EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 November 2013
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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Thymus vulgaris* L. and *Thymus zygis* L., herba

Final

Initial assessement	
Discussion in Working Party on Community monographs and Community list (MLWP)	October 2006 March 2007 May 2007
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	8 May 2007
End of consultation (deadline for comments).	15 August 2007
Rediscussion in MLWP	October 2007
Adoption by HMPC Monograph (EMEA/HMPC/234113/2006) AR (EMEA/HMPC/234073/2006) List of references (EMEA/HMPC/207858/2007) Overview of comments received during the public consultation (EMEA/HMPC/489157/2007) HMPC Opinion (EMEA/HMPC/453713/2007)	31 October 2007
First systematic review	
Discussion in MLWP	July 2013 September 2013
Adoption by HMPC for release for consultation	N/A
End of consultation (deadline for comments)	N/A
Rediscussion in MLWP	N/A
Adoption by HMPC	12 November 2013

A search for the versions adopted in October 2007 can be made via the EMA document search function, using the documents' reference number, at:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/document_library/landing/document_library_search.jsp&mid=

Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Thymus vulgaris* L. and *Thymus zygis* L., herba; Thymi herba; thyme

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BG (bălgarski): Мащерка, стрък CS (čeština): tymiánová vňať DA (dansk): Timian DE (Deutsch): Thymian EL (elliniká): πόα θύμου EN (English): thyme ES (espanol): Tomillo, partes aéreas de ET (eesti keel): liivatee ürt FI (suomi): timjami FR (français): Thym (parties aériennes de) HU (magyar): Kakukkfű HR (hrvatska) : timijanova zelen IT (italiano): Timo foglia e fiore	LT (lietuvių kalba): Vaistinių čiobrelių žolė LV (latviešu valoda): Timiānu laksti MT (malti): Timu NL (nederlands): tijm PL (polski): Ziele tymianku PT (português): Tomilho RO (română): Iarbă de cimbru SK (slovenčina): Tymianová vňať SL (slovenščina): zel vrtne materine dušice SV (svenska): Timjan *IS (íslenska)*: *NO (norsk):* timian

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[1,2]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *Thymus vulgaris* L. *and Thymus zygis* L., or a mixture of both species, herba (thyme) i) Herbal substance Not applicable. ii) Herbal preparations a) Liquid extract (DER 1:1), extraction solvent ethanol 24% (V/V) b) Liquid extract (DER 1:1.16), extraction solvent glycerol 85% (m/m): ethanol 25% (m/m) (0.1:2) c) Liquid extract (DER 1:2-2.5), extraction solvent ammonia solution 10% (m/m) : glycerol 85% (m/m) : ethanol 90% (V/V) : water (1:20:70:109) d) Tincture (1:10), extraction solvent ethanol 70% (V/V) e) Tincture (1:5), extraction solvent ethanol 70% (V/V) f) Soft extract (DER 5-8:1), extraction solvent ethanol 25% - 30% (V/V) g) Liquid extract fresh herb[3] (DER 1:1.5-2.4), extraction solvent water (often referred as 'expressed juice') h) Dry extract (DER 6-10:1), extraction solvent ethanol 70% (v/v) i) Dry extract (DER 1.6-2.4:1), extraction solvent ethanol 96% (V/V)

1 The material complies with the Ph. Eur. monograph (ref.: 04/2009:0865).
2 The declaration of the active substance for an individual finished product should be in accordance with relevant herbal quality guidance.
[3] The fresh material complies with the Ph. Eur. monograph (ref.: 04/2009:0865) when dried

Well-established use	Traditional use
	j) Liquid extract (DER 1:4.5), extraction solvent ammonia solution 10% (m/m) : glycerol 85% (m/m) : ethanol 96% (V/V) : water (1.2:25:112:113) k) Dry extract (DER 7-13:1), extraction solvent water l) Comminuted herbal substance

3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea for oral use. Herbal preparations in liquid or solid dosage forms for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Traditional herbal medicinal product used in productive cough associated with cold. The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology *Adolescents, adults and elderly* a) Liquid extract (DER 1:1): Single dose: 1-2 ml, 3-4 times daily b) Liquid extract (DER 1:1.16): Single dose 1.2-2.4 ml, 3-4 times daily c) Liquid extract (DER 1:2-2.5): Single dose 1-4 g, 1-7 times daily, maximum daily dose 14 g

Well-established use	Traditional use
	d) Tincture (1:10): Single dose 40 drops, 3 times daily e) Tincture (1:5): Single dose 2-6 ml, 3 times daily f) Soft extract: Single dose 50 mg, 6 times daily g) Liquid extract (DER 1:1.5-2.4) Single dose 10 ml, 3-4 times daily h) Dry extract (DER 6-10:1): Single dose 75-200 mg, 3 times daily i) Dry extract (DER 1.6-2.4:1) Single dose 135 mg, 1-3 times daily j) Liquid extract (1:4.5) Single dose 480 – 960 mg, 3-4 times daily k) Dry extract (DER 7-13:1) Single dose 100 – 200 mg, 3-4 times daily l) Comminuted herbal substance Herbal tea: 1-2 g of the comminuted herbal substance in 150 ml of boiling water as a herbal infusion 3-4 times daily *Children between 4 and 12 years of age:* c) Liquid extract (DER 1:2-2.5): Single dose 0.5-0.9 ml, 3-5 times daily g) Liquid extract (DER 1:1.5-2.4): Single dose 7-10 ml, 2-3 times daily Herbal preparations a, b, d, e, f, h, i, j, k, l: The use in children under 12 years of age is not recommended (see 4.4 Special warnings and precaution for use). Herbal preparations c, g: The use in children under 4 years of age is not recommended (see 4.4 Special warnings and precaution for use). **Duration of use** 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. **Method of administration** Oral use.

4.3. Contraindications

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

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	If dyspnoea, fever or purulent sputum occurs, a doctor or a qualified health care practitioner should be consulted. If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. 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. Herbal preparations a, b, d, e, f, h, i, j, k, l The use in children under 12 years of age has not been established due to lack of adequate data. Herbal preparations c, g The use in children under 4 years of age has not been established because medical advice should be sought.

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
	Gastric disorders may occur. The frequency is not known. If other adverse reactions not mentioned above 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. Adequate 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

12 November 2013