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**COMMITTEE ON HERBAL MEDICINAL PRODUCTS
(HMPC)**

DRAFT

**COMMUNITY LIST ENTRY ON
THYMUS VULGARIS L. AND *THYMUS ZYGIS* LOEFL. EX L., AETHEROLEUM**

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	November 2009 January 2010
ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION	14 January 2010
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REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	
ADOPTION BY HMPC	

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KEYWORDS	Herbal medicinal products; HMPC; Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products; traditional use; <i>Thymus vulgaris</i> L.; <i>Thymus zygis</i> Loeft. ex L.; Thymi aetheroleum; thyme essential oil.
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**ENTRY TO LIST OF HERBAL SUBSTANCES, PREPARATIONS AND
COMBINATIONS THEREOF FOR USE IN
TRADITIONAL HERBAL MEDICINAL PRODUCTS**

**ENTRY TO LIST OF HERBAL SUBSTANCES, PREPARATIONS AND
COMBINATIONS THEREOF FOR USE IN
TRADITIONAL HERBAL MEDICINAL PRODUCTS:**

***THYMUS VULGARIS* L. AND
THYMUS ZYGIS LOEFL. EX L., AETHEROLEUM**

Scientific name of the plant	
<i>Thymus vulgaris</i> L. and <i>Thymus zygis</i> Loebl. ex L.	
Botanical family	
Lamiaceae	
Herbal substance	
Not applicable	
Common name in all EU official languages of herbal substance	
BG (bălgarski): CS (čeština): DA (dansk): DE (Deutsch): EL (elliniká): EN (English): ES (español): ET (eesti keel): FI (suomi): FR (français): HU (magyar):	IT (italiano): LT (lietuvių kalba): LV (latviešu valoda): MT (malti): NL (nederlands): PL (polski): PT (português): RO (română): SK (slovenčina): SL (slovenščina): SV (svenska): IS (íslenska): NO (norsk):
Herbal preparation(s)	
Essential oil obtained by steam distillation from the fresh flowering aerial parts of <i>Thymus vulgaris</i> L., <i>Thymus zygis</i> Loebl. ex. L. or a mixture of both species	
European Pharmacopoeia monograph reference	
Thyme oil - Thymi aetheroleum; (01/2008:1374)	
Indication(s)	
Traditional herbal medicinal product for the relief of symptoms in coughs and colds. The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.	

Type of tradition
European
Specified strength
See ‘Specified posology’
Specified posology
<i>Adolescent, adults and elderly</i> Cutaneous use: in liquid and semi-solid dosage forms in concentrations up to 10%; apply up to 3 times daily. Use as bath additive: 0.007 – 0.025 g per litre <i>Children 6-12 years</i> Use as bath additive: 0.0035 – 0.017 g per litre <i>Children 3-6 years</i> Use as bath additive: 0.0017 – 0.0082 g per litre One bath every day or every second day. The cutaneous use in children and adolescents under 18 years of age is not recommended (see ‘Special warnings and precaution for use’). The use as bath additive in children under 3 years of age is not recommended (see ‘Special warnings and precaution for use’).
Route of administration
Cutaneous use: apply to the chest and the back. Use as a bath additive: recommended temperature of bath: 35-38°C
Duration of use or any restrictions on the duration of use
Duration of a bath: 10-20 minutes If the symptoms persist longer than 1 week, a doctor or a qualified health care practitioner should be consulted.
Any other information necessary for the safe use
Contraindications Hypersensitivity to the active substance. Use as bath additive: Full baths are contraindicated in cases of open wounds, large skin injuries, acute skin diseases, high fever, severe infections, severe circulatory disturbances and cardiac insufficiency. Special warnings and precautions for use Like other essential oils, thyme oil should not be applied to the face particularly in the nasal area of babies and infants under the age of two years because of the risk of a laryngospasm. When dyspnoea, fever or purulent sputum occurs, a doctor or a qualified health care practitioner should be consulted.

Use as bath additive:

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.

In cases of hypertension, a full bath should be used with caution.

Cutaneous use:

The use in children and adolescents under 18 years of age is not recommended due to lack of adequate data.

Interactions with other medicinal products and other forms of interaction

None reported.

Pregnancy and lactation

Safety during pregnancy and lactation has not been established.

In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed.

Undesirable effects

Hypersensitivity reactions and skin irritation have been observed. The frequency is not known.

If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.

Overdose

No case of overdose has been reported.

Pharmaceutical particulars [If necessary]

Not applicable.

**Pharmacological effects or efficacy plausible on the basis of long-standing use and experience
[If necessary for the safe use of the product]**

Not applicable.

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