <p>The use as <b>bath additive</b> in children under 3 years of age is not recommended (see 4.4 Special</p>

Well-established use	Traditional use
	<p>warnings and precaution for use).</p> <p><b>Duration of use</b></p> <p>Indication 2)</p> <p>Duration of a bath: 10-20 minutes</p> <p>Indications 1) and 2)</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>Indication 1)</p> <p>Oral use</p> <p>Indication 2)</p> <p>Cutaneous use: Apply on the chest and the back.</p> <p>Use as bath additive: recommended temperature of bath 35–38°C.</p>

#### 4.3. Contraindications

Well-established use	Traditional use
	<p>Hypersensitivity to the active substance.</p> <p><b>Use as bath additive:</b></p> <p>Full hot baths are contraindicated in cases of large skin injuries and open wounds, acute skin diseases, high fever, severe infections, severe circulatory disturbances and cardiac failure.</p>

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

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

Well-established use	Traditional use
	<p>care practitioner should be consulted.</p> <p><b>Indication 2)</b></p> <p><b>Use as bath additive:</b></p> <p>When dyspnoea, fever or purulent sputum occurs, a doctor or a qualified health care practitioner should be consulted.</p> <p>The use in children under 3 years of age is not recommended because medical advice should be sought and due to lack of adequate data.</p> <p>In cases of hypertension, a full bath should be used with caution.</p> <p><b>Cutaneous use:</b></p> <p>Thyme oil should not be applied to the face particularly in the nasal area of babies and infants under the age of 2 years because of the risk of a laryngospasm.</p> <p>When dyspnoea, fever or purulent sputum occurs, a doctor or a qualified health care practitioner should be consulted.</p> <p>The use in children and adolescents under 18 years of age is not recommended due to lack of adequate data.</p> <p>If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</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>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>

Well-established use	Traditional use
	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
	<p><b>Indication 1)</b></p> <p>Hypersensitivity reactions have been observed. The frequency is not known.</p> <p><b>Indication 2)</b></p> <p>Hypersensitivity reactions and skin irritation have been observed. The frequency is not known.</p> <p>If other adverse reactions not mentioned above 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.

### 5.2. Pharmacokinetic properties

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

### 5.3. Preclinical safety data

Well-established use	Traditional use
	<p>Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC, unless necessary for the safe use of the product.</p> <p>Thyme oil had no mutagenic activity in the Ames test (strains TA1535, TA1537, TA98, TA100) with and without metabolic activation and in <i>Bacillus subtilis</i> rec-assay.</p> <p>Equivocal results have been observed for the constituents of thyme oil: thymol and carvacrol in assays for genotoxicity <i>in vitro</i> and <i>in vivo</i>.</p> <p>Tests on reproductive toxicity and carcinogenicity have not been performed.</p>

## 6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable

## 7. Date of compilation/last revision

25 September 2019