

2.7.3 Summary of Clinical Efficacy

2.7.3.1 Background and Overview of Clinical Efficacy

THIOPECTOL THYM SANS SUCRE EDULCORE AU MALTITOL, 6,5 g/100 ml, sirop is a traditional herbal medicinal product used as an expectorant for relief of productive cough associated with common colds.

According to the assessment report on *Thymus vulgaris* L., *vulgaris zygis* L., herba” from the European Medicines Agency (EMA) (5), “the published data on pharmacology and from observational trials support the safe traditional oral use of herbal preparations of Thyme for the treatment of cough associated with cold”.

2.7.3.1.1 Clinical Efficacy of *Thymus vulgaris* L. Liquid Extract in the Claimed Indications

In a randomised, double-blind, comparative study, 60 patients with productive cough complaints resulting from uncomplicated respiratory infections were treated with Thyme syrup (3×10 ml daily, n=31, no details regarding DER, extraction solvent and amount of herbal preparation in the syrup) or a bromhexine preparation (n=29) for 5 days. No significant difference was observed between Thyme syrup and bromhexine in self-reported alleviation of the complaints on days 2 and 5 of treatment (8). The study concluded that bromhexine may be no better in alleviating coughing complaints than syrup of thyme.

Without a placebo arm, these results cannot be discriminated from the natural course of disease.

The results from following company report are cited in (2):

In an open, multicenter study, 154 children aged 2 months to 14 years (mean 4.4 years) with bronchial catarrh or bronchitis were treated daily with 15-30 ml of thyme syrup, containing 97.6 mg of thyme fluid extract (2-2.5:1) per ml; for a period of 7-14 days (mean 7.9 days); 46 patients did not receive any co-medication. Compared to the start of the treatment an improvement in the intensity of coughing was reported in 93.5% of patients.

2.7.3.2 Summary of Results of Individual Studies

The efficacy and safety of *Thymus vulgaris* L. liquid extract in the treatment of cough associated with cold is very well documented. These substances have been available for several decades and clinical trials support the traditional use of Thyme syrup and make the use in the proposed indication plausible.

These claims are consistent with the spectrum of activity reported in standard references and published literature, and also with the traditional use of the drug. The description of the efficacy profile of the drug and the dosage recommended in the Summary of Product Characteristics as proposed by the applicant corresponds accurately with that described in standard reference works.

2.7.3.3 Analysis of Clinical Information Relevant to Dosing Recommendations

No data available regarding dose response studies.

2.7.3.4 Appendix

Table 3: *Thymus vulgaris* L. liquid extract efficacy studies

Study ID	Number of study centres Location(s)	Study period	Design Control type	Study & Ctrl Drugs Dose, route & Regimen	Study Objective	# subjects by arm entered / completed	Duration	Gender M/F Median age (Range)	Diagnosis Inclusion Criteria	Primary Endpoint(s)
Knols et al 1996 (8)	5 medical practices The Netherlands	December 1992 – March 1993	Randomised, double-blind, comparative study.	Thyme syrup (no details regarding DER, extraction solvent and amount of herbal preparation in the syrup); 3x10 ml daily. Bromhexine preparation.	Effect of treatment on symptoms of productive cough complaints.	31 (thyme syrup) 29 (bromhexine)	5 days	19 ♂ 41 ♀ Adults	Common cold with reproductive cough	Self-reported alleviation of productive cough complaints.
Cited in (2)	No information on number of involved centres. Germany (?)	Not available	Randomised, double-blind, multicenter study.	Thyme syrup containing 97.6 mg of thyme fluid extract (2-2.5:1). 15 – 30 ml of Thyme syrup daily.	Improvement in cough.	154	7-14 days (mean 7.9 days)	No information on gender. 2 months to 14 years (mean 4.4 years).	Bronchial catarrh or bronchitis	Improvement in cough.