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Evaluation of Medicines for Human Use

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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

DRAFT

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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ADOPTION BY HMPC	

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KEYWORDS	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Thymus vulgaris* L.; *Thymus zygis* L.; Thymi herba; thyme herb.

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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[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. or *Thymus zygis* L. or a mixture of both species, herba (thyme herb) i) Herbal substance Whole leaves and flowers separated from the previously dried stems. ii)Herbal preparations A) Liquid extract (ÖAB) (1:1); solvent ethanol 24% (v/v) B) Liquid extract (Czech Pharm.) (1:1.16); extraction solvent: glycerol 85% (m/m): ethanol 25% (m/m) (0.1 : 2) C) Liquid extract (DAB 2006) (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) E) Essential oil[3] F) Comminuted herbal substance for tea preparation

3. PHARMACEUTICAL FORM

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

[1] The material complies with the Ph. Eur. monograph (ref. 01/2005:0865).
[2] The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.
[3] The essential oil complies with the Ph. Eur. monograph (ref. 01/2005:1374)

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4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Well-established use	Traditional use
	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.

4.2 Posology and method of administration

Well-established use	Traditional use
	Posology *Adolescents over 12 years of age, adults and elderly* Single dose Herbal substance: 1 - 2 g A) Liquid extract (ÖAB): 1 - 2 ml B) Liquid extract (Czech Pharm.): 1.2 - 2.4 ml C) Liquid extract (DAB 2006): 1.5 - 4 g D) Tincture (1:10): 40 drops E) Essential oil: 4 - 5 drops F) Comminuted herbal substance for tea preparation: 1 - 2 g Dosage frequency: May be taken up to a maximum of 4 times daily. Daily dose Herbal substance: 3 - 8 g A) Liquid extract (ÖAB): 3 - 8 ml B) Liquid extract (Czech Pharm.): 3.5 - 9.3 ml C) Liquid extract (DAB 2006): 4.5 - 14 g D) Tincture (1:10): 120 drops E) Essential oil: 12 - 25 drops F) Comminuted herbal substance for tea preparation: 3 - 8 g *Children between 4 to12 years of age* C) Liquid extract (DAB 2006) Single dose: 0.5 – 0.9 ml Daily dose: 2.5 - 4 ml, divided into 3 - 5 single doses. The use in children under 4 years of age is not recommended (see 4.4 Special warnings and precautions for use)

	Duration of use *Children between 4 to 12 years of age* No longer than 5 days. *Adolescents over 12 years of age, adults, elderly* Medical attention should be sought if after 1 week of treatment the symptoms do not improve. If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. **Method of administration** Oral use Tea preparation: 1-2 g of herbal substance or comminuted herbal substance for infusion. As an expectorant 3-4 cups of tea per day.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance or to other members of the Lamiaceae family. Children with a history of acute stenosing laryngo-tracheitis. Asthma.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	The use in children under 4 years of age is not recommended because medical advice should be sought. When dyspnoea, fever or purulent sputum occurs, a doctor or a qualified health care practitioner should be consulted. For tinctures and extracts, 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.

4.5. Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
	None reported.

4.6. 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.

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
	Hypersensitivity reactions (e.g. dyspnoea, skin rash, urticaria as well as facial edema, edema of the mouth and throat (Quincke edema), anaphylactic shock) or stomach disorders (spasms, nausea, vomiting) have been observed. The frequency is not known.

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. Thyme essential oil had no mutagenic or DNA-damaging activity in either the Ames or *Bacillus subtilis* rec-Assay. Thyme essential oil did not show an influence on the growth and development of mouse embryos *in vivo*. Thymol did not show mutagenicity in several *Salmonella typhimurium* - strains. Tests on reproductive toxicity, genotoxicity and carcinogenicity with extracts have not been performed.

6. PHARMACEUTICAL PARTICULARS

Well-established use	Traditional use
	Not applicable.

7. DATE OF COMPILATION/LAST REVISION

8 May 2007