The European Agency for the Evaluation of Medicinal Products
Evaluation of Medicines for Human Use

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WORKING PARTY ON HERBAL MEDICINAL PRODUCTS

FINAL PROPOSAL FOR A CORE DATA THYMI HERBA

DISCUSSION IN THE HMPWP	March 2002, July 2003
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Final Proposal for a Core-data on Thyme

The Working Party on Herbal Medicinal Products proposes the following core-data for *Thymi herba*.

1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

i) Thyme[1]

ii) Quantified extracts[2]
Thyme fluid extract (Deutsches Arzneibuch 2003)

3. PHARMACEUTICAL FORM

The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Herbal medicinal product for the relief of symptoms in coughs and colds with viscous mucus[3]

4.2 Posology and method of administration

Posology
Oral use
Herbal substance
Adults and children from 4 years: 1 – 2 g of thyme as an infusion 3 to 4 times a day.

Fluid extract
Adults and children from 4 years: single dose of 2 – 4 g, 3 to 4 times a day.

Method of administration
Oral use.

Duration of use
See 4.4 Special warnings and precautions for use.

1 The material complies with the European Pharmacopoeia.
[2] Type of extract as defined in the general monograph on extracts of the Ph. Eur. (ref 765)
[3] Decision by majority

4.3 Contra-indications

Patients with known hypersensitivity to thyme should not use thyme preparations.

4.4 Special warnings and precautions for use

If symptoms persist or worsen during the first week of use, or if dyspnoea, fever or purulent sputum occurs, a physician should be consulted.

Because there is no experience available, use of this product is not recommended in children below the age of 4 years.

4.5 Interaction with other medicaments and other form of interaction

None reported.

4.6 Use in pregnancy and lactation

Because data on the use during pregnancy and lactation are not available, the use is not recommended as a general precaution.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

In very rare cases, hypersensitivity reactions (e.g. dyspnoea, skin rash, urticaria as well as facial oedema, oedema of the mouth and throat (Quincke oedema)) or stomach disorders (spasms, nausea, vomiting) have been observed.

4.9 Overdose

None reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmaco-therapeutic group: Expectorants
ATC code: R05CA

Thyme is acting as an expectorant.

In vitro the essential oil has antibacterial and antifungal activity, when tested on Gram-positive and Gram-negative bacteria, fungi, and yeasts. The activity is mainly attributed to thymol and carvacrol.
The expectorant effects of thyme preparations have long been recognised empirically. The use is made plausible by pharmacological data, comparative and observational clinical studies.

Level of evidence: level III[4]

5.2 Pharmacokinetic properties

No data are available on Thymi herba.

5.3 Preclinical safety data

Toxicity tests in animals have not given cause for concern within the recommended dosage range.

6. DATE OF COMPILATION

February 2004

[4] Points to consider on the evidence of safety and efficacy required for well established herbal medicinal products in bibliographical applications (HMPWP/23/99)

